Proposal for a Harmonised Structure of Technical Documentation and basic Functionalities of a Submission Software Tool under EU-MDR

Wissenschaftliche Prüfungsarbeit
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Contents

List of Abbreviations

Abbreviation	Description
21 CFR	Code of Federal Regulations of the United States, Title 21
ASEAN	Association of Southeast Asian Nations
CA	Competent Authority
Class I_m	Low risk medical device under EU-MDR with a measuring function, that needs to comply with metrological requirements (see EU-MDR, Art. 52, (7))[1].
Class I_r	Low risk medical device under EU-MDR, intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out. (see EU-MDR, Annex VIII, (2.3)) [1].
Class I_s	Low risk medical device under EU-MDR[1], provided in a sterile condition.
CS	Common Specification
CTD	Common Technical Documentation
E. P.	Essential Principles in different legislative frameworks, e.g.: - Essential Requirements: Annex I of EU-MDD; - General Safety and Performance Requirements: Annex I of EU-MDR[1]; - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices of IMDRF
eCTD	electronic Common Technical Documentation
eRPS	electronic Regulated Product Submission
ERP-system	Enterprise Resource Planning-system
EU	European Union
EU-MDD	Council directive 93/42/EEC of 14 June 1993 concerning medical devices
EU-MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) Text with EEA relevance[1]
GHTF	Global Harmonization Task Force
HC	Health Canada
i.a.	If applicable

Abbreviation	Description
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
(Row)ID	Abbreviation for the individual chapters of the ToC
IMDRF	International Medical Device Regulators Forum
MD	Medical Devices
MDCG	Medical Device Coordination Group
NB	Notified Body; means a conformity assessment body designated in accordance with regulation 2017/745[1].
NMPA	National Medical Products Administration (China)
OCR	Optical Character Recognition
OEM	Original Equipment Manufacturer
PLM	Private Label Manufacturer
PRRC	Person Responsible for Regulatory Compliance
SME	small and medium-sized enterprises
STED	Summary Technical Documentation guide GHTF/SG1/N011[31]
TD	Technical Documentation
Team-NB	The European Association Medical devices of Notified Bodies
ToC	Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC); IMDRF/RPS WG/N9 (Edition 3) Final:2019[33]
US	United States of America
US-FDA	United States Food & Drug Administration
WHO	World Health Organization

1 Introduction and Aim of the Thesis

> It is not the strongest of the species that survive, nor the most intelligent,
> but the most responsive one to change.
>
> Charles Darwin

Market access for *medical devices* ('*MD*') is only allowed after a proof of compliance with region-specific requirements is provided, following a defined system of each region. Within the *European Union* ('*EU*'), the European Parliament and the Council outlined those requirements in *regulation (EU) No. 2017/745* ('*EU-MDR*'), which entered in force in May 2017. During the transition time ending in general in May 2020*, industry, notified bodies and *competent authorities* ('*CA*') are obliged to align their processes to meet the new legislative framework. Twenty-seven percent of the global medical device sales volume is made within the EU[2] and therefore is affected by this new regulation. For manufacturers, the creation of *technical documentation* ('*TD*') to provide evidence of compliance with the legislatively stipulated quality and safety requirements is one of these obligations, influencing not only the industry itself, but also the *notified bodies* ('*NB*'), assessing the TD in order to issue certificates. For medical devices, there is no harmonised structure for TD submission defined neither by law nor by the authorities, leading to different approaches within the industry and different preferences amongst notified bodies as recent survey at NBs, carried out by the author of this master thesis, revealed (see annex 8.8 of this thesis, question 12). Unlike the pharmaceutical market, being controlled by big corporate groups, the medical device industry is dominated by *small and medium-sized enterprises* ('*SME*')[3]. Ongoing changes in international regulatory environments such as the revision and expansion of quality standard requirements lead to an expert shortage in the quality and regulatory field. More stringent requirements under EU-MDR even intensify the lack of human resources to address the workload also for notified bodies.[4, 5] As there is a high

* Due to the Corona pandemic, the transition period might get extended for a certain time frame. The proposal is currently in preparation by the European Commission and is expected to be submitted for decision to the European Council and the Parliament in April of 2020.

quantity of individual manufacturers, but only a limited number of notified bodies, many different structures of technical documentation need to be handled from their side.

The implementation of the new EU-MDR provides a chance to find a structure to streamline the submission process by following a harmonised structure that is accepted by each notified body. Even though there are a lot of changes requiring the attention of the regulatory personnel in short-term, implementing such a structure would enable the industry to focus on other new obligations such as frequent reports while enabling notified bodies to manage the increased workload on the long run no matter if there are new employees on board or changes of notified bodies.

Based on the current regulatory changes happening, this thesis focusses on EU-market access requirements regarding the required content of a technical documentation, expectations set for and from different involved parties, existing approaches for harmonisation, and the feasibility for EU-MDR, evaluating gaps in currently available literature and limitations of a one-fits-all structure as well as general requirements regarding implementation of software for increased process streamlining.

2 Medical Device Assessment Process under EU-MDR

2.1 Definition of a Medical Device

Only insignificantly deviating from the *World Health Organization* ('*WHO*') definition, the EU-MDR[1] defines a medical device as follows:

> 'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
>
> - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
> - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
> - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
>
> and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> EU-MDR, Article 2, (1)

Unlike other regions, the EU covers in-vitro diagnostics, a specific sub-category of medical devices, in a separate regulation.

2.2 Classification of Different Medical Device Types

Based on the broad definition, medical devices are of inhomogeneous nature and can appear in various forms and functions. Dependent on the medical treatment itself, varying in complexity, invasiveness, and duration of application, the resulting potential patient risk for each device is different. To fulfil the 'intended use', physical forms, attributes, and needs for compatibility are designed to support patient's treatment as good as possible. Devices specifically manufactured based on one patient's needs, so-called 'custom-made devices', such as highly specified contact lenses or unique prostheses, are covered by the same regulation as mass-produced devices in any shape or size are (see Figure 1).

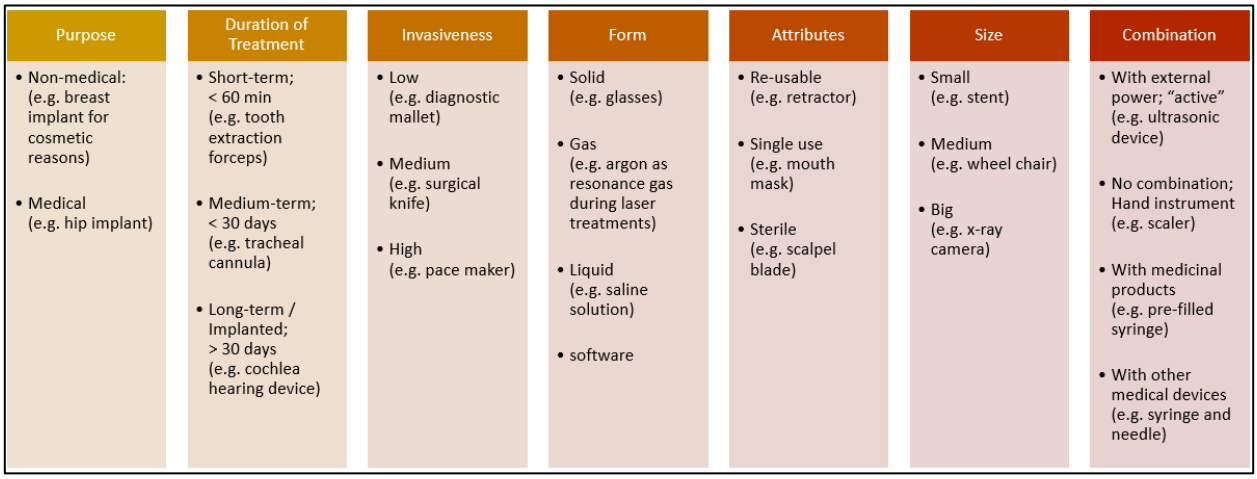


Figure 1: Differences within Medical Devices; presentation by the author.

To address the potential patient risk, EU-MDR provides 22 rules in Annex VIII to reduce all variables to a minimum and define an overall risk classification. It is the manufacturer's obligation to evaluate which rule describes the device, its form and function and the treatment that it is intended to support best. The device then either is falling under risk classification I, only carrying limited risk to the patient during a non-invasive treatment; class IIA in case there is a slightly increased risk potential either due to invasiveness of the treatment, treatment duration or in case an external power supply creates additional risks; IIB for devices that bear even higher risks; and class III for devices that have a high impact on patients life such as life-sustaining devices or devices that will be implanted and will

remain in the patient's body for an extended period of time. Specific functions or attributes like a sterile state, measuring function or reusability in a surgical procedure narrow the broad group of devices summarised under class I down to create the more accurate sub-categories class I_s (for sterile), class I_r (for surgical reusable) and class I_m (for measuring function). An impression on the different risk classes individual medical devices fall under is provided in Figure 2).

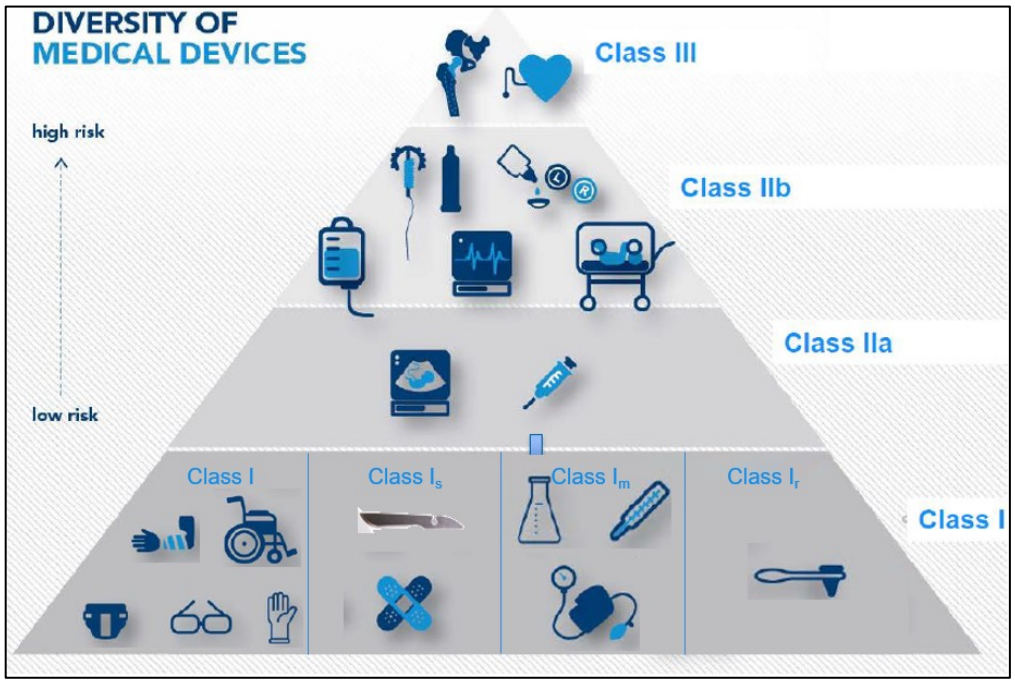


Figure 2: Diversity of medical devices, split up in different risk classifications; presentation by the author, based on figure by Pascale Brasseur[6].

2.3 System of Notified Bodies

The EU legislator transferred the responsibility of assessing the conformity of products to independent parties, the 'notified bodies' ('*NB*'), which are supervised by the corresponding competent authority of each individual member state, where the individual NB is located in.

Based on technical competence with different product categories, forms and attributes of medical devices, the designation scope of NBs can vary and either cover all types of devices or just specific groups[7].

Under EU-MDR, each NB needs to newly apply for its designation, leading to a complete new assessment by the Joint Assessment Team, consisting of experts chosen by European Commission and the member states, even though the NB might have been designated before under EU-MDR's predecessor, the council directive 93/42/EEC concerning medical devices, 'EU-MDD'.

Carrying out the imposed activities under EU-MDR, the notified bodies have the obligation to be independent of manufacturers and other economic operators.

While the industry was facing a relatively high number of NBs under the previously active EU-MDD, the number has slightly decreased during the years because of increased scrutiny.[8] With a new designation being necessary for all existing NBs, the number of NBs currently designated for EU-MDR is twelve (status: 22.03.2020) but can decrease again as the United Kingdom is currently leaving the EU, which results in all UK-NBs to no longer own a designation, in case no corresponding contact on mutual recognition is concluded.

Year	**2001**	**2013**	**2019**	**2019 (Nov 24)**	**2020 (Apr 22)**
NBs	60 [9]	75 [10]	55 [11]	7 [12]	12 [12]
Designated under the legislative framework	EU-MDD	EU-MDD	EU-MDD	EU-MDR	EU-MDR

Table 1: Overview on numbers of designated notified bodies; presentation by the author.

2.4 Technical Documentation

2.4.1 Purpose of Technical Documentation

To ensure the safety of the MDs, each manufacturer needs to fulfil general duties such as registration of product(s) and company, preparing frequent reports, and informing the authorities about adverse events that they were made aware of, but also need to document all essential information during design and manufacturing stages, evaluating whether they are appropriate to ensure correct performance and function of the devices. This information needs to be collected and made available for review purposes.

Depending on similarities and differences of individual catalogue numbers, devices can either be grouped within one TD – e.g. tubes in different lengths – or need to be split up into individual TDs for each article.

Within the EU, specific parts or even the complete technical documentation needs to be reviewed by the notified body. The extent depends on the risk class (see Figure 3).

Risk Classification	Risk Potential	Examples	Requirement for External Review of TD by NBs
I	Low	Diagnostic mallet, glasses, saline solution, mouth mask, wheel chair, scaler	No
		Sterile: dressing material Measuring function: clinical thermometer , scale Surgical reusable: Tooth extraction forceps, surgical knife, retractor	Yes, but only aspects that are relevant to the special function (measuring, reusability) or condition (sterility)
IIA	Medium	Tracheal canula, scalpel blade, ultrasonic device	Yes
IIB	Increased	X-ray camera	Yes
III	High	Breast implant, hip implant, cochlea hearing device, pace maker, stent	Yes

Figure 3: TD review by NB in relation to risk classification; presentation by the author.

A competent authority is entitled to sample TD from directly from industry or via NBs to assess conformity to requirements and processes for scrutiny, independent of the assigned risk class.

2.4.2 Available Electronic Systems for Document and Submission Handling

Even though in 2014, half of the MD companies still used a paper-based system for documentation purposes, a lot of companies started organising files related to technical

documentation by using electronic tools[13]. There are already different levels of electronic support available on the market.

2.4.2.1 Document Management Systems

Mainly supporting quality management processes, document management systems can be used to control life cycles and define processes to approve and archive documents. This ensures that the most current and approved version can be easily identified, while access to archived files is generally restricted and only possible for users with extended rights.

A nomenclature of individual document types usually needs to be created by each company itself. This leads to very flexible software that can control documents, no matter if they are related to manufacturing, sales or if these documents are essential parts of a TD. All documents being assigned to one group or document type can be extracted from the system by using an automated function. Examples for non-MD-specific software are *SharePoint* (www.docs.microsoft.com/en-gb/sharepoint/dev/), *Documentum* (www.amplexor.com/ en/our-solutions/collaboration-compliance/our-platforms/documentum.html), *TrackWise* (www.spartasystems.com) or *SAP* (www.SAP.com).

MD-specific software tools usually comply with ISO 13485 and the *Code of Federal Regulations of the United States, Title 21*, (‘*21 CFR’*) covering the requirements of part 820, e.g. *MasterControl* (www.mastercontrol.com) or *DocXellent* (www.docxellent.com).

2.4.2.2 Document Exchange Systems

Two or more entities can inherit different roles and responsibilities within a supply chain of a product, acting as so-called economic operators under EU-MDR. There is not only the role of a manufacturer, but also European Authorised Representatives, suppliers, notified bodies or competent authorities.

Amongst economic operators, the majority of file sharing still is done by sending documents via email. As this is a simple and efficient way to share small amounts of data for one single time, the method has limitations regarding the file size. A manual system to ensure updated documents are sent whenever changes occurred needs to be implemented as well.

Sharing access to the entire Document Management System might violate confidentiality of the document-providing party. While there might be specific features allowing direct access to certain files within the Document Management System without providing full visibility to other documents when using MD-specific software like *MasterControl*, software generated for non-medical markets usually struggle to provide this functionality.

Using such digital platforms, documents can be provided either permanently to obtain complete and most current technical documentation even from so-called critical suppliers or for a specific time only to provide access for one-time review purposes for competent authorities and NBs. Examples of such digital platforms are *DropBox* (www.dropbox.com), *Medtech Vault* (www.medtechvault.com) or *Dracoon* (www.dracoon.com).

2.4.2.3 Regulatory Submission Systems

Software focusing on manufacturer-to-reviewer processes are available on the market as well. Such software supports global product registrations by providing an overview of all processes initiated, the latest status of the submissions and results including potential expiry date management for received certificates. Tracking of specific documents submitted is also possible. Examples for such software are *RIMSYS* (www.rimsys.io) or *Right Submission* (www.rightsubmission.com).

These systems need a regulatory affairs team ensuring that the latest documents are uploaded to the system and no information is missed during the transfer from the Document Management System to the Regulatory Submission System. Even though communication between these software tools and other software are strived, most of the data import still needs to happen manually.

Such software solutions are highly customizable to cover any company's needs, but still are mainly created to submit documents to bigger official authorities like the United States Food & Drug Administration ('*US-FDA*') rather than to relatively small organisations like notified bodies.

In general, the software *Meddevo* (www.meddevo.com) focusses on the same process, but uses the idea of content management to reach the goal, preferring information that is filled into fields rather than finalized documents that are uploaded. This allows logic inspections in the background to evaluate the consistency of information provided to a certain extent.

2.4.3 Notified Bodies as the Main Hub for Receiving Technical Documentation

The comparably small number of remaining NBs need to review technical documentation provided by different manufacturers, as soon as they plan to sell the devices within the European Union.

Different studies provide an estimated number of roughly 5.300 to 5.600 medical device companies within the United States, 88% have less than 100 employees.[14] Germany, Europe's leading country for medical technology, has a total of 1.352 MD manufacturers with more than 20 employees, 82% of MD companies have less than 100 employees.[15] Within Europe, even 95% of medical technology companies have less than 50 employees.[3]

Based on this data, the NBs act as the hub to assess all kinds of documentation.

A survey amongst notified bodies, carried out by the author of this master thesis, revealed that six out of seven employees of notified bodies support the idea of a harmonised structure for medical device technical documentation (see annex 8.8 of this thesis, question 3).

Amongst some NBs within the *European Association Medical devices of Notified Bodies* ('*TEAM-NB'*), there is a voluntary code of conduct, that defines the depth of assessment for the TDs under EU-MDD. As per that document, "the evaluation time of the technical documentation of a medical device of high complexity, including the verification of the

consistency with the implemented manufacturing processes, should be between six to eight hours", which would be approximately one man-day. High complexity within this context means a complex level in technology, the number of technologies and/or materials used.[16]

According to a personal written information from Klaus Jung / TÜV NORD CERT GmbH from March 2020, the expected review duration under EU-MDR will be between six to fourteen man-days per documentation review, depending on risk class and complexity. Additional complexity results in increased requirements for the NB personnel to demonstrate their technical expertise. Combined with additional administrative burdens, an increase of review costs of up to 30.000 € per review can be expected, as per Klaus Jung. This would provide an additional financial load, hitting especially SMEs with different product lines that require individual TDs.

Based on the survey, it can be expected that the time savings of the overall review process on the NB's end could be approx. one third, when a uniform structure is used (see annex 8.8 of this thesis, question 10b)).

3 A Common Technical Documentation for Medical Devices

3.1 The *Common Technical Dossier* in the Pharmaceutical Industry

For pharmaceuticals, a dossier that is compiling quality and manufacturing related as well as non-clinical and clinical aspects, must be provided during application for marketing authorisation to EU member states. This is defined in directive 2001/83/EC for medicinal products for human use and its amendments, succeeding several individual directives that regulated the pharmaceutical industry since 1965.

The *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use* ('*ICH*') provided a granular structure of such a dossier already in 2000, currently available in its latest revision as *Volume 2B Notice to Applicants*[17] to meet the obligations. In over 300 pages, the document describes an order, headlines and content of the individual sections within five different modules, containing examples and references to other applicable documents or guidelines that should be taken into consideration, where applicable (example, see Figure 4).

3.2 Body of Data

3.2.S DRUG SUBSTANCE[1] (NAME, MANUFACTURER)

Reference CPMP Guidelines:
"On summary of requirements for active substances in part II of the dossier", including the Certification of Suitability of monographs of the European Pharmacopoeia (see also NTA, Vol. 2B – introduction).
"Active Substance Master File procedure"

3.2.S.1 General Information (name, manufacturer)

3.2.S.1.1 Nomenclature (name, manufacturer)

Information on the nomenclature of the drug substance should be provided. For example:

- Recommended International Nonproprietary Name (INN);
- Compendial name (e.g. European Pharmacopoeia) if relevant;
- Chemical name(s);
- Company or laboratory code;
- Other non-proprietary name(s), e.g., national name, United States Adopted Name (USAN), Japanese Accepted Name (JAN); British Approved Name (BAN), and
- Chemical Abstracts Service (CAS) registry number.

Reference CPMP-Guidelines: "Chemistry of New Active Substance" and "Chemistry of the Active Substance"

Figure 4: Volume 2B - Notice to Applicants; exemplary chapter belonging to Module 3 – Quality.[17]

This dossier structure is known as *Common Technical Documentation* (‘*CTD*’).

Because EU, *United States of America* (‘*US*’), Japan, Switzerland, and Canada are members of the ICH, the structure leads to an easier compilation of applications in these regions. National deviations are covered by the first module of the structure. Besides time and cost reduction, this system enhances the transparency of scientific data, as every authority receives information in a similar structured way, opening the possibility of future harmonisation of the review process in order to obtain the marketing authorisation.

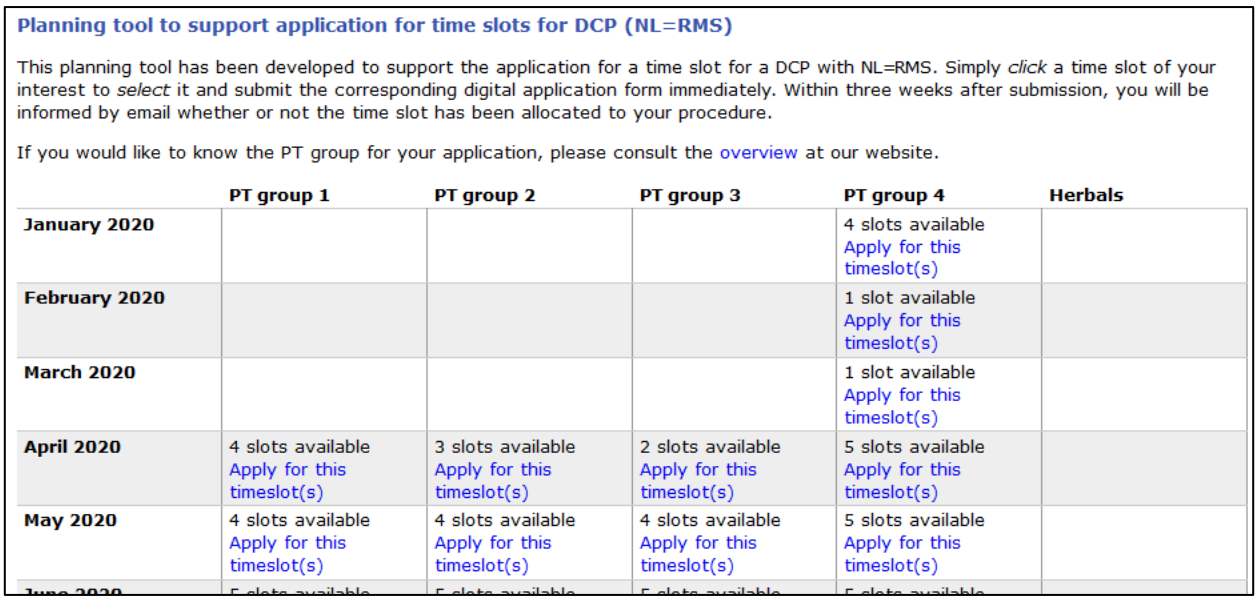
3.1.1 Electronic Submission of *Common Technical Dossiers within the Pharmaceutical Industry*

The pharmaceutical industry is using an *electronic automatization of dossier submission* (‘*eCTD*’) for several years now. This method narrows down the flexibility of submitted content to a minimum and allows submission software to be used.

Advantages of electronic submission are within are constant on-line access, fast navigation by using hyperlinks and a well-known structure, easy update of individual files, and automated splitting into individual content for different review groups (*DocuBridge* by Lorenz; www.lorenz.cc).

In addition, several administrative tasks could be automated such as the use of software to check completeness and compliance for a certain level already from the manufacturer’s side (*eValidator* by Lorenz; www.lorenz.cc).

Another administrative task that is already taken over by software within the pharmaceutical industry is the assignment of review slots. The Dutch Ministry of Health, Welfare and Sport has established a Medicines Evaluation Board, which is providing a webpage to online book an individual slot for dossier submission and review (see Figure 5).



Planning tool to support application for time slots for DCP (NL=RMS)

This planning tool has been developed to support the application for a time slot for a DCP with NL=RMS. Simply *click* a time slot of your interest to *select* it and submit the corresponding digital application form immediately. Within three weeks after submission, you will be informed by email whether or not the time slot has been allocated to your procedure.

If you would like to know the PT group for your application, please consult the overview at our website.

	PT group 1	PT group 2	PT group 3	PT group 4	Herbals
January 2020				4 slots available Apply for this timeslot(s)	
February 2020				1 slot available Apply for this timeslot(s)	
March 2020				1 slot available Apply for this timeslot(s)	
April 2020	4 slots available Apply for this timeslot(s)	3 slots available Apply for this timeslot(s)	2 slots available Apply for this timeslot(s)	5 slots available Apply for this timeslot(s)	
May 2020	4 slots available Apply for this timeslot(s)	4 slots available Apply for this timeslot(s)	4 slots available Apply for this timeslot(s)	5 slots available Apply for this timeslot(s)	

Figure 5: Screenshot from webpage www.dcp-time-slot.cbg-meb.nl, accessed: 05.01.2020.

3.2 Requirements and Aims related to Technical Documentation in the Medical Device Industry

While reviewing authorities for medicinal products can create and enforce the implementation of structures like the CTD, the medical device industry faces two industrial partners – the notified body and the manufacturer – that need to align with their visions while following individual obligations provided by a third party, the EU. Even though they are empowered to take samples and review independently, competent authorities usually are not involved in the document compiling process of the manufacturer or the review process at the NBs, but creation and enforcement of submission guidance documents would still fall under the CA's responsibility.

3.2.1 EU-MDR related Requirements

The term '*technical documentation*' is mentioned in various places within the EU-MDR. Besides only referring to the term by mentioning it in relation to other aspects, there are

sections either specifically focusing on content, administrative requirements or required attributes and features related to the TD.

In the following sub-chapters within the EU-MDR, citations of the EU-MDR are provided in grey boxes. The detailed source is mentioned in the below right of each box. Red letters are made by the author to highlight the main aspects of each citation.

Other national laws for the implementation of EU-MDR or amendments to already existing laws might give additional information on technical documentation. However, the German Medizinprodukte-EU-Anpassungsgesetz MPEUAnpG (draft of Nov. 6, 2019) for instance, does not.

3.2.1.1 Attributes

> The technical documentation and, if applicable, the summary thereof […] shall be presented in a clear, organised, readily searchable and unambiguous manner […].
>
> EU-MDR, Annex II

> The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed.
>
> EU-MDR, Article 10 (4)

Annexes II and III lay down the major attributes of the TD using the exact same phrasing. To avoid misunderstandings within the documentation, the need of clarity of information is addressed. This requirement is even supported by requesting unambiguous information. The information provided in the TD needs to be understandable and precise. To streamline the review process, a proper organisation is addressed, leaving open whether this addresses structure and information and how exactly this should look like. In the end, all necessary information to check conformity needs to be provided. To further support the reviewing process, documents need to be provided in a manner that enables a software

to read the information. Whenever there are scans of documents, this might not be possible on default. In such cases, there is the possibility for the industry to use *Optical Character Recognition* ('*OCR*') software that can identify text from various sources (e.g. in writing, pictures or scanned documents) and transfers it into machine-encoded text. Usage of indexing phrases instead might be possible to a certain extent, always bearing the risk that reviewers cannot find the required information right ahead.

> The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, […] be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.
>
> EU-MDR, Article 52 (12)

Dependent on which NB was chosen, this might have an impact on the TD as well: Even though English is usually accepted as language a TD is presented in, individual member states can decide differently and request documentation in their mother tongue.

Especially whenever there is a switch of notified bodies, this fact might bear complications.

3.2.1.2 Administrative Requirements

> Manufacturers of devices […] shall draw up and keep up to date technical documentation for those devices.
>
> EU-MDR, Article 10 (4)

> Data gathered by the manufacturer's post-market surveillance system shall in particular be used: (a) to update the benefit-risk determination and to improve the risk management […]; (b) to update the design and manufacturing information, the instructions for use and the labelling; (c) to update the clinical evaluation; […]. The technical documentation shall be updated accordingly.
>
> EU-MDR, Article 83 (3)

It is the responsibility of each legal entity putting medical devices on the European market to create a TD. The content needs to reflect the individual current state of the devices; means whenever there is any change of information that impacts the content, the individual sections need to be revised to provide the most up to date information.

> The person responsible for regulatory compliance shall at least be responsible for ensuring that: […]
> (b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date.
>
> EU-MDR, Article 15 (3)

Within the industry, at least one *Person Responsible for Regulatory Compliance* (‘*PRRC*’) is accountable for the execution of the existence and validity of the data. Appointed by a manufacturer and authorised representative, a corresponding person fulfilling the criteria to take over responsibility stipulated under b) needs to be available. This role needs access to the entire TD, as well as to critical device history records and relevant processes.

> The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed.
>
> EU-MDR, Article 10 (4)

> Manufacturers shall keep the technical documentation […] available for the competent authorities for a period of at least 10 years after the last device […] has been placed on the market. In the case of implantable devices, the period shall be at least 15 years […].
>
> Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.
>
> EU-MDR, Article 10 (8)

> The authorised representative shall […]:
>
> (a) verify that the […] technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer.
>
> (b) keep available a copy of the technical documentation, […] at the disposal of competent authorities for the period referred to in Article 10(8).
>
> EU-MDR, Article 11 (3)

The notified body needs to have access to the TD whenever a review needs to take place. This usually happens during initial registration or for recertification reasons. Therefore, access to relevant information needs to be granted.

Competent authorities also have the right to review the TD whenever the need to do so arises and even can request insight for documentation for already discontinued products. To be prepared for such requests, any kind of archiving system is required that is providing the TD content not only in the most up to date version but also reflecting every single produced lot of products for the defined period of 10, resp. 15 years.

Both scenarios described above imply a one-time and time-restricted access, allowing different methods of file sharing. In cases where manufacturers are located outside the EU, a local authorised representative is required. In such cases, this party desires access to the TD whenever needed to verify that the devices still comply with legal requirements.

In addition, the competent authority may ask the representative to provide the TD and all related certificates.

> A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:
>
> — the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, […]
>
> EU-MDR, Article 61 (5)

Even though Article 61 focusses on clinical evaluations, the citing of full access to documentation owned by another supplier might be important for the entire TD, depending on which parts of the information are about to be shared.

Permanent access to all relevant documents for the *Private Label Manufacturer*, (‘*PLM*’), provided by the *original equipment manufacturer* (‘*OEM*’), is required so that the PLM’s PRRC can verify and assess compliance independently within OEM/PLM relationships.

3.2.1.3 Content-related Requirements

> As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.
>
> EU-MDR, Article 27 (7)

Together with Annex II paragraph 1.1 lit (b), stipulating that the TD should cover the so-called Basic UDI-DI – an identifier for device models – this section leads to the requirement of one article clearly having assigned on TD file covering the device in its entireness, but also allows multiple (comparable) articles to be assigned to one TD. This fact is useful

for catalogue numbers that only have small deviations, e.g. a different length, bending angle or colour.

> […], the Commission, […], may, by means of implementing acts, adopt common specifications (CS) in respect of […] the technical documentation set out in Annexes II and III, […].
>
> EU-MDR, Article 9 (1)

The content of a TD is highly dependent on additional guidance provided by the European Commission. There are not only specific national or international standards or directives covering important aspects of the medical device or processes related to it, but also a new kind of documents called *Common Specification* (‘*CS*’). Such CS will be subsequently published as implementing acts within an undefined period, resulting in potential changes to the TD whenever there is a newly published CS for devices defining new requirements.

> The technical documentation shall include the elements set out in Annexes II and III.
>
> EU-MDR, Article 10 (4)

The essential content of the TD is outlined in more than four pages in small type, providing six headlines, most of them even divided into further sub-headings. Further guidance on how to provide the information on each sub-heading is generally not given. The complete content of the MDR-Annexes is outlined in annex 8.3 of this thesis.

> […] For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II.
>
> EU-MDR, Article 84

> [..] That PSUR shall, except in the case of custom-made devices, be part of the technical documentation […].
>
> EU-MDR, Article 86

Articles 84 to 86 already contain the quintessence of Annex III, mentioning post-market surveillance activities such as a plan and a report. The Annex provides clarification on which information shall be addressed and what aspects shall be covered within the technical documentation.

3.2.2 Notified Body related Requirements

> Manufacturers of class IIb devices, […] shall be subject to a conformity assessment as […] including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.
>
> However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device. […]
>
> EU-MDR, Article 52 (4)

> Manufacturers of class IIa devices […] shall be subject to a conformity assessment […] including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices. […]. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.
>
> EU-MDR, Article 52 (6)

With several medical device manufacturers having a relatively high quantity of individual catalogue numbers, where usually the many devices can be divided up into only a few generic groups, the EU-MDR allows a sampling method for medium risk classification items for the NB to fulfil their obligation of reviewing without assessing each TD for each single catalogue number. That means during the first audit the NB reviews one TD of each generic group, and during the next audit the NB reviews the TD of another device of each generic group, and so on. This is already described further in the guidance document by MDCG 2019-13[18] by the *Medical Device Coordination Group* (‘*MDCG*’), which was created to advise to and assist the Commission and the Member States in ensuring a harmonised implementation of the regulations (EU) 2017/745 and 2017/746.[19]

Before the MDCG guidance document came into existence, experts from EU competent authorities designating notified bodies, the *Notified Body Operations Group* (‘*NBOG*’) created a similar document to harmonise their review approaches under EU-MDD[20].

> Manufacturers of class I devices, […] shall declare the conformity […] after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, […] the involvement of the notified body in those procedures shall be limited:
>
> (a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;
>
> (b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;
>
> (c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
>
> EU-MDR, Article 52 (7)

For devices with low risk classification, but special conditions like measuring ('I_m'), reusability ('I_r') or sterility ('I_s'), only specific information must be provided to the notified body for assessment. A complete TD needs to be existent, either way.

The notified body personnel conducting the TD assessment – the so-called product reviewers – need to fulfil specific requirements. EU-MDR outlines the qualification such persons need to meet for having the appropriate knowledge and background to completely understand the individual content (see Annex VII, 3.2 of EU-MDR).

3.2.3 Competent Authority related Tasks and Duties

> The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the clinical evaluation documentation as further outlined in Article 45.
>
> EU-MDR, Article 44 (8)

> The authority responsible for notified bodies […] shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the clinical evaluation documentation […].
>
> EU-MDR, Article 45 (1)

> The authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment. […]
>
> EU-MDR, Article 45 (3)

Even though Article 44 (8) of EU-MDR explains the level of scrutiny conducted by the competent authority to ensure high quality of the notified bodies' review, assessing the manufacturer's technical documentation and the related NB's report is an essential tool to check compliance with the related requirements outlined in EU-MDR.

> Based on the reports of the reviews and assessments by the authority responsible for notified bodies […], the MDCG may recommend that the sampling, carried out under this Article, cover a greater or lesser proportion of the technical documentation and clinical evaluation documentation assessed by a notified body.
>
> EU-MDR, Article 45 (5)

Just as the notified bodies can use a sampling method to assess a manufacturer's compliance with the regulation (see chapter 3.2.2 of this thesis), the competent authority is allowed to pick a certain amount of TD assessments and its particular content to fulfil the scrutiny obligation, too.

> The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation […].
>
> EU-MDR, Article 45 (6)

An additional implementing act might be available that provides additional details on how exactly the scrutiny of NB's assessments of technical documentation should be conducted. This will be a document helping different competent authorities to assess using the same criteria.

3.2.4 Manufacturer related Requirements

Pursuing an efficient use of human resources, there is the aim to cover as many products as possible within one TD, or at least all covered by the same basic unique device identifier. This is not only helpful for the initial compiling of the TD, but also for the maintenance including the writing of frequent reports. In addition, submission costs for frequent reviews conducted by the NB are reduced to a minimum. Contrary to this benefit, this method increases the risk for the company portfolio in case of negative review results. Multiple

technical files allow the personnel to distribute maintenance work throughout the year instead of having a few deadlines in a short time period.

Whenever the order of information to be created or gathered follows the internal processes, this supports completeness and consistency of data. Every time information needs to be duplicated or transferred in order to be implemented into the TD, this increases the risk of data incompleteness or conflicting data. So does the need to jump back and forth in document creation to follow the internal process flow. In some cases, this might lead to different documents containing the same information to support processes, in other cases processes might get slightly aggravated in favour of good data gathering.

Whenever an OEM/PLM-relationship is existent, easy accessibility of information for the PLM is a must. PLM needs to evaluate an entire TD of the product to fulfil the legal responsibility. In the interest of the OEM, access should be restricted to the critical and applicable documents only, but non-relevant information should be separated due to proprietary reasons. For European authorised representatives, taking over the duty of evaluating the availability and completeness of the TD, the situation is the same.

3.2.5 Other Legislative Frameworks to Consider

For Germany – the by-far biggest exporter of medical devices within Europe – EU member states are the main market (42,1%), followed by Asia (18,7%) and North America (18,5%). In particular, the US is the country with the highest import rates for German medical devices, followed by China.[21]

Medical devices entering the market of the United States are reviewed by the US-FDA, providing clearance based on the submitted information. The eCopy program supports electronic submission for medical device files but currently limits the medium to be a CD, DVD or a flash drive[22]. In addition, it must be accompanied by specific statements still provided in paper. A TD structure according to the ToC document, further explained in chapter 4.3 of this thesis, addresses US-FDA requirements as the United States is

participating in the group that created that structure but the use of the structure still is in the pilot state.[23]

China also centralizes review of TDs and market authorisation permissions in an institution run by the government, the *National Medical Products Administration* (‘*NMPA*’). NMPA already implemented a portal for *electronic Regulated Product Submission* (‘*eRPS*’).[24] Based on information available online, the eRPS portal supports submissions following the TD structure according to the ToC document, too.[25] Submitted documents must be either in Chinese or a Chinese translation must be provided in addition to the original documents.[26]

3.2.6 Software and IT related Requirements

For medicinal products, the eCTD process outlined in chapter 3.1.1 is relying on the use of an XML backbone. A defined folder structure with optional sub-folders for individual files is currently used to submit the dossier. For ease of use, software tools provide basic navigation via a user interface.[27] The Canadian health authority *Health Canada* (‘*HC*’) released validation rules for electronic submissions of the so-called “non-eCTD electronic-only” formats, outlining checks a software needs to pass before a submission can be transferred.[28] Implementing electronic submission processes within the medical device field, HC has received approximately 100 license applications before sharing their experience. It was identified that the granularity of the structure led to the need for adjustments but received an overall positive feedback.[29]

Based on this experience, they published a technical guide, in which e.g. the maximum variable characters (15 for device names and 50 for file names) for electronic paths were defined to enable suitability to Microsoft Office’s maximum character length of 259. Uploading files in the PDF format is preferred, other Microsoft Office formats are accepted. Whenever hyperlinking is done, the links should be relative. Scanned documents should be avoided whenever possible. In general, one file size is limited to 100 MB, and the complete submission package needs to be less than 4 GB.[30] However, the medical device industry does not yet have any experience in such submissions.

4 Approaches of Structuring a Technical Documentation

Especially for those MDs being up-classified because of new classification rules under EU-MDR, either being within the scope of the regulation and weren't before, or needing an NB approval while those devices previously entered the market without NB involvement under EU-MDD, a complete and most current revision of a TD might not even be in existence. International companies might have all the necessary information available, but this could be spread around several storage areas at one site or even at multiple sites. Available documentation might be created to suit the needs of a different market such as the United States, Brazil or China, resulting in incomplete fulfilment of the EU-MDR requirements.

A lot of devices falling under the new class I surgical reusable (I_r) are manufactured under an OEM/PLM-relationship, where the entity acting as a manufacturer in fact only sold the article under its own private label to complete their portfolio, while the OEM produced the device, but was never revealed to the end-user.

Since the availability of a TD is not a new requirement and was already existent under EU-MDD, there already are different approaches available to structure the submission documents. This structuring will need to be revised as EU-MDR now defines requirements more specifically, which will be outlined in the following sub-chapters.

4.1 EU-MDR – TD Structure according to Annexes II and III

Consisting of six chapters, Annex II of EU-MDR lists elements covering the sections product description, accessories, requirements on information for users, general safety and performance requirements, risk management, and validation of the product, which fulfilment is the prerequisite for market access of the products. During the post-market phase, additional elements are listed to include experience gained from the market into the documentation. These elements are described in Annex III of the EU-MDR.

Even though the Annexes outline the minimum content of the TD and relieve the burden of creating an internal template for industry using them as a structure would rather create a reference table for already existing documents rather than reworking the documentation structure to suit the needs of the new requirements, which would make it more a checklist than an actual structure of a TD. One source document might be either used as evidence for multiple elements, or multiple references would be needed to cover one element listed (many-to-many relationships). This would lead to the possibility of having redundant information within the entireness of the TD or even removal of important information within the specific source document during revision with no one realizing the consequences. As soon as existing documents are updated to align with the new structure, the advantage of an existing table of content is gone as additional time is needed for the industry to re-structure the documents available.

A completeness check conducted by NBs would be smoothened in case the Annex structure is followed as general gaps are easy to identify.

EU-MDR Annexes II and III	**Industry**	**Notified body**
Pro	+ existing table of content + Splitting of design-related and post-market documentation	+ Easy to assess
Con	- redundant information, that can be inaccurate or deleted without anyone noticing - many-to-many relationship between elements and documents - Checklist format would be best to fill the structure with information	- expert-review group related information might appear in different chapters

Table 2: Summarized Pros and Cons with regard to TDs structured according to EU-MDR Annexes II and III; presentation by the author.

4.2 GHTF – TD Structure according to the STED Guide

The *Global Harmonization Task Force* (‘*GHTF*’) was a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States, Canada, Japan, and Australia; founded in 1992. Amongst other harmonisation tasks, the GHTF started the attempt to create a standardised TD structure resulting in a nonbinding *Summary Technical Documentation guide GHTF/SG1/N011* (‘*STED*’), initially published in 2008.[31] Based on this circumstance, the member countries are accepting the format for registration purposes, resulting in some manufacturers already being familiar with this structure (hereafter called ‘STED structure’).

The name of the guide already indicates that the summary is not set up to cover all aspects of a complete TD under the EU jurisdiction, but rather is an additional document providing an initial overview to get more familiar with the device itself and the main features. This is even more the case for increased requirements under EU-MDR. Nevertheless, the EU-MDR suggests taking existing guidance documents like the STED into account to fulfil obligations of EU-MDR (see recital (5) of EU-MDR). This explains why the EU-MDR and the STED follow the same style.

Even the STED itself outlines its use for “selected premarket and post-market conformity assessment activities” only, respectively mentions that “the regulatory requirements of some countries do not […] align fully with this guidance”. [31]

By using examples, abstracts, high-level summaries or existing controlled documents, the main aspects of a TD like device description, product specification, labelling, design, and manufacturing information, safety and performance information, risk management and product verification and validation are addressed within that format. Figure 6 shows that there is a difference within the depth of detail between a TD and a STED, which is especially obvious for design and manufacturing, as well as for risk management and verification and validation information, where the STED only provides summaries.

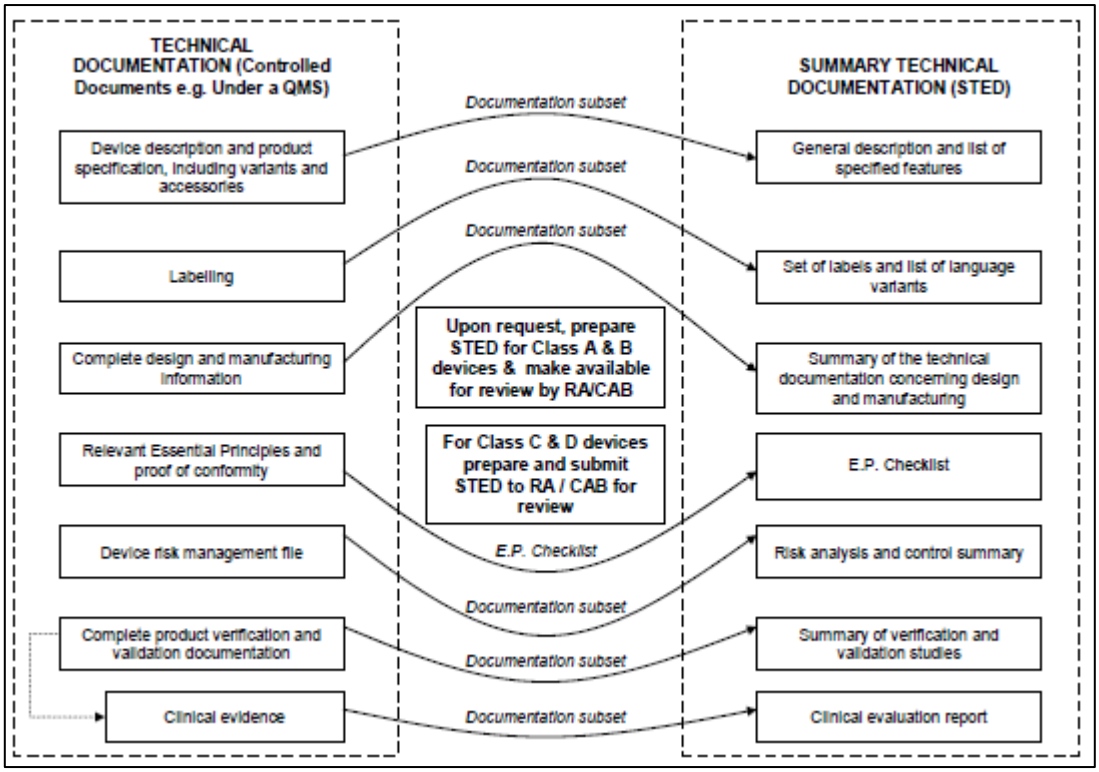


Figure 6: Premarket use of the STED, extracted from GHTF/SG1/N011:2008.[31]

The STED lists headings and explains the content that should be covered, making it easy for manufacturing companies to adopt the structure. It still allows a high level of flexibility regarding how and what information will be provided, leading to less streamlined content to be reviewed by the NB. Chapter 12 states that following the structure would be “helpful to both manufacturers and reviewers”. Annex A of the STED provides a template on the Essential Principle Checklist and explains how to use it, making it best practice for covering the essential requirements under EU-MDD, which will be substituted by the General Safety and Performance Requirements under EU-MDR.

STED Guide	Industry	Notified body
Pro	+ One document can be used in different countries all over the world + Well-explained headings + EU-MDR is structured in a similar way	+ Worldwide known format
Con	- not covering all aspects of a TD - no information about the depth of detail - Essential Principal Checklist template and EU-MDD referenced	- Flexibility leads to high differences in specific STEDs regarding content and layout/style.

Table 3: Summarized Pros and Cons with regard to TDs, structured according to STED guide; presentation by the author.

4.3 IMDRF – TD Structure according to the ToC Document

The *International Medical Device Regulators Forum* ('*IMDRF*') is a voluntary group of MD regulatory authorities from around the world who, working together with industry expertise on demand, focus on building and accelerating international medical device regulatory harmonisation and convergence limitations of a paper format.[32]

Founded in 2011, IMDRF finalized the document *IMDRF/RPS WG/N9 (Edition 3) Final:2019* ('*nIVD MA ToC*'), hereinafter also called '*ToC*' structure, addressing specifics about the TD content requested by participating regulators, that initially was started by the GHTF. [33]

The recommendation made by the IMDRF "provides an internationally harmonised, modular, format for use when filing medical device submissions to regulatory authorities for market authorisation. […]. To create a comprehensive submission structure that can be used as a harmonised international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is intended to provide guidance regarding the location of submission elements. This document

is intended to work together with a separate document created for each participating jurisdiction — a classification matrix."[33] and can be seen as the successor of the STED structure. Consisting of 53 pages and more than 200 sub-chapters, the document is relatively extensive and complex to follow, but covers all types of medical devices by providing a granulated structure covering all eventualities. The structure enables quick access to relevant information for NBs. For the industry, the related information would need to be split upon multiple documents, requiring a change in mindset.

In conjunction with IMDRF/RPS WG/N27 FINAL:2019, the *Assembly and Technical Guide for IMDRF Table of Contents Submissions* is addressing specific questions outlining the steps on how to start gathering the information.[34] For example, the document suggests to initially download the folder structure. This saves a lot of time for manufacturing companies as there is no need to identify an own structure. It can be considered cutting in both ways for the reviewers as on the one hand, they can find documents easily and improve document consistency, but on the other hand might be faced with empty folders that haven't been deleted by the manufacturer as intended (see Figure 7).

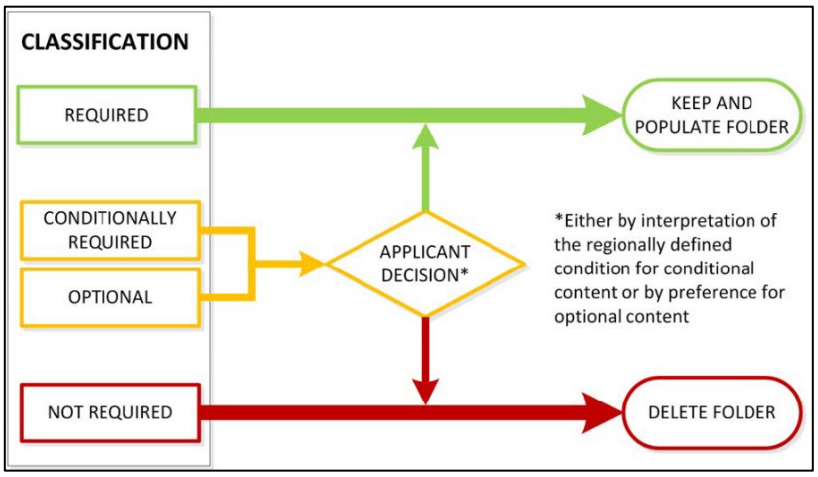


Figure 7: Decision chart for folder inclusion, figure 2 of Health Canada adapted assembly and technical guide for IMDRF table of contents submissions[30]

Individual region-specific requirements and risk class dependencies are outlined in regional Classification Matrices, allowing the manufacturer to easily identify required vs. optional or conditionally required aspects. Whenever the devices are about to be sold into

multiple markets, the guidance document suggests having a complete set of information and subsequently delete the non-required information within the copy dedicated to the individual region. Without technical support, these actions might lead to incorrectly manipulated data as either unintentional deletion of important data relevant for the region could occur, or the accidental omitting of deletion might result in difficulties during the review phase. Multiple almost identical file compositions increase the risk of a mix-up during submission phases for different regions. However, even though it is upon each regulator to provide a Classification Matrix, such a matrix is not yet available for the EU or its individual countries. In addition, the current version of the ToC still contains comments referring to EU-MDD.

Canada already requests the manufacturers to use the ToC structure for certain devices and provides a Classification Matrix draft for specific classifications and submission types[35]. US, Brazil, Australia, China, and the EU are accepting the structure.[36, 37]

The usage of a submission software is already anticipated (see chapter 3.2 and Annex I of the ToC document).

ToC Structure	Industry	Notified body
Pro	+ Accepted by the major markets + Granulated folder structure + Use of software is possible + Regional-specific deviations from the default-template are addressed + Covers all types of devices in one single format	+ Pre-structured folders improve consistency for reviewers
Con	- Complex to follow and fill as related information is not necessarily in one document. - Incorrect manual modifications - Regulators need to create Classification Matrices first	- Empty folders might increase review times

Table 4: Summarized Pros and Cons with regard to TDs, structured according to the ToC guide; presentation by the author.

4.4 Team-NB – Recommendation Paper / NB-MED/2.5.1/Rec5

Team-NB today consists of 26 different notified bodies, aiming for increased transparency of their work to ensure a harmonious standard is achieved amongst the members throughout Europe.

To support its customers, Team-NB frequently publishes recommendation papers. One of them – NB-MED/2.5.1/Rec5[38] – is dealing with technical documentation and is highly accepted amongst Team-NB members.

In its latest revision of 2000, the existing recommendation does not consider possibilities of electric document transfer or software usage yet. In addition, EU-MDR wasn't yet published when the last changes to the document were made. This increases the workload of the industry because gap assessments are required, as well as of the NBs for creating a reference matrix.

Team-NB indicates within the document that a justification should be provided whenever recommended information is not provided for a reason.

Providing guidance on content and structure separately in the chapters 3 and 4 of the document, it still takes additional effort to identify where each content should live (see Figure 8).

NB-MED 2.5.1 Rec5	
Part A	**Part B**
I - Name/Address of the Manufacturer	I - Risk Analysis
II - Identification of the Device	II - Test Reports
III - Name/Address of the Facilities	III - Quality Manual
IV - Name/Address of the Notified Body	IV - Plans
V - Conformity Assessment Procedure	V - Description of Products and Processes
VI - Declaration of Conformity	VI - Standards applied
VII - Brief Description of the Device	
VIII - Label and Instruction	
IX - Relevant Regulations	
X - Technical Standards with Compliance	
XI - Brief Statement of Bench Testing and Clinical Data	

Figure 8: Structure of document NB-MED/2.5.1/Rec5; presentation by the author.

NB-MED Recommenda-tion	Industry	Notified body
Pro	+ High acceptance in case respective NB is part of Team-NB + Both, structure and required content are outlined	+ Was created by NBs solely
Con	- Not incorporating the latest technical status - Not addressing EU-MDR - Not addressing other regions - Content and structure still need to be aligned	- Increased workload to identify EU-MDR related information

Table 5: Summarized Pros and Cons with regard to TDs, structured according to the corresponding NB-MED/2.5.1/Rec5 recommendation; presentation by the author.

4.5 Other Structures

Besides the more well-known recommendations and guidelines mentioned in the previous sub-chapters, there are numerous individual solutions by other parties.

4.5.1 Notified Body specific Structure Recommendations

Each NB has developed its own preferred structure that fits best to internal workflows. Some of them are only used internally and are not shared with customers, others can be purchased on demand (e.g. *Submission Form on the completeness of sterilization validation Documentation according to ISO 17664:2017 requirements* for Class I_r devices by TÜV SÜD) or may be published on the internet. The best-to-find example for the last option is provided by MDC. Even being part of Team-NB, MDC offers additional clarification in *Structure of Technical Documentation* (*ID: 2379*, 002/07.2019)[39] regarding general MDs; while *Technical Documentation for reusable surgical instruments (class I_r)* (*ID: 3468*; 001/07.2019)[40] addresses class I_r devices.

These two documents are noteworthy because EU-MDR related information is already included. While *ID: 2379* in its current revision provides headlines only, *ID: 3468* contains additional information on what a TD for low risk devices should cover, explaining the level of detail and circumstances for specific headlines.

4.5.2 ASEAN CSDT

The *Association of Southeast Asian Nations* (‘*ASEAN*’) has published a draft paper called *Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN Common Submission Dossier Template*[41], which is based on the STED structure.

4.5.3 US-FDA

The *Format for Traditional and Abbreviated 510(k)s Recommendation paper*[42], issued by the US-FDA, contains recommendations for a premarket submission type dealing with device groups comparable to class I within the EU. This specific submission type mainly focusses on design aspects and verification and validation, while the TD per EU-MDR includes additional aspects. A comparison of the requirements for the 510(k)-submission package to the EU-MDR requirements is provided in annex 8.1 of this thesis. Comparing the general documentation requirements for the premarket notification process – PMA – outlined in 21CFR §807.87[43], the result is similar (see annex 8.2 of this thesis).

The ToC structure is accepted by the US-FDA (see chapter 3.2.5).

4.6 Possible Approach of a Common Technical Document Structure for EU-MDR

Constantly increasing expectations and stricter scrutiny led to the demand for harmonisation of the content of a TD not only regional but even on a global scale.[44] Culminating into the requirements set within the EU-MDR, the demand for not only a harmonised content, but also a harmonised structure increased by different involved parties.

The recommendation laid down in IMDRF's ToC guideline (see chapter 4.3 of this thesis) already provides an excellent base as a granular structure is already defining the requested content in a very detailed manner, while Annexes II and III of the EU-MDR (see chapter 4.1) provide information about content, but do not guide regarding a feasible submission structure. Succeeding the STED guide (see chapter 4.2), the ToC structure already considers electronic submission. Using the structure recommended by NB-MED (see chapter 4.4 of this thesis) might provide slight advantages when dealing with an NB which is member of that association, but as soon as a notified body change is requested for variable reasons, there is the risk of a demand to restructure the documentation. In addition, the recommendation is not referring to the latest EU-legislation.

Whenever the same MDs are also about to be sold within other regions – especially Canada, the US, and China – not using the structure recommended by the ToC document would entail redundant efforts maintaining at least two files per product group.

Disadvantages like the compulsory structure can cause challenges during document creation as it does not fit to process flows within the industry, leading to necessary manual modifications, or empty, but non-deleted folders, that would cause an increase of review time. This could be suspended by creating helpful internal process descriptions or using software that supports the data gathering.

For the purpose of this thesis, it was decided to use the structure as laid down in the IMDRF's ToC structure and cross-reference relevant headings corresponding with EU-MDR. In addition, a proposal for the Classification Matrix for the EU will be provided to enable manufacturers to use the system. The result of these exercises are presented in annex 8.4 of this thesis.

5 Discussion

All regulatory requirements described in the previous chapters and related information on their implementation, especially in operational practice, are reviewed in a scientific way within this chapter to identify the strengths, weaknesses and uncertainties of the proposal made in chapter 4.6 and the use of submission software.

5.1 The Author's Proposal for a Regional Classification Matrix for EU and Cross-Reference to EU-MDR Requirements for the ToC (Annex 8.4 and 8.5 of this Thesis)

The information in annex 8.4 of this thesis about individual chapters respectively subchapters, herein after called only chapters (also referred to as '*Row IDs'*), heading classes and heading levels, name of the chapter (referred to as heading) and a description of the content, as well as EU-related additional information were extracted from the ToC document IMDRF/RPS WG/N9 (Edition 3) Final:2019 [33]. This information was laid down in columns one to six of annex 8.4 and was amended by an evaluation done by the author, providing a proposal for the Classification Matrix (column seven) and a justification why the individual evaluation was chosen (column eight), the reference section of EU-MDR that would be covered by the corresponding chapter (column nine), and an evaluation of if this chapter is referring to specific functions or attributes (column ten). For the complete evaluation, please refer to annex 8.4 of this thesis.

To evaluate the need for certain Row IDs, similar terminology to the Canadian Classification Matrix[35] was used (see Table 6). Whenever the assignment wasn't clear based on available information, the author provided a proposed classification assignment (PR or PCR, etc.).

Classification Evaluation	Description
R	Required; there is a specific source mentioning this aspect within the EU-MDR.
PR	Required (proposal by the author); there is no specific source mentioning this aspect within the EU-MDR but to provide this chapter is recommended as the same aspect was required per comment section in the ToC under EU-MDD.
CR	Conditionally required, in case the conditions lead to this assumption; there is a specific source mentioning this aspect within the EU-MDR under certain circumstances.
PCR	Conditionally required (proposal by the author), in case the conditions lead to this assumption; there is no specific source mentioning this aspect, but as soon as certain circumstances are met, to provide this chapter is recommended as the same aspect was required per comment section in the ToC under EU-MDD.
O	Optional; decision to be made by the manufacturer
PO	Optional (proposal by the author); decision to be made by the manufacturer
NR	Not required; there is no source mentioning this aspect within the EU-MDR and per comment section in the ToC under EU-MDD.
PNR	Not required (proposal by the author); there is no source mentioning this aspect within the EU-MDR and per comment section in the ToC under EU-MDD.

Table 6: Legend for Classification Evaluation (column seven of annex 8.4 of this thesis); presentation by the author.

Comparing the proposed EU-Classification Matrix with the Canadian Classification Matrix, the following similarities and discrepancies could be identified (see annex 8.5 of this thesis):

For chapter 1.04 of the ToC, that was marked as “required” within the Canadian Classification Matrix, it could be observed that it is also required per EU-MDR. For chapters where HC set further conditions like specific classifications as an additional condition to the evaluation “required”, the author of this thesis would either mark them as “required” or “conditionally required”. There is one outstanding chapter that was identified by HC to be

conditionally required but was evaluated to be an optional chapter under EU-MDR, which is 5.10 of the ToC, dealing with additional information on labelling and packaging that might not be covered by other chapters.

Health Canada has evaluated far fewer chapters as being “required” or “conditionally required” than what the result of the evaluation of EU-MDR was indicating (see Table 7).

Health Canada		**EU-MDR Evaluation**	
R	4	R	60
		PR	3
CR	11	CR	64
		PCR	43

Table 7: Comparison of Classification Matrix settings of Health Canada draft[35] and EU-MDR Classification Matrix created by the author; presentation by the author.

Based on the evaluation done, there is no specific need for further EU member state specific classification matrices as EU-MDR is already setting clear requirements. Differences from NB to NB might occur, though. Those would be related to administrative information, fees or previous correspondences.

Only for the global market history (chapter 2.06.01 of the ToC), where under EU-MDD the commission provided some additional information, the evaluation down-classified the chapter to “not required as per proposal by the author”. The sub-chapter’s content will be, according to EU-MDR, part of the post-market surveillance reports, as the post-market surveillance plan stipulates to provide “publicly available information about similar medical devices” (see Annex III, 1.1 (a) of EU-MDR) and therefore is considered to no longer be needed by the author.

Based on the evaluation done, all other commented chapters under EU-MDD will remain required even under EU-MDR.

5.2 Feasibility of the Author's Proposal to meet Requirements

Cross-referencing the individual requirements for a TD outlined in Annexes II and III of the EU-MDR to the chapters outlined in IMDRF's ToC, each EU-MDR requirement is at least covered once by any chapter of the ToC guide (see Figure 9).

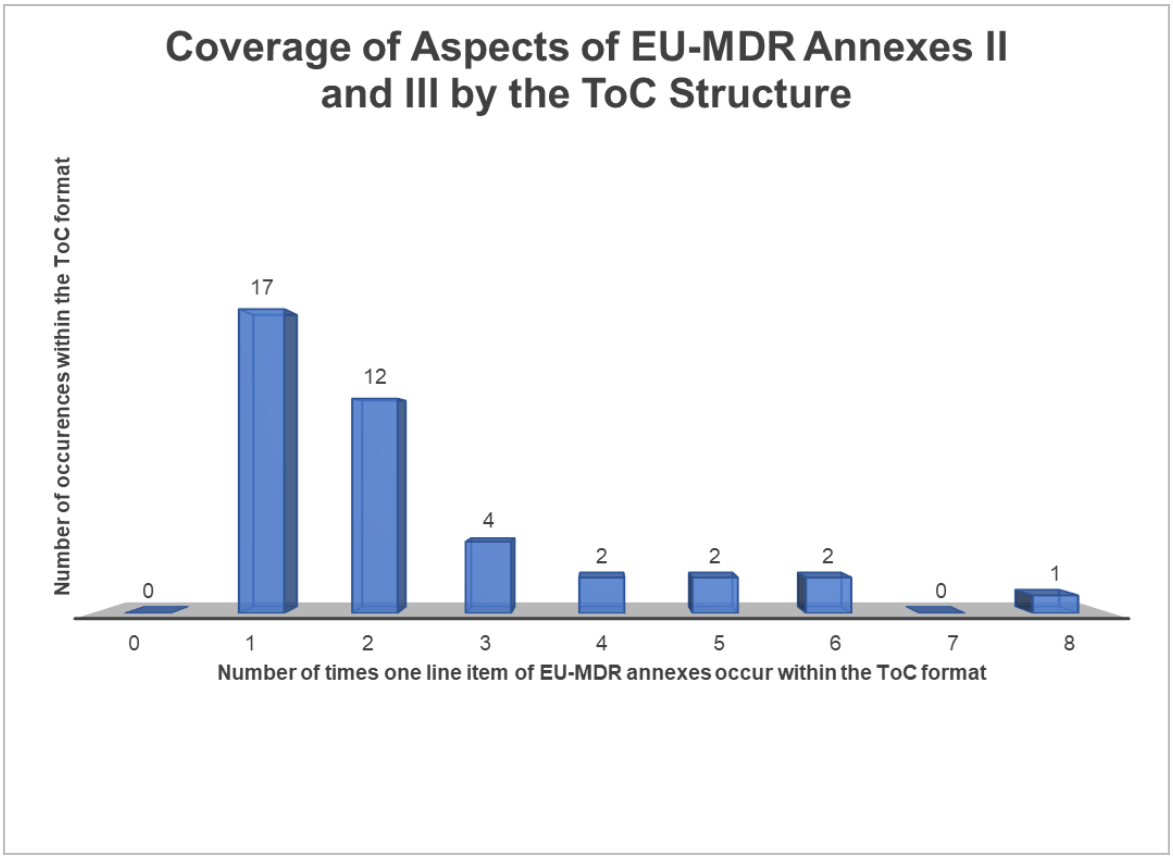


Figure 9: Coverage of aspects and requirements of EU-MDR Annexes II and III by those laid down in IMDRF's ToC guide; presentation by the author.

Not visualized in Figure 9, the requirements for product verification and validation documentation (Annex II, (6) of EU-MDR), as well as the results of pre-clinical and clinical data or other testing (Annex II, (6) (a) of EU-MDR) were assigned 39, resp. 22 times within the ToC structure, making them outliers to the statistics. They were disregarded because ToC is splitting up the requirements 'study-related information'; e.g. physical and mechanical, electrical, radiation, material-specific or condition-specific testing areas, into individual chapters rather than just combining them under a chapter called 'Studies'.

Considering all chapters of the ToC structure that are evaluated as either completely, conditionally, optionally or high likely be required (R, CR, PR, PCR, O, PO), 86% of the overall chapters are needed to compile a complete TD per EU-MDR (see Table 8).

Classification Matrix Evaluation Result	Occurrence in ToC (Quantity; %)	
R	60	29%
PR	3	1%
CR	64	31%
PCR	43	21%
O	6	3%
PO	0	0%
NR	24	12%
PNR	4	2%

Table 8: Distribution of Classification Matrix evaluation results in 'ToC structure' that are needed for a technical documentation under EU-MDR; presentation by the author.

Approximately 1/3rd of the chapters are referring to special conditions and attributes of the MD (see Table 9). This high number is mainly due to medical software, which is addressed in 17 chapters specifically applicable for such devices. This leads to the assumption that the ToC structure is feasible for being used to support compliance with EU-MDR in general, no matter which attributes or conditions the device might have.

I_m	Single use	Software	Implant
I_r	Reprocessing of single use	MDs listed in Regulation (EU) No. 207/2012†	Radiative
Biological origin	Sterile		Active

Table 9: Different conditions and attributes identified during ToC assignment tasks; presentation by the author.

The ToC structure needs to address all requirements outlined in chapter 3.2 of this thesis in order to be feasible for the new EU-regulation. Within annex 8.6, the author of this thesis summarized the individual requirements extracted from sub-chapters of 3.2, evaluated whether fulfilment is a must (M) or optional (opt) and to what extent each requirement could be addressed in the author's proposal of using the ToC structure.

While not even half of the identified requirements could be addressed by a structure approach alone, a combination with an appropriate software would cover 19 out of 21 listed mandatory requirements and 4 out of 5 beneficial requirements (see Table 10 and chapter 5.3).

† Regulation (EU) No. 207/2012 deals with specific medical devices, manufacturers may, under certain conditions, provide instructions for use in electronic form instead of in paper form, such as active implantable devices and their accessories intended to be used exclusively for the implantation or programming of a defined active implantable MDs, implantable MDs intended to be used exclusively for the implantation or programming of a defined active implantable MD, fixed installed MDs, MDs and their accessories fitted with a built-in system visually displaying the instructions for use and stand-alone software.

	Requirements identified (see annex 8.6)	Requirements addressed with the author's proposal	Requirements addressed with an appropriate software
Must	21	9	10
Nice to have	5	2	2

Table 10: Evaluation of requirement fulfilment (annex 8.6 of this thesis); presentation by the author.

5.3 Electronic Submission Support for the Medical Device Industry

After evaluating which requirements cannot be met by providing a feasible, annex 8.7 of this thesis focusses on main functionalities of a software for an electronic submission to close these gaps. This tool would need to ensure fulfilment of the remaining requirements identified in the previous sub-chapter of this thesis. While the Canadian validation guide[28] only is applicable for the pharmaceutical industry, the author defines these rules to be state of the art and therefore were considered as a must. All features identified to be mandatory in annex 8.7 are summarized in Table 11.

Software Tool	Required Feature to Fulfil Requirements
Content Management	User interface
	Automatic creation of bookmarks
	Archiving function
	Online access
	Different user setting options
Validator	User interface
	Automatic deletion of empty folders
	Verification of file and submission size
	Automatic conversion to accepted formats and latest versions
	Verification of accessibility and enabled copy and printing options
	Verification of functional hyperlinks and bookmarks
	Automatic path length verification
	Searchability check / OCR function
	Information dependency trees for information
Submission	User interface
	Defined harmonised structure

Table 11: Required features of software tools as per evaluation by the author of this thesis, results of execution see in annex 8.7 of this thesis; presentation by the author.

For other features, there might be different options or workarounds. Therefore, the author defined them as optional, but beneficial. The extraction of those features is listed in Table 12.

Software Tool	Beneficial Features to Fulfil Requirements
Content Management	Data relationship settings
	Data entry flow
Submission	XML backbone
	Language package

Table 12: Beneficial, but non-mandatory features of software tools as per evaluation by the author of this thesis, results of execution see in annex 8.7 of this thesis; presentation by the author.

5.4 Notified Body's Views on structured Technical Documentation

Asking notified body employees, it could be revealed during the recent survey carried out by the author of this master thesis, that only one out of eight notified bodies does not divide up the documentation into internal expert groups. Most of them have groups dealing with clinical, or sterilization or biocompatibility. Other, not as often existing expert groups within NBs are focusing on quality, risk management, software, electrical or biomechanical aspects (see annex 8.8 of this thesis, question 9).

Besides the purely documentation related preferences, the need for a proper inclusion of information gathered from the supply chain into the technical documentation was expressed by the participants of the survey, while there was no particular trend on weather a summary should be part of the TD, a non-applicable document should be just provided containing a rationale for no further content or not, or whether it is better to have fewer individual documents covering more information, or vice versa (see annex 8.8 of this thesis, question 11).

Most notified bodies supported the idea of an automated document completeness check to support their assessment, including an extended logic test that checks specific dependencies like e.g. that a sterile device automatically requires the availability of a sterilization validation (both 87%). A function to support reviews by enabling commenting within the original documentation, that can be either extracted by the system to create review reports and lists of deficiencies or enable the manufacturer to have a direct link between comment and the particular document section was considered an interesting feature by the majority as well (75%) (see annex 8.8 of this thesis, question 15). In general, the notified bodies participating in the survey were open-minded for an implementation of a notified body review software tool.

5.5 Uncertainty of Information, Documents, and Data

Even though it is based on official information and guidance documents, aspects like interpretation or information availability are influencing the outcome of evaluations done within this thesis. This chapter refers to uncertainties that might lead to different outcomes or need to be considered during recension.

5.5.1 State of the Art

EU-MDR's rapidly approaching application date on 26 May 2020 leads to a drumbeat of new information from official sources such as the European Commission or MDCG, from industry and industry associations and from individual stakeholders like experts or consultants.

During the preparation of this thesis, no evidence of any activity to update the ToC structure to EU-MDR or the creation of a Classification Matrix for the EU could be found.

For about 25% of the chapters of the ToC, there was no other way than to propose the necessity for the chapters to create the Classification Matrix based on the experience of the author and on previous evaluation by the European Commission under EU-MDD because no obvious evidence for the decision could be found in official papers.

There might be additional approaches used for structuring a TD provided by other notified bodies than those listed, software tools mentioned or independent structures used within the industry, which could not be revealed before finishing this thesis.

To evaluate the original idea of using the experience of notified bodies to create a feasible structure for a harmonised TD, covering all varieties of medical devices, a survey was set up. Out of 56 notified bodies either designated under EU-MDD or EU-MDR, of which 26 were contacted via e-mail or social media profiles for professionals, responses of eight individual notified bodies could be retrieved. It is noticeable that most responses were gathered from NBs currently applying for EU-MDR but weren't designated yet (see annex 8.8 of this thesis, question 1). If more notified bodies already designated under EU-MDR

would have provided their feedback, there might be a slightly different result, as those are the biggest players in that field.

Especially responses to the questions about implemented expert groups (see annex 8.8 of this thesis, question 9) and the individual preferences for main features of a harmonised document structure (see annex 8.8 of this thesis, question 11) showed a big discrepancy amongst individual opinions. This disunity of preferences resulted in refraining from the initial idea of using a structure that is tailored to notified body needs to support the review process and turned the focus on internationally accepted approaches instead.

5.5.2 Scope of Technical Documentation

The focus of this thesis was on new applications which need complete documentation rather than post-market surveillance reviews or reduced scope of documentation, e.g. amendments to existing registrations or classifications that require an assessment of defined sections related to specific functions and attributes only.

For such special activities, only a few chapters of a complete TD might be presented for review, therefore the thesis is expected to cover such TD extracts, too, but no detailed evaluation hereof is done. A complete technical documentation needs to be in place either way.

Small companies with only a limited number of long-time employees creating and maintaining the TD might find the ToC structure too massive. After identifying the fact by the author that even with this granular structure, there mostly is a direct relationship between the ToC structure and the requirements outlined for the content of a TD under EU-MDR (see Figure 9), the validity of this impression (ToC structure too massive) is challenged. However, it might be possible that employees still prefer to generate fewer documents covering more aspects rather than multiple files with very limited content.

The ToC structure allows the upload of multiple documents within one folder, which makes it feasible to cover few or many catalogue numbers within one TD.

5.5.3 Usage of Software Tools

The author's experience working in a middle-sized company with multiple sites in different countries, using an *Enterprise Resource Planning-system* ('*ERP-system'*) and a Document Management System was pointing to the direction of increased usage of software. Small companies with one site might not benefit from a system where process steps are conducted electronically. In addition, such software tools are quite expensive and need technically experienced personnel to maintain the integrity of the system.

For companies with a small portfolio which might not even undergo a lot of changes during the product life cycle, handling documents without using software might be easier and less expensive while providing the same data integrity level.

Following the ToC structure, there are a lot of individual documents required. The more individual documents used to create one technical documentation, the more important an automated revision control and software tool becomes in order to avoid compilation mistakes. The importance even increases when dealing with a broader portfolio.

Based on the survey, almost all participants from notified bodies expect a harmonised structure to support further integration of software and automatization and even 50% of them expect less mistakes and data errors (see annex 8.8 of this thesis, questions 5 and 6).

6 Conclusion and Outlook

This chapter outlines the chances and limitations of having a harmonised structure for technical documentation that is used across the medical device industry. In addition, the proposals made in previous chapters are reflected and possibilities for future implementations are made. The idea of increased software use will be critically discussed based on the research results provided within this thesis.

6.1 Common Technical Documentation Structure for Medical Devices

Within this thesis, it could be elaborated that a harmonised structure of the technical documentation for medical devices is evaluated being beneficial by several organisations to streamline their processes. In general, this idea of a harmonised structure is not new, and the pharmaceutical industry already has successfully implemented such a structure concerning the application of medicinal products for market authorisation. Also, there were several attempts from various entities such as task forces, regulator forums or single notified bodies to define a structure also for a TD of medical devices. Strengths and weaknesses of different approaches were outlined, showing that the requirements of EU-MDR can be met by using already existing approaches (see especially chapters 5.2 and 5.5.1 to 5.5.2 of this thesis).

Especially the ToC structure supported all aspects relevant of a technical documentation under EU-MDR (see Figure 9) in a manner that it can be considered the most promising structure to continue harmonisation efforts. This got more obvious after an assignment of ToC chapters to individual requirements of EU-MDR was conducted by the author (see chapters 5.1 and 5.5.2 of this thesis).

The assessment addresses gaps existing as the EU-MDR is brand new and is still missing important guidance documents. Providing a proposal for a Classification Matrix, this thesis supports the implementation of the ToC structure for the EU market, defining whether chapters are required, conditionally required, optional or non-required to be part of an EU-MDR compliant technical documentation. For chapters where no clear evaluation could

be made, a proposal was provided, being easily identified as such (see chapters 5.2 and 5.5.1 to 5.5.2 of this thesis).

The notified bodies employees participating on the survey conducted by the author of this thesis were not sure about whether one given structure could cover the broad variety of medical devices (see annex 8.8 of this thesis, question 4). These voices declaring that the structure of a TD is highly related to the classification and the specifics of the product could be disproved by providing evidence that only a few of the chapters of a TD following the ToC structure would be related to specifics. A significant difference in the TD content could only be observed for software devices, being non-physical products.

If the medical device industry would follow the ToC structure, this would mean, according to the author of this thesis, savings in time because there would be no longer differing structures per manufacturer that employees would have to understand when they are newly hired, and notified body review processes at the notified bodies could be set up more efficiently, too.

While a harmonised structure helps to address a lot of questions with regards to required data and their location within the documentation, quality of the content is not impacted and therefore still is the most critical aspect of a TD. In fact, a harmonised structure even highlights gaps in quality of information, providing comparability of different manufacturers and devices that hasn't been there before, so the opinion of the author further on. This would be in favour of EU-MDRs main objective to protect patients from any harm.

Dealing with global markets, harmonisation efforts have a high likelihood of being successful whenever they are addressing multiple regions at once. Future harmonisation might continue to happen on that level, reducing approval times and removing trade barriers[31] for participating regions, not only for the EU.

Manufacturers, being on the market for some time, already have EU-MDD compliant documentation in place that needs to be updated to meet the new requirements. Implementing a new structure would be a big time and administrative burden that they will probably try to avoid in favour of just closing the gaps to comply with the new regulation before the deadline is reached.

Seven out of eight notified bodies generally support the idea of a harmonised technical document structure; five of them even completely support (see annex 8.8 of this thesis, question 13). They could enforce the use of such a harmonised structure by only accepting submissions done in this format. In lack of such an officially supported structure of a TD, notified bodies have already created their own proposals and aligned their processes to them, so that it is uncertain that there will be any action from their side to support a different uniform structure of a TD.

The European Commission could make the ToC structure a harmonised standard or a common specification to successfully facilitate the implementation of a uniform structure and should execute this step as to the opinion of the author of this thesis.

6.2 Use of Software for Technical Documentation Creation and Submission

Evaluating the responses received within the survey, notified bodies seem open-minded for new software solutions. The current status of using software tools to address regulatory processes and particularly elements of a TD were summarized within this thesis, providing a foundation for an evaluation of what aspects would be compulsory for EU-MDR compliant software solutions. By showing that some requirements identified cannot be addressed by a structure only, but most of them would be covered by a combination of software and structure, this thesis highlights the benefits of such software tools.

Required features of software focussing on content management, completeness verification, and data transfer could be derived from assessing individual demands identified. While document management systems – mainly for quality management aspects – are already common in the industry, regulatory submission software is a relatively new subarea.

Evaluating the similarities of individual requirements of Annexes II and III of EU-MDR and the chapters of the ToC structure, the unambiguous assignment to that was identified could be considered a good indicator for the benefit of using not even document management systems, but even leaning towards content management systems. Not managing

documents anymore, but provide content instead would open doors to extended features such as complete language packages, as written texts would be generated using a modular system based on content decision trees, which would be appreciated in an environment that generally tends towards electronic data processing.

With this topic providing additional aspects to consider such as interconnectivity to other software like already used document management systems, ERP- or computer-aided design systems, and IT security. Requirements that can be derived to support these interconnections would require additional investigation with focus on technical rather than on regulatory aspects, and therefore goes beyond the bounds of this thesis.

At one point, the European database on medical devices EUDAMED could become the submission gate that links all parties: manufacturers uploading their documents and submitting it to the NB; individual reviewers of notified body assessing the portion of a TD that is related to their expertise only; and competent authorities that could sample TDs electronically to ensure quality of the NB assessments. Automatically created response letters based on the comments by the individual reviewers within the original files could be possible.

7 Summary

Being one of the biggest markets for medical devices, the European Union obliges the medical device industry to undergo major changes for the transition to the new legislative framework EU-MDR.

One of these changes is the adjustment of existing technical documentation to address all requirements outlined in the EU-MDR, impacting not only manufacturers but also notified bodies and competent authorities. Using this momentum, existing approaches were evaluated to find a structure not only meeting the requirements of the new EU-MDR, but also reducing the complexity of writing and assessing the TD by harmonisation. This proposal requires to also cover each medical device, independent of risk classification, purpose, duration of treatment, invasiveness, form, size or other attributes. To what extent software tools can be helpful to reach conformity was assessed, too, resulting in additional requirements from the IT point of view.

Within this thesis, it could be outlined that amongst several existing proposals such as using the order of MDR-Annex II and III as a structure, the STED format or recommendations by notified bodies, the ToC structure – published by IMDRF in 2019 – covers all identified requirements that are defined in the Annexes II and III of EU-MDR for technical documentation. A conducted evaluation even showed that for almost 50% of the requirements, a one-to-one relationship between the EU-MDR requirement and the chapters of the ToC structure is existing. Besides software as medical devices, all other devices – no matter what attributes and special conditions they are in (e.g. single use, biological origin, sterile, reusable surgical, implant) – did not differ much regarding the individual content to be provided within a TD, proving the feasibility of the ToC structure for covering all styles of medical devices under EU-MDR.

The aim of the thesis to provide a uniform structured TD that will be well-accepted by all involved parties is met as the evaluation supports a document that was created to even harmonise the documentation of the quality and safety of a device on an international level (see chapter 4.6 and annex 8.4 of this thesis).

While conducting this evaluation for the structure itself, a proposal for a not yet existent Classification Matrix for the EU could be made, closing an existing gap by providing guidance on whether individual chapters of the ToC are required, conditionally required or not required (see annex 8.4 of this thesis).

The thesis substantiates the feasibility of the structure under the new legislative framework and provides a contribution to the creation of an official Classification Matrix. The final creation of the matrix lies within the duty of the European Commission and will clarify whether chapters of the ToC structure, where no final decision based on the content of the EU-MDR could be made within this thesis, will be required or not.

Even though some of the expectations and requirements identified and discussed could be addressed by the ToC structure, there still was more than half of the requirements stipulated in the EU-MDR not yet covered. A software was identified to be helpful to close these gaps and the main software features necessary were outlined. Addressing further requirements for software development would go beyond the scope of this thesis; nevertheless, the thesis provides additional thoughts that should be taken into consideration when addressing this gap, which software providers has already started to address.

Interaction between structure, methods and regulatory intelligence was found to be providing a chance for further streamlining of processes, resulting in time and cost savings.

Even though every manufacturer on the market has already created technical documentation following individual structuring approaches in the current structure and every NB has built processes supporting their own recommended structure, investing time to reorganize documents to fit the ToC structure will be reasonable. It is better to adapt changes and build a new and sustainable structure, supported by a streamlined process rather than to continue with old methods and find supposedly smart workarounds to close obvious gaps to meet requirements outlined by EU-MDR instead.

> It is not the strongest of the species that survive, nor the most intelligent,
> but the most responsive one to change.
>
> Charles Darwin

8 Annexes

Each annex can be obtained in an editable spreadsheet upon request via professional networking portals such as LinkedIn (https://www.linkedin.com/in/nicole-heumesser-9b601b62/) or Xing (https://www.xing.com/profile/Nicole_Heumesser/cv).

8.1 Comparison of Content between US-FDA 510(k) submission and EU-MDR Requirements on TD

Legend:

x requirements are covered by EU-MDR

\- requirements are not contained in EU-MDR

Row US-FDA 510(k) submission

Column EU-MDR requirements

Comparison of Content between US-FDA PMA (row) and EU-MDR (column) Requirements		Device Description and Specification, including Variants and Accessories	Information to be supplied by the Manufacturer	Design and Manufacturing Information	General Safety and Performance Requirements	Benefit-Risk Analysis and Risk Management	Product Verification and Validation	Post-Market Surveillance Plan	Post-Market Surveillance Report
		EU-MDR: Annex II, 1.	EU-MDR: Annex II, 2.	EU-MDR: Annex II, 3.	EU-MDR: Annex II, 4.	EU-MDR: Annex II, 5.	EU-MDR: Annex II, 6.	EU-MDR: Annex III, 1.1	EU-MDR: Annex III, 1.2
PMA 21CFR 807.87	(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device	x	-	-	-	-	-	-	-
	(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission	-	-	-	-	-	-	-	-
	(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.	x	-	-	-	-	-	-	-
	(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.	-	-	-	x	-	-	-	-
	(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.	-	x	-	-	-	-	-	-
	(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.	-	-	-	-	-	x	-	-
	(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.	-	-	-	-	x	-	-	-

	(h) A 510(k) summary as described in 807.92 or a 510(k) statement as described in 807.93	-	-	-	-	-	-	-	-
	(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.	-	-	-	-	-	-	-	-
	(j) For a submission supported by clinical data: (1) If the data are from clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, or was not subject to the regulations under 56.104 or 56.105, and the investigational device exemptions regulations in part 812 of this chapter, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. (2) If the data are from clinical investigations conducted outside the United States, the requirements under 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in 812.28(a) of this chapter, include either a waiver request in accordance with 812.28(c) of the chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately	-	-	-	-	-	x	-	-
PMA 21CFR 807.87	(k) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act: (1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and (2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.	-	-	-	-	-	x	-	-
	(l) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.	-	-	-	-	-	-	-	-
	(m) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn	-	-	-	-	-	-	-	-

8.2 Comparison of Content between US-FDA PMA and EU-MDR Requirements on Documentation

Legend:

x requirements are covered by EU-MDR

\- requirements are not contained in EU-MDR

Row US-FDA PMA

Column EU-MDR requirements

Comparison of Content between US-FDA PMA (row) and EU-MDR (column) Requirements		Device Description and Specification, including Variants and Accessories	Information to be supplied by the Manufacturer	Design and Manufacturing Information	General Safety and Performance Requirements	Benefit-Risk Analysis and Risk Management	Product Verification and Validation	Post-Market Surveillance Plan	Post-Market Surveillance Report
		EU-MDR: Annex II, 1.	EU-MDR: Annex II,	EU-MDR: Annex II,	EU-MDR: Annex II,	EU-MDR: Annex II,	EU-MDR: Annex II,	EU-MDR: Annex III, 1	EU-MDR: Annex III, 1
PMA 21CFR 807.87	(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device	x	-	-	-	-	-	-	-
	(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission	-	-	-	-	-	-	-	-
	(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.	x	-	-	-	-	-	-	-
	(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.	-	-	-	x	-	-	-	-
	(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.	-	x	-	-	-	-	-	-
	(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.	-	-	-	-	-	x	-	-
	(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.	-	-	-	-	x	-	-	-

8.3 Annexes II and III of EU-MDR

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 1. (a) - 1	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(a) product or trade name and a general description of the device including its intended purpose and intended users;	product/trade name, general description
II, 1. (a) - 2	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(a) product or trade name and a general description of the device including its intended purpose and intended users;	intended purpose
II, 1. (a) - 3	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(a) product or trade name and a general description of the device including its intended purpose and intended users;	intended users
II, 1. (b)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;	Basic UDI-DI
II, 1. (c)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;	
II, 1. (d)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary;	
II, 1. (e)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(e) the rationale for the qualification of the product as a device;	
II, 1. (f)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;	
II, 1. (g)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(g) an explanation of any novel features;	
II, 1. (h)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;	
II, 1. (i)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(i) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;	
II, 1. (j)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 1. (k)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;	
II, 1. (l)	Annex II, 1.	Device Description and Specification, including Variants and Accessories	(l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.	
II, 1.2 (a)	Annex II, 1.2	Device Description and Specification, including Variants and Accessories	(a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;	
II, 1.2 (b)	Annex II, 1.2	Device Description and Specification, including Variants and Accessories	(b) an overview of identified similar devices available on the Union or international markets, where such devices exist.	
II, 2 - 1	Annex II, 2.	Information to be supplied by the Manufacturer	A complete set of the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and	Packaging / Labelling / Artwork
II, 2 - 2	Annex II, 2.	Information to be supplied by the Manufacturer	A complete set of the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold	IfU
II, 3. (a)	Annex II, 3.	Design and Manufacturing Information	(a) information to allow the design stages applied to the device to be understood;	
II, 3. (b)	Annex II, 3.	Design and Manufacturing Information	(b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;	
II, 3. (c)	Annex II, 3.	Design and Manufacturing Information	(c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.	
II, 4. (a)	Annex II, 4.	General Safety and Performance Requirements	The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include: (a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;	
II, 4. (b)	Annex II, 4.	General Safety and Performance Requirements	(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 4. (c)	Annex II, 4.	General Safety and Performance Requirements	(c) the harmonised standards, CS or other solutions applied; and	
II, 4. (d)	Annex II, 4.	General Safety and Performance Requirements	(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.	
II, 5. (a)	Annex II, 5.	Benefit-Risk Analysis and Risk Management	(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and	
II, 5. (b)	Annex II, 5.	Benefit-Risk Analysis and Risk Management	(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.	
II, 6.	Annex II, 6.	Product Verification and Validation	The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.	
II, 6.1 (a)	Annex II, 6.1	Product Verification and Validation	6.1. Pre-clinical and clinical data (a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the preclinical safety of the device and its conformity with the specifications;	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 6.1 (b)	Annex II, 6.1	Product Verification and Validation	(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular: — the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user; — physical, chemical and microbiological characterisation; — electrical safety and electromagnetic compatibility; — software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer); — stability, including shelf life; and — performance and safety. Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council (1) shall be demonstrated. Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;	
II, 6.1 (c)	Annex II, 6.1	Product Verification and Validation	(c) the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV;	
II, 6.1 (d)	Annex II, 6.1	Product Verification and Validation	(d) the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.	
II, 6.2 (a)	Annex II, 6.2	Product Verification and Validation	(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 6.2 (b)	Annex II, 6.2	Product Verification and Validation	(b) Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.	
II, 6.2 (c)	Annex II, 6.2	Product Verification and Validation	(c) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to: — absorption, distribution, metabolism and excretion; — possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions; — local tolerance; and — toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device. In the absence of such studies, a justification shall be provided.	
II, 6.2 (d)	Annex II, 6.2	Product Verification and Validation	(d) In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex.	
II, 6.2 (e)	Annex II, 6.2	Product Verification and Validation	(e) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.	
II, 6.2 (f)	Annex II, 6.2	Product Verification and Validation	(f) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
II, 6.2 (g)	Annex II, 6.2	Product Verification and Validation	(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.	
III, 1.1 (a)	Annex III, 1.1	Post-Market Surveillance Plan	1.1. The post-market surveillance plan drawn up in accordance with Article 84. The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83. (a) The post-market surveillance plan shall address the collection and utilization of available information, in particular: — information concerning serious incidents, including information from PSURs, and field safety corrective actions; — records referring to non-serious incidents and data on any undesirable side-effects; — information from trend reporting; — relevant specialist or technical literature, databases and/or registers; — information, including feedbacks and complaints, provided by users, distributors and importers; and — publicly available information about similar medical devices.	

Individual Requirements	**EU-MDR Source**	**Heading**	**Content** (Original wording of EU-MDR)	**Main Aspect** (only if text is split up)
III, 1.1 (b)	Annex III, 1.1	Post-Market Surveillance Plan	(b) The post-market surveillance plan shall cover at least: — a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market; — effective and appropriate methods and processes to assess the collected data; — suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I; — effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field; — methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period; — methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users; — reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86; — systematic procedures to identify and initiate appropriate measures including corrective actions; — effective tools to trace and identify devices for which corrective actions might be necessary; and — a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.	
III, 1.2	Annex III, 1.2	Post-Market Surveillance Report	1.2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.	

8.4 Recommended Structure laid down in ToC-Guideline including EU-MDR References and The Author's Proposal for an EU Classification Matrix

Legend:

R	Required; there is a specific source mentioning this aspect within the EU-MDR.
PR	Required (proposal by the author); there is no specific source mentioning this aspect within the EU-MDR but to provide this chapter is recommended as the same aspect was required under EU-MDD.
CR	Conditionally required, in case the conditions lead to this assumption; there is a specific source mentioning this aspect within the EU-MDR under certain circumstances.
PCR	Conditionally required (proposal by the author), in case the conditions lead to this assumption; there is no specific source mentioning this aspect, but as soon as certain circumstances are met, to provide this chapter is recommended as the same aspect was required under EU-MDD.
O	Optional; decision to be made by the manufacturer
PO	Optional (proposal by the author); decision to be made by the manufacturer
NR	Not required; there is no source mentioning this aspect within the EU-MDR.
PNR	Not required (proposal by the author); there is no source mentioning this aspect within the EU-MDR.
IMDRF	Used by most regulators and are therefore considered an IMDRF heading. Content of IMDRF heading contain common elements and may contain regional elements in addition to the common elements
IMDRF, RF	"Content needs to be considered with the specific region in mind and will likely need to be adapted for that region (e.g. regional approval numbers or regulatory history, regional variation in approved or requested intended use/indications for use)"
IMDRF, not all	In cases where not all regulators use the heading, the applicable jurisdictions are listed following the heading classification.
Regional	It contains no common elements. In this case, the heading name is consistent amongst IMDRF members, but the content will be specific and different for each region. Headings are also classified as Regional if they are required by only one jurisdiction

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
Chapter 1 - Regional Administrative									

1.01	IMDRF, RF	I	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission. c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample). d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated. e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s). f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. NOTE: The cover letter should not contain any detailed scientific information.		R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 1 II, 1. (a) - 2	
1.02	IMDRF	I	Submission Table of Contents	a) Includes at least level 1 & 2 headings for the entire submission b) Specifies the page number for each item referred to in the table. NOTE: Refer to the Pagination Section of this document for information about submission pagination.		P R	Summary of all required chapters for completeness check		
1.03	IMDRF	I	List of Terms / Acronyms	Terms or acronyms used in the submission that require definition, should be defined here.		P R	No requirement under MDR, but useful to avoid misunderstandings		

1.04	Regional	I	Application Form/Administrative Information	-	Notified Bodies (NBs) will each have their own application form and company information form, including details on the submission type (new, renew, changes), administrative data of the manufacturer, overview of subcontractors and their QMS certification documentation, underlying CE certificates in case of Own Brand labelling, general information of the product, including sterilisation method where applicable, nature of selected starting materials (e.g. drugs, animal tissue), applicable directive and classification. Consult relevant NB. N.B. Under EU legislation, the Own Brand	R	Notified body and case specific content; e. g. documentation of reason for review (e.g. application form of individual notified bodies or any kind of reverence in case a competent authority request technical documentation).		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
					Labeller is to be considered as the legal manufacturer and bears the regulatory responsibility of a manufacturer including the need to dispose of the entire technical documentation (see the EU Guideline on OBL: http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf)				

1.05	IMDRF, RF	I	Listing of Device(s)	A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each variant/model: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description that provides (e.g. Trade name, size, material) NOTE: i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant. ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit. iii. This is classified as RF in recognition that identification numbers may vary from jurisdiction to jurisdiction. RUSSIA: Any model/variant/configuration of device(s) listed should be limited (covered) by a single Global Medical Device Nomenclature (GMDN) Code and Term. The components within a kit/set can have their own GMDN Codes/Terms.	The listing should include the relevant Global Medical Device Nomenclature (GMDN) Code and Term	R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 1 II, 1. (b)	
1.06	Regional	I	Quality Management System, Full Quality System or Other Regulatory Certificates	-	EN ISO 13485 certificate in case it is issued by another Notified Body or registrar. CE full quality system certificates (QMS and annex II.3 MDD) covering the scope of products when	C R	Depending on the conformity assessment path chosen for the devices.	II, 1. (a) - 1 II, 1. (b)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
					issued by another Notified Body.				
1.07	Regional	I	Free Sale Certificate/ Certificate of Marketing Authorisation	-		NR	EU has its own process and is not relying on other marketing authorisations.		
1.08	Regional	I	Expedited Review Documentation	-		NR	There is no fast track review option available within the EU.		
1.09	Regional	I	User Fees	-	Signed quote and agreement for dossier review/audits	CR	Depending on the notified body, there might be the request to provide the signed quote to facilitate the review process internally.		

1.10	IMDRF, RF	I	Pre-Submission Correspondence and Previous Regulator Interactions	a) During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the regulator and the applicant. Further, the specific subject device may have been subject to previous regulatory submissions to the regulator. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, the following elements should be provided: i. List prior submission or pre-submissions where regulator feedback was provided ii. Prior submissions should include identification of submission iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application. iv. Issues identified by the regulator in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied marketing submission) for the subject device v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor. vi. Explain how and where the prior advice was addressed within the submission OR b) Affirmatively state there has been no prior submissions and/or pre-submission interactions for the specific device that is the subject of the current submission. NOTE The scope of this section is limited to the particular regulator to which the submission is being submitted (i.e. Health Canada does not	a) A statement is required that the product to be reviewed is not under application with another Notified Body, and has not previously been refused or cancelled by another notified body. b) For “borderline products”, where applicable, any rationale, supportive documentation and key documentation on communication with an EU Competent Authority and/or COM services, relating to the qualification/classification decision on such product. c) In case of transfer from another Notified Body, that status, including any open Non-conformity, and the associated dossier review reports, the latest audit report and for QMS transfer all	R	a) A statement is required that the product to be reviewed is not under application with another Notified Body and has not previously been refused or cancelled by another notified body. (Art. 53) b) For “borderline products”, where applicable, any rationale, supportive documentation and key documentation on communication with an EU Competent Authority and/or COM services, relating to the qualification/classification decision on such product. c) In case of transfer from another Notified Body, that status, including any open Non-conformity, and the associated dossier review reports, the latest audit report and for QMS transfer all audit reports from the existing certification cycle, will need to be submitted along with a letter of access from the new		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
				need pre-submission information relating to interactions with ANVISA).	audit reports from the existing certification cycle, will need to be submitted along with a letter of access from the new notified body to contact the old notified body to confirm any open issue. This will allow a specific date of transfer of application and CE marking.		notified body to contact the old notified body to confirm any open issue. This will allow a specific date of transfer of application and CE marking. (Art. 58)		
1.11	Regional	I	Acceptance for Review Checklist	-		NR	There is no such requirement outlined in EU-MDR		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
1.12	Regional	I	Statements/Certifications/Declarations of Conformity	No content at this level		NR	There is no such requirement outlined in EU-MDR		
1.12.01	Regional	II	Performance and Voluntary Standard	-		NR	There is no such requirement outlined in EU-MDR		
1.12.02	Regional	II	Environmental Assessment	-		NR	There is no such requirement outlined in EU-MDR		
1.12.03	Regional	II	Clinical Trial Certifications	-		NR	There is no such requirement outlined in EU-MDR		
1.12.04	Regional	II	Indications for Use Statement with Rx and/or OTC designation Enclosure	-		NR	There is no such requirement outlined in EU-MDR		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
1.12.05	Regional	II	Truthful and Accurate Statement	-		NR	There is no such requirement outlined in EU-MDR. Would be covered by 1.10, if needed		
1.12.06	Regional	II	USFDA Class III Summary and Certification	-		NR	There is no such requirement outlined in EU-MDR		
1.12.07	IMDRF, not all	II	Declaration of Conformity	As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with: a) the applicable provisions of the Essential Principles/Requirements b) the classification rules c) an appropriate conformity assessment procedure		R	Requirement per EU-MDR. (Art. 19)	II, 1. (f)	
1.13	IMDRF	I	Letters of Reference for Master Files	Letter from any Master File owner granting access to the information in the master file. The letter should specify the scope of access granted.		NR	There is no such requirement outlined in EU-MDR		
1.14	Regional	I	Letter of Authorization	-		CR	Whenever a manufacturer is located outside the EU, an authorized Represenatitive mandate is needed. (Art. 11)		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
1.15	IMDRF	I	Other Regional Administrative Information	Heading for other administrative information that may be important to the submission but that does not fit in any of the other headings of this chapter. NOTE: To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.		R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 1 II, 1. (a) - 2	
Chapter 2 - Submission Context									
2.01	IMDRF	I	Chapter Table of Contents	a) Includes all headings and sub-headings for the chapter. b) Specifies the page number for each item referred to in the table.		PR	Summary of all required chapters for completeness check		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.02	IMDRF, RF	I	General Summary of Submission	a) Statement of the device type (e.g. hip implant, infusion pump, standalone software) and name (e.g. trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (i.e. studies that are unique to the risks of this device type, for example burst testing of a ceramic femoral head; electrical safety evaluation (IEC 60601) testing for an infusion pump). b) Summary of submission, including i. The type of submission (e.g. new, amendment, change of existing application, renewal); ii. if amendment/supplement, the reason of the amendment/supplement; iii. if a change to existing approval, description of the change requested (e.g., changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers); iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission).	If renewal, amendment or change, identification of product (family) currently Marketed under CE mark and related certificate of MDD annex.	R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 1 II, 1. (a) - 2 II, 1. (e) II, 1. (f) II, 1. (g)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.03	Regional	I	Summary and Certifications for Premarket Submissions	-		NR	Premarket submissions are not possible within the EU.		
2.04	IMDRF	I	Device Description	No content at this level		R	Chapter contains requirements of EU-MDR		

2.04.01	IMDRF, RF	II	Comprehensive Device Description and Principle of Operation	a) A general description of the device, including: i. A statement of the device name ii. What the device does? iii. Who uses it and for what? (high level statement) iv. Where to use it? (places/environment where the device is intended to be used) v. How it works? Including a description of the features/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action) and if not readily apparent or typical for the device type, a brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function. vi. If applicable, labelled pictorial representation (diagrams, photos, drawings). vii. If system, how the components relate? viii. If applicable, identify if the device incorporates software/firmware and its role b) Product specification, including: i. Physical characteristics or relevance to the end user (dimensions, weight) ii. Features and operating modes iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits) iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images) v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text). c) List of accessories intended to be used in combination with the devices. d) Indication of any other medical devices or general product intended to be used in combination with the medical device (e.g. infusion sets and infusion pumps, bipolar electrode and RF equipment). e) Components or accessories that can be sold	For invasive, inhaled, ingested product, a list of ingredients, including their quantity, purity and or other relevant information to determine potential pharmaceutical supportive action.	R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 1 II, 1. (a) - 2 II, 1. (c) II, 1. (d) II, 1. (g) II, 1. (h) II, 1. (i) II, 1. (j) II, 1. (k) II, 1. (l)	

				separately should be identified. f) If approved by the regulator, provide the approval number and identification for each component or accessory. g) If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) OR an affirmative statement that the device is non-sterile when used. NOTE: The validation report is not expected be presented at this point, only the device sterility condition shall be indicated here. If appropriate, for the validation report, see Chapter 3 – Non-Clinical Studies. h) Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient. When required, full details to support how these specifications are met are to be provided in 3.5.02 – Chemical/Material Characterization. NOTE: If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description. i) If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material), source (e.g. blood, bone, heart, any other tissue or cells), and the intended reason for its presence and, if applicable, its primary mode of action. j) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary					

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				mode of action. k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). l) NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device					

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.04.02	IMDRF, not all	II	Description of Device Packaging	a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated; b) Specific packaging of accessories marketed together with the medical devices shall also be described; c) If the user needs to package the medical device or its accessories before they perform sterilization, information about the correct packaging (e.g. material, composition, dimension) should be provided.		R	Requirement per EU-MDR. (Annex II)	II, 2 - 1	
2.04.03	IMDRF	II	History of Development	For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version). For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and effectiveness of the final device design.		R	Requirement per EU-MDR. (Annex II)	II, 3. (a)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.04.04	IMDRF, RF	II	Reference and Comparison to Similar and/or Previous Generations of the Device	a) A list of similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject regulator. b) Description of why they were selected. c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device.		R	Requirement per EU-MDR. (Annex II)	II, 1. (l) II, 1.2 (a) II, 1.2 (b)	
2.04.05	Regional	II	Substantial Equivalence Discussion	-		NR	There is no market authorisation based on substantial equivalence within the EU.		
2.05	IMDRF	I	Indications for Use and/or Intended Use and Contraindications	No content at this level		R	Chapter contains requirements of EU-MDR		

2.05.01	IMDRF, RF	II	Intended Use; Intended Purpose; Intended User; Indications for Use	This section should include, as appropriate: a) Intended Use: The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (e.g. Diagnosis in vivo or in vitro, treatment monitoring rehabilitation, contraception, disinfection). b) Intended Purpose: What is expected with the use of this medical device? Which results are expected? c) Intended user and skills/knowledge/training that the user should have to operate or use the device. d) Identify if the device is intended for single or multiple use e) Indications for Use: i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use. ii. If applicable, information about patient selection criteria. iii. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended. f) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval. NOTES: i. The statements of intended use and purpose and the intended user and indications for use must be as presented in the labelling. ii. If more than one device is included, the information should be provided for each device		R	Requirement per EU-MDR. (Annex II)	II, 1. (a) - 2 II, 1. (a) - 3 II, 1. (c)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.05.02	IMDRF, RF	II	Intended Environment/Setting for use	a) The setting where the device is intended to be used (e.g. domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated. b) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).		PCR	Only needed if specific limitations occur.		
2.05.03	Regional	II	Pediatric Use			NR	There is no different market authorisation path for pediatrics within the EU.		
2.05.04	IMDRF, RF	II	Contraindications For Use	If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile. NOTE: The statement if contraindications for the device must be as presented in the labelling.		R	Requirement per EU-MDR. (Annex II)	II, 1. (c)	
2.06	IMDRF	I	Global Market History	No content at this level		R	Chapter contains requirements of EU-MDR		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.06.01	IMDRF	II	Global Market History	a) Up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing, including any marketing under compassionate use regulations. b) Should include history of the marketing of the device by any other entity in as much detail as possible, acknowledging that detailed information may not be available in all cases. c) If the subject device is different in any way (e.g. design, labelling, specifications) from those approved or marketed in other jurisdiction, the differences should be described. d) The month and year of market approval in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made. e) For each of the markets listed in (a) above, and statement of the commercial names used in those markets OR a clear statement that the commercial names are the same in all jurisdictions. f) State the date of data capture for the market history data g) If the subject device has been the subject of any previous compassionate use and/or clinical trials this should be identified and, if applicable, relevant reference numbers provided.	The commercial names used by the Original Equipment Manufacturer in case of Own Brand Labelling should be identified.	PNR	Original equipment manufacturing is no longer allowednder EU-MDR in the same way it used to be. Rest of this chapter iSurveillance reports.		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
2.06.02	IMDRF, RF	II	Global Incident Reports and Recalls	a) List adverse events/incidents associated with the device and a statement of the period associated with this data. b) If the number of adverse events is voluminous, provide a summary by event type that state the number of reported events for each event type. c) List of the medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case. d) A description of any analysis and/or corrective actions undertaken in response to items listed above. e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device. NOTES i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).		PNR	Aspects are covered under post market surveillance activities and reports.		

2.06.03	IMDRF, RF	II	Sales, Incident and Recall Rates	a) A summary of the number of units sold in each country/region and a statement of the period associated with this data. b) Provide the rates calculated for each country/region, for example: i. Incident rate = # adverse events/incidents divided by # units sold, expressed as a percentage ii. Recall rate = # recalls divided by # units sold, expressed as a percentage Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported. c) Critical analyses of the rates calculated (e.g. Why are they acceptable? How do they break down in terms of incidents? Is there some outlier data that has driven the rates up? Are there any trends associated with any sub-groups of the devices that are subject of the submission (e.g. size, version)?). NOTES i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF). ii. Sales in this context should be reported as the number of units sold. iii. The summary of sales should be broken down by components when appropriate.		P N R	Aspects are covered under post market surveillance activities and reports.		
2.06.04	Regional	II	Evaluation/Inspection Reports	-		R	Requirement per EU-MDR. (Annex II)	III, 1.2	
2.07	IMDRF	I	Other Submission Context Information	Heading for other submission context information that may be important to the submission but that does not fit in any of the other headings of this chapter. NOTE: To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong		O	Optional to address important information.		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
				under any heading described above.					
Chapter 3 - Non-Clinical Evidence									
3.01	IMDRF	I	Chapter Table of Contents	a) Includes major headings for the chapter, to the level of the custom headings. b) Specifies the page number for each item referred to in the table.		R	Summary of all required chapters for completeness check		
3.02	IMDRF	I	Risk Management	a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. c) Where a standard is followed, identify the standard.	A formal signed statement accepting the residual risk upon completing the risk-benefit analysis before placing product on the EU market.	R	Requirement per EU-MDR. (Annex II)	II, 5. (a) II, 5. (b)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.03	IMDRF, not all	I	Essential Principles (EP) Checklist	a) An EP checklist established for the medical devices, information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used. b) For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission. c) If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply. NOTE: Methods used to demonstrate conformity may include one or more of the following: a) conformity with recognised or other standards; b) conformity with a commonly accepted industry test method(s); c) conformity with an in-house test method(s); d) the evaluation of pre-clinical and clinical evidence; e) comparison to a similar device already available on the market.		R	Requirement per EU-MDR. (Annex I and II)	II, 4. (a) II, 4. (b) II, 4. (d) II, 6. II, 6.2 (g)	
3.04	IMDRF	I	Standards	No content at this level		R	Chapter contains requirements of EU-MDR		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.04.01	IMDRF, RF	II	List of Standards and Guidance Documents	This section should include: a If applicable, a list the standards that have been complied with in full or in part in the design and/or manufacture of the device. i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance. ii. If partial compliance, a list the sections of standard that • Are not applicable to the device, and/or • have been adapted, and/or • were deviated from for other reasons – discussion to accompany b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified. c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified.	An overview of used standards typically is added in the essential requirements checklist, including rationales for using standards that are non-harmonised or complied with only in part. This information needs only to be presented once in the application.	R	Requirement per EU-MDR. (Annex II)	II, 4. (c)	
3.04.02	Regional	II	Declaration and/or Certification of Conformity	-		P C R	Applicable whenever there are external certificates or test reports to support GSPR		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05	IMDRF	I	Non-clinical Studies	No content at this level		R	Chapter contains requirements of EU-MDR		
3.05.01	IMDRF	II	Physical and Mechanical Characterization	Evidence that support the physical or mechanical properties of the subject device is to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	a) Where applicable, the accreditation status of laboratories used in physical and mechanical testing. b) Include evidence of accreditation, e.g. certificate of the lab (or reference to the certificate), which might be part of purchasing department/supplier documentation	R	Requirement per EU-MDR. (Annex II)	II, 6.2 (f) II, 6.2 (g) II, 6.1 (b) II, 6.2 (c) II, 6.2 (d)	

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.01.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL. This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Component A Fatigue Test, MT4203, 2010-10-10 Summary of MT4203 Full Report for MT4203 Assembly B Compatibility Test, MT4584, 2011-01-23 Summary of MT4584 Full Report for MT4584		CR	Applicable whenever there are external certificates or test reports to support GSPR		Im
3.05.01.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Im
3.05.01.01.02	IMDRF	IV	Full Report			PCR	If previous level is applicable and complete report is available		Im
3.05.01.01.03	Regional	IV	Statistical Data			PCR	If previous level is applicable and complete report is available		Im

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.02.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		
3.05.02.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.05.02.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.05.02.01.03	Regional	IV	Statistical Data			PCR	If previous level is applicable and complete report is available		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.03	IMDRF	II	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		CR	Requirement per EU-MDR. (Annex I and II)	II, 6.1 (b)	Active

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.03.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Active
3.05.03.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Active
3.05.03.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Active
3.05.03.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and complete report is available		Active

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.04	IMDRF	II	Radiation Safety	Studies supporting radiation safety, where the device emits radiation or where the device is exposed to radiation are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		CR	Requirement per EU-MDR. (Annex I and II)		Radiative

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.04.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Radiative
3.05.04.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Radiative
3.05.04.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Radiative
3.05.04.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and complete report is available		Radiative
3.05.05	IMDRF	II	Software/Firmware	NO CONTENT AT THIS LEVEL Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished device, are to be included in this section and the associated sub-sections. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling		CR	Requirement per EU-MDR. (Annex I and II)	II, 6.1 (b)	Software

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.05.01	IMDRF	III	Software/Firmware Description	a) Specify the name of the software b) Specify the version of the software - The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided. c) Provide a description of the software including the identification of the device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable) , a description of the realization process. d) Provide a statement about software version naming rules; specify all fields and their meanings.		CR	Requirement per EU-MDR. (Annex I)		Software
3.05.05.02	IMDRF	III	Hazard Analysis	The Hazard Analysis should take into account all device hazards associated with the device's intended use, including both hardware and software hazards. NOTE: i. This document can be in the form of an extract of the software-related items from comprehensive risk management documentation, described in ISO 14971. ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device.		CR	Requirement per EU-MDR. (Annex I)		Software

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.05.03	IMDRF	III	Software Requirement Specification	The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements,		CR	Requirement per EU-MDR. (Annex I and II)	II, 1. (j)	Software
3.05.05.04	IMDRF, not all	III	Architecture Design Chart	Detailed description of functional units and software modules. May include state diagrams as well as flow charts.		CR	Requirement per EU-MDR. (Annex I)		Software
3.05.05.05	IMDRF, not all	III	Software Design Specification	The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the requirements in the SRS are implemented.		CR	Requirement per EU-MDR. (Annex I)		Software
3.05.05.06	IMDRF	III	Traceability Analysis	A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.		PCR	Summary and linkage of all available individual documents		Software
3.05.05.07	IMDRF	III	Software Life Cycle Process Description	A summary describing the software development life cycle and the processes that are in place to manage the various life cycle activities.		CR	Requirement per EU-MDR. (Annex I)		Software

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.05.08	IMDRF	III	Software Verification and Validation	This heading should include: a) An overview of all verification, validation and testing performed prior to final release b) For each test presented, identify the testing environment (e.g. in-house, in a simulated or actual user environment). c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		CR	Requirement per EU-MDR. (Annex I)		Software
3.05.05.08.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Software

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.05.08.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Software
3.05.05.08.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Software
3.05.05.08.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and complete report is available		Software
3.05.05.09	IMDRF	III	Revision Level History	Revision history log, including release version number and date.		R	Requirement per EU-MDR. (Annex II)	II, 3. (a)	Software
3.05.05.10	IMDRF	III	Unresolved Anomalies (Bugs or Defects)	All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems).		PNR	There is no such a requirement in EU-MDR, but the aspect should be part of the risk management file.		Software

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.05.11	IMDRF, not all	III	Cybersecurity	Evidence to support the cybersecurity should be provided here. For example, but not limited to: a) Cybersecurity vulnerabilities and risks analysis b) Cybersecurity controls measures c) Traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks		PCR	If previous level is applicable: Requirement per EU-MDR. (Annex I)		Software
3.05.05.12	IMDRF, not all	III	Interoperability	If the device can communicate with other devices. Evidence to support the interoperability should be provided.		PCR	If previous level is applicable: Requirement per EU-MDR. (Annex I)		Software

3.05.06	IMDRF	II	Biocompatibility and Toxicology Evaluation	Studies supporting biocompatibility and assessing toxicology are to be included in this section. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives are to be included in this section. This should include: a) A list of all materials in direct or indirect contact with the patient or user. b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. OR e) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTES: i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device ii. Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (b)	
3.05.06.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		C R	Applicable whenever there are external certificates or test reports to support GSPR		
3.05.06.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		C R	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.06.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.05.06.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and complete report is available		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.07	IMDRF	II	Non-Material-Mediated Pyrogenicity	Studies to support pyrogenicity evaluation of final release are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		R	Requirement per EU-MDR. (Annex II)	II, 6.2 (d)	
3.05.07.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.07.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.05.07.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.05.07.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		

3.05.08	IMDRF	II	Safety of Materials of Biological Origin (human/animal)	Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section. This should include: a) A description of biological material or derivate b) State the harvesting, processing, preservation, testing and handling of tissues, cells and substances c) If applicable, discussion of infectious agents/transmissible agents known to infect the source animal d) Clarify the origin (including details of donor screening and source country), and describe the tests on validation of removal or inactivation methods of viruses and other pathogens in the manufacturing process. e) A brief summary of process validation should be included to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. f) The system for record-keeping to allow traceability from sources to the finished device should be fully described g) Discussion to support why the evidence presented is sufficient to support the application. OR h) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	In case of materials from animal origin being utilised that bear TSE risk, the submission should clarify if an EDQM certificate is available for the starting material, and if so it will need to be provided.	C R	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.2 (b)	Biological Origin
3.05.08.01	IMDRF, not all	III	Certificates	Certificates that support the safety of materials of biological origin (e.g. certificate of abattoir inspection).		O	There is no such requirement in EU-MDR. It would make sense to provide as much information as possible		Biological Origin

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
							nevertheless.		
3.05.08.02	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		C R	Applicable whenever there are external certificates or test reports to support GSPR		Biological Origin
3.05.08.02.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		C R	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Biological Origin
3.05.08.02.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		P C R	If previous level is applicable and complete report is available		Biological Origin
3.05.08.02.03	Regional	IV	Statistical Data	-		P C R	If previous level is applicable and manufacturer is willing to share additional statistical data		Biological Origin
3.05.09	IMDRF	II	Sterilization Validation	NO CONTENT AT THIS LEVEL		C R			Ir; Sterile

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.01	IMDRF	III	End-User Sterilization	Information and validation of end-user sterilization where it is necessary for the end-user to sterilize the device. This should include: a) A description of the sterilization process (method, parameters) b) A summary of the non-clinical evidence that falls within this category c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) If applicable, state the rationale on the durability of the product against two or more sterilization. e) Discussion to support why the evidence presented is sufficient to support the application. OR f) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		CR	Requirement per EU-MDR. (Annex I)		Ir

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.01.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Ir
3.05.09.01.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Ir
3.05.09.01.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Ir
3.05.09.01.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		Ir

3.05.09.02	IMDRF	III	Manufacturer Sterilization	Information and validation of manufacturer sterilization where the device is provided sterile. This should include: a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL) b) State if parametric release is used c) A summary of the non-clinical evidence that falls within this category d) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes. e) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) f) Discussion to support why the evidence presented is sufficient to support the application. OR g) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device		C R	Requirement per EU-MDR. (Annex II)	II, 2 - 1 II, 6.2 (e)	Sterile
3.05.09.02.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		C R	Applicable whenever there are external certificates or test reports to support GSPR		Sterile
3.05.09.02.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		C R	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Sterile

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.02.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Sterile
3.05.09.02.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		Sterile

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.03	IMDRF	III	Residual Toxicity	Contain the information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		CR	Requirement per EU-MDR. (Annex II)	II, 6.2 (e)	Single use, Sterile, Reprocessing of Single Use

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.03.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Single use, Sterile, Reprocessing of Single Use
3.05.09.03.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Single use, Sterile, Reprocessing of Single Use
3.05.09.03.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Single use, Sterile, Reprocessing of Single Use
3.05.09.03.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		Single use, Sterile, Reprocessing of Single Use

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.04	IMDRF	III	Cleaning and Disinfection Validation	Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		CR	Requirement per EU-MDR. (Annex I)		Ir
3.05.09.04.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Ir

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.04.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Ir
3.05.09.04.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Ir
3.05.09.04.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		Ir
3.05.09.05	IMDRF, not all	III	Reprocessing of Single Use Devices, Validation Data	The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		CR	Requirement per EU-MDR. (Annex I)		Reprocessing of Single Use

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.09.05.01	IMDRF	IV	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		Reprocessing of Single Use
3.05.09.05.01.01	IMDRF	V	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	Reprocessing of Single Use
3.05.09.05.01.02	IMDRF	V	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		Reprocessing of Single Use
3.05.09.05.01.03	Regional	V	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		Reprocessing of Single Use

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.10	IMDRF	II	Animal Testing	Contains information about any animal studies conducted to support the submission. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.05.10.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.05.10.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.05.10.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.05.10.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		

3.05.11	IMDRF	II	Usability/Human Factors	Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. This should include: a) A summary of the non-clinical evidence that falls within this category b) A statement of the test environment and relation to the intended use environment c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) If a clinical study has been conducted that includes human factors/usability endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated. e) Discussion to support why the evidence presented is sufficient to support the application. OR f) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTES: i. If a clinical study has been conducted that includes usability/human factors endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		R	Requirement per EU-MDR. (Art. 83 (3) f) and Annex I)		
3.05.11.01	IMDRF	III	[Study description, study	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and		C R	Applicable whenever there are external certificates or test		

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					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
			identifier, date of initiation]	created for each study under the parent heading. The sub headings below would be for this study alone.			reports to support GSPR		
3.05.11.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.05.11.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.05.11.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.06	IMDRF, RF	I	Non-clinical Bibliography	This heading should include: a) A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments) b) A legible copies of key articles , including translation where applicable to meet the regulators language requirements c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement that no literature related to the device was found.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.07	IMDRF	I	Expiration Period and Package Validation	This heading should include: a) An indication of environmental conditions for correct storage of the device (e.g. temperature, pressure, humidity, luminosity). b) A statement of the expiration period considering the materials and sterilization (when applicable), indicated as a period of time or any other means of appropriate quantification. OR c) A rationale that storage conditions could not affect device safety or effectiveness	For devices that do not have an expiration period (e.g. electromedical equipment or other devices of multiple use), information regarding the estimated mean "lifetime". This mean "lifetime" can be indicated as number of procedures to be performed with the device and/or its accessories, as a period of time or any other means of appropriate quantification.	R	Requirement per EU-MDR. (Annex II)	II, 6.2 (e)	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.07.01	IMDRF	II	Product Stability	Contains details relating to product stability under specified storage conditions and in final packaging or simulated conditions. This should include: a) A statement of the shelf-life (for each component if there are differences between components) b) A summary of the non-clinical evidence that falls within this category c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. OR e) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (b)	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.07.01.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		
3.07.01.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.07.01.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.07.01.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.07.02	IMDRF	II	Package Validation	Contains details relating to package integrity over the claimed shelf-life and in the packaging and distribution environment (transport and packaging validation) and when applicable, following exposure to the sterilization process. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. OR d) A statement of why this category of non-clinical laboratory study is not applicable to this case. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (b)	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.07.02.01	IMDRF	III	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		
3.07.02.01.01	IMDRF	IV	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
3.07.02.01.02	IMDRF	IV	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.07.02.01.03	Regional	IV	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.08	IMDRF	I	Other non-clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter. This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device that are not delineated in the rest of the Chapter 3. This should include a) A description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.		O	Only necessary if not already covered by previous subchapters.		
3.08.01	IMDRF	II	[Study description, study identifier, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.		CR	Applicable whenever there are external certificates or test reports to support GSPR		
3.08.01.01	IMDRF	III	Summary	A summary of the specific study described in the custom heading above.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
3.08.01.02	IMDRF	III	Full Report	The test report for the test described in the custom heading above.		PCR	If previous level is applicable and complete report is available		
3.08.01.03	Regional	III	Statistical Data	-		PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		
Chapter 4 - Clinical Evidence									
4.01	IMDRF	I	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.		R	Summary of all required chapters for completeness check		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
4.02	IMDRF	I	Overall Clinical Evidence Summary	a) This should be a brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (RCT, case study, literature review) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b) If any of the study devices differ from the devices to be marketed, including competitors devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application. c) A discussion of the clinical evidence considered for the device and support for their selection (i.e. what type of evidence was considered and why they were or were not used) d) Discussion to support why the evidence presented is sufficient to support the application. NOTE: Human factors testing that include patients should be included here.	Clinical evidence is always required, regardless of risk class.	R	Requirement per EU-MDR. (Annex II)	II, 6.1 (a) II, 6.2 (a)	

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
4.02.01	IMDRF, not all	II	Clinical Evaluation Report	a) A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (c)	
4.02.02	IMDRF	II	Device Specific Clinical Trials	NO CONTENT AT THIS LEVEL Clinical trial information under this heading should be grouped by trial		R	Justification in case no clinical trials have been conducted.		
4.02.02.01	IMDRF	III	[Trial description, protocol #, date of initiation]	NO CONTENT AT THIS LEVEL This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Level 3: EU Pilot Study, CT4203, 2010-10-10 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report Level 3: NA RCT Study, CT4584, 2011-01-23 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report		CR	Applicable whenever there are external certificates or test reports to support GSPR		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
4.02.02.01.01	IMDRF	IV	Clinical Trial Summary	a) A summary of the specific study described in the custom heading above. b) 2-3 page summary document that presents a summary of: i. The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, # patients, inclusion/exclusion criteria) and ii. Summary of the results of the analysis iii. Summary of conclusions related to the endpoints NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.		CR	If previous level is applicable: Requirement per EU-MDR. (Annex II)	II, 6.1 (a)	
4.02.02.01.02	IMDRF	IV	Clinical Trial Report	a) A clinical trial report of the specific study described in the custom heading above. NOTES: i. The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial report.		PCR	If previous level is applicable and complete report is available		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
4.02.02.01.03	Regional	IV	Clinical Trial Data			PCR	If previous level is applicable and manufacturer is willing to share additional statistical data		
4.02.03	IMDRF	II	Clinical Literature Review and Other Reasonable Known Information	a) Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or effectiveness of the device b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. OR c) A statement that no literature related to the device was found. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject device		R	Requirement per EU-MDR. (Annex II)	II, 6.1 (d)	
4.03	Regional	I	IRB Approved Informed Consent Forms			NR	This document is part of the clinical investigation application per EU-MDR. (XV)		

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
4.04	Regional	I	Investigators Sites and IRB Contact Information			NR	This document is part of the clinical investigation application per EU-MDR. (XV)		
4.05	IMDRF	I	Other Clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.		O	Optional to address important information.		
Chapter 5 - Labelling and Promotional Material									
5.01	IMDRF	I	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.		R	Summary of all required chapters for completeness check		
5.02	IMDRF, RF	I	Product/Package Labels	Samples of the primary and secondary packaging labels. NOTES: i. Do not include shipping labels. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device.	a) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. b) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided.	R	Requirement per EU-MDR. (Annex II)	II, 2 - 1	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
5.03	IMDRF, RF	I	Package Insert/Instructions for Use	Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable. NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device	a) At minimum the IFU in a relevant acceptable language, required by Notified Bodies following their national law, should be provided. Further language version will need to be available for verification during audits. b) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. c) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided.	R	Requirement per EU-MDR. (Annex II)	II, 2 - 2	

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Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
5.04	IMDRF, RF	I	e-labelling	The following should be provided: a) For eligible medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website). b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here c) A description of the procedure and operations on providing IFU's when requested d) Written information for user Information on webpage where IFU and further information can be found in relevant languages. e) A description on how the requirements detailed for the website have been met. f) If a video/App is available to demonstrate how the test is to be performed and interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.	For fixed installed medical devices provide text message / information which will be given on or with the device itself as well as description of place where it would be placed	C R	Requirement per EU-MDR. (Annex II)	II, 2 - 1 II, 2 - 2	Specific MDs outlined in regulation (EU) No 207/2012
5.05	IMDRF, not all	I	Physician Labelling	Labelling directed at the physician other than the package insert, such as the surgical manual		C R	Requirement per EU-MDR. (Annex II)	II, 2 - 2	
5.06	IMDRF, not all	I	Patient Labelling	Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver		C R	Requirement per EU-MDR. (Annex II)	II, 2 - 2	

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
5.07	IMDRF, not all	I	Technical/Operator Manual	Labelling directed the technical users and operators of medical devices focusing on the proper use and maintenance of the device		CR	Requirement per EU-MDR. (Annex II)	II, 2 - 2	
5.08	Regional	I	Patient File Stickers/Cards and Implant Registration Cards			CR	Requirement per EU-MDR. (Art. 18)		Implant
5.09	Regional	I	Product Brochures			R	Either brochure or a list with what typically appears on the brochures, no attachment is required.	II, 1. (l)	
5.10	IMDRF	I	Other Labelling and Promotional Material	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.		O	Optional to address important information.		
Chapter 6A - Quality Management System Procedures									
6A.01	Regional	I	Cover Letter	-		NR	There is no such requirement within EU-MDR.		
6A.02	IMDRF, not all	I	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.		R	Summary of all required chapters for completeness check		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6A.03	IMDRF, not all	I	Administrative	NO CONTENT AT THIS LEVEL. Administrative information needed to evaluate the premarket submission related to the QMS		R	Chapter contains requirements of EU-MDR		
6A.03.01	IMDRF, not all	II	Product Descriptive Information	Abbreviated description of the device, operating principles and overall manufacturing methods		R	Requirement per EU-MDR. (Annex II)	II, 1. (d)	
6A.03.02	IMDRF, RF	II	General Manufacturing Information General Manufacturing Information	a) Address and contact information for all sites where the device or its components are manufactured. b) Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component or raw material production (e.g. animal tissue, drugs), and sterilisation, will need to be provided.		R	Requirement per EU-MDR. (Annex II)	II, 1. (k) II, 3. (c) II, 6.2 (a) II, 6.2 (b)	
6A.03.03	IMDRF, RF	II	Required Forms	Any regional specific forms to be completed associated with Quality management Systems in the premarket review process		R	Depending on the notified body		
6A.04	IMDRF, not all	I	Quality management system procedures	High level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records ISO 13485 Elements– SOPs to satisfy clause 4		NR	There is no such requirement within EU-MDR.		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6A.05	IMDRF, not all	I	Management responsibilities procedures	Procedures that document the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review. ISO 13485 Elements – SOPs implementing clause 5		NR	There is no such requirement within EU-MDR.		
6A.06	IMDRF, not all	I	Resource management procedures	Procedures that document the adequate provision of resources to implement and maintain the QMS including human resources, infrastructure and work environment. ISO 13485 Elements – SOPs implementing clause 6		NR	There is no such requirement within EU-MDR.		
6A.07	IMDRF, not all	I	Product realization procedures	High level product realization procedures such as those addressing planning and customer related processes ISO 13485 Elements – SOPs implementing sub clause 7.1 and 7.2		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6A.08	IMDRF, not all	I	Design and development procedures	Design and development procedures		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6A.09	IMDRF, not all	I	Purchasing procedures	Procedures that document that purchased products/services conform to established quality and/or product specifications. ISO 13485 Elements – SOPs to implement sub clause 7.4		R	Requirement per EU-MDR. (Annex II)	II, 3. (c) II, 6.2 (a)	

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6A.10	IMDRF, not all	I	Production and service controls procedures	Procedures that document the production and service activities are carried out under controlled conditions. These SOPS address issues such as cleanliness of product and contamination control; installation and servicing activities; process validation; identification and traceability; etc. ISO 13485 Elements – SOPs implementing sub clause 7.5		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6A.11	IMDRF, not all	I	Control of monitoring and measuring devices procedures	Procedure that document that monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements. ISO 13485 Element- SOPs for implementing sub clause 7.6		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6A.12	IMDRF, not all	I	QMS measurement, analysis and improvement procedures	Procedures that document how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS. ISO 13485 Element – SOPS for implementing clause 8		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6A.13	IMDRF, not all	I	Other Quality System Procedures Information	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.		O	Optional to address important information.		
Chapter 6B - Quality Management System Device Specific Information									

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6B.01	IMDRF, not all	I	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.		R	Summary of all required chapters for completeness check		
6B.02	IMDRF, not all	I	Quality management system information	Documentation and records specific to the subject device that results from the high level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents, noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 4		NR	There is no such requirement within EU-MDR.		
6B.03	IMDRF, not all	I	Management responsibilities information	Documentation and records specific to the subject device that result from the implementation the management responsibilities procedures noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 5		NR	There is no such requirement within EU-MDR.		
6B.04	IMDRF, not all	I	Resource management information	Documentation and records specific to the subject device that result from the implementation the resource management procedures noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 6		NR	There is no such requirement within EU-MDR.		

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6B.05	Regional	I	Device Specific Quality Plan			CR	Requirement per EU-MDR. (Annex III)	III, 1.1 (a) III, 1.1 (b)	
6B.06	IMDRF, not all	I	Product realization information	Documentation and records specific to the subject device that results from the implementation of the high level product realization procedures noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.1 and 7.2		NR	There is no such requirement within EU-MDR.		
6B.07	Regional	I	Design and development information	Documentation and records specific to the subject device that results from the implementation of the design and development procedures noted in Chapter 6A. NOTE: The source of this information is the Design and Development Records (e.g. DHF - Design History File). ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.3		R	Requirement per EU-MDR. (Annex II)	II, 3. (a)	
6B.08	IMDRF, not all	I	Purchasing information	Documentation and records specific to the subject device that results from the implementation of purchasing procedures noted in Chapter 6A ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.4		R	Requirement per EU-MDR. (Annex II)	II, 6.2 (a)	

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019						Evaluation done by the Author			
Row ID	**Heading Class**	**Level**	**Heading**	**Common Content** (Original wording of ToC)	**Regional Content under EU-MDD**	**Regional Content under EU-MDR**			
					Additional Information	**Classification**	**Justification for Classification**	**EU-MDR Reference** (i.a.)	**Specific functions / attributes** (i. a.)
6B.09	Regional	I	Production and service controls information			R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6B.10	IMDRF, not all	I	Control of monitoring and measuring devices information	Documentation and records specific to the subject device that results from the implementation of the control of monitoring and measuring device procedures noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.6		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6B.11	IMDRF, not all	I	QMS measurement, analysis and improvement information	Documentation and records specific to the subject device that results from the implementation of the QMS measurement, analysis and improvement procedures noted in Chapter 6A. ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 8		R	Requirement per EU-MDR. (Annex II)	II, 3. (b)	
6B.12	IMDRF, not all	I	Other Device Specific Quality Management System Information	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this Chapter.		R	Requirement per EU-MDR. (Annex III)	III, 1.1 (a) III, 1.1 (b)	

8.5 Comparison of the Canadian Classification Matrix (Draft) to the Author's Proposal of an EU Classification Matrix

Legend:

R	Required; there is a specific source mentioning this aspect within the EU-MDR.
PR	Required (proposal by the author); there is no specific source mentioning this aspect within the EU-MDR but to provide this chapter is recommended as the same aspect was required under EU-MDD.
CR	Conditionally required, in case the conditions lead to this assumption; there is a specific source mentioning this aspect within the EU-MDR under certain circumstances.
PCR	Conditionally required (proposal by the author), in case the conditions lead to this assumption; there is no specific source mentioning this aspect, but as soon as certain circumstances are met, to provide this chapter is recommended as the same aspect was required under EU-MDD.
O	Optional; decision to be made by the manufacturer
PO	Optional (proposal by the author); decision to be made by the manufacturer
NR	Not required; there is no source mentioning this aspect within the EU-MDR.
PNR	Not required (proposal by the author); there is no source mentioning this aspect within the EU-MDR.

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
Chapter 1 - Regional Administrative				
1.01	Cover Letter	CR		R
1.02	Submission Table of Contents		no information	PR
1.03	List of Terms / Acronyms		no information	PR
1.04	Application Form/Administrative Information	R		R
1.05	Listing of Device(s)		no information	R
1.06	Quality Management System, Full Quality System or Other Regulatory Certificates	R	only for new class 2 applications or when changes to manufacturer's name or address occur	CR
1.07	Free Sale Certificate/ Certificate of Marketing Authorisation		no information	NR
1.08	Expedited Review Documentation		no information	NR
1.09	User Fees	CR		CR
1.10	Pre-Submission Correspondence and Previous Regulator Interactions		no information	R
1.11	Acceptance for Review Checklist		no information	NR
1.12	Statements/Certifications/Declarations of Conformity		no information	NR
1.12.01	Performance and Voluntary Standard		no information	NR
1.12.02	Environmental Assessment		no information	NR
1.12.03	Clinical Trial Certifications		no information	NR
1.12.04	Indications for Use Statement with Rx and/or OTC designation Enclosure		no information	NR
1.12.05	Truthful and Accurate Statement		no information	NR
1.12.06	USFDA Class III Summary and Certification		no information	NR
1.12.07	Declaration of Conformity		no information	R
1.13	Letters of Reference for Master Files		no information	NR
1.14	Letter of Authorization	R	only for private labels or classes 3 and 4	CR
1.15	Other Regional Administrative Information		no information	R
Chapter 2 - Submission Context				
2.01	Chapter Table of Contents		no information	PR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
2.02	General Summary of Submission		no information	R
2.03	Summary and Certifications for Premarket Submissions		no information	NR
2.04	Device Description		no information	R
2.04.01	Comprehensive Device Description and Principle of Operation		no information	R
2.04.02	Description of Device Packaging		no information	R
2.04.03	History of Development		no information	R
2.04.04	Reference and Comparison to Similar and/or Previous Generations of the Device	R	only for new applications for classes 3 and 4	R
2.04.05	Substantial Equivalence Discussion		no information	NR
2.05	Indications for Use and/or Intended Use and Contraindications		no information	R
2.05.01	Intended Use; Intended Purpose; Intended User; Indications for Use		no information	R
2.05.02	Intended Environment/Setting for use		no information	PCR
2.05.03	Paediatric Use		no information	NR
2.05.04	Contraindications for Use		no information	R
2.06	Global Market History		no information	R
2.06.01	Global Market History		no information	PNR
2.06.02	Global Incident Reports and Recalls		no information	PNR
2.06.03	Sales, Incident and Recall Rates		no information	PNR
2.06.04	Evaluation/Inspection Reports		no information	R
2.07	Other Submission Context Information		no information	O
Chapter 3 - Non-Clinical Evidence				
3.01	Chapter Table of Contents		no information	R
3.02	Risk Management		no information	R
3.03	Essential Principles (EP) Checklist		no information	R
3.04	Standards		no information	R
3.04.01	List of Standards and Guidance Documents		no information	R
3.04.02	Declaration and/or Certification of Conformity		no information	PCR
3.05	Non-clinical Studies		no information	R
3.05.01	Physical and Mechanical Characterization		no information	R
3.05.01.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.01.01.01	Summary		no information	CR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
3.05.01.01.02	Full Report		no information	PCR
3.05.01.01.03	Statistical Data		no information	PCR
3.05.02.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.02.01.01	Summary		no information	CR
3.05.02.01.02	Full Report		no information	PCR
3.05.02.01.03	Statistical Data		no information	PCR
3.05.03	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility		no information	CR
3.05.03.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.03.01.01	Summary		no information	CR
3.05.03.01.02	Full Report		no information	PCR
3.05.03.01.03	Statistical Data		no information	PCR
3.05.04	Radiation Safety		no information	CR
3.05.04.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.04.01.01	Summary		no information	CR
3.05.04.01.02	Full Report		no information	PCR
3.05.04.01.03	Statistical Data		no information	PCR
3.05.05	Software/Firmware		no information	CR
3.05.05.01	Software/Firmware Description		no information	CR
3.05.05.02	Hazard Analysis		no information	CR
3.05.05.03	Software Requirement Specification		no information	CR
3.05.05.04	Architecture Design Chart		no information	CR
3.05.05.05	Software Design Specification		no information	CR
3.05.05.06	Traceability Analysis		no information	PCR
3.05.05.07	Software Life Cycle Process Description		no information	CR
3.05.05.08	Software Verification and Validation		no information	CR
3.05.05.08.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.05.08.01.01	Summary		no information	CR
3.05.05.08.01.02	Full Report		no information	PCR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
3.05.05.08.01.03	Statistical Data		no information	PCR
3.05.05.09	Revision Level History		no information	R
3.05.05.10	Unresolved Anomalies (Bugs or Defects)		no information	PNR
3.05.05.11	Cybersecurity		no information	PCR
3.05.05.12	Interoperability		no information	PCR
3.05.06	Biocompatibility and Toxicology Evaluation		no information	R
3.05.06.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.06.01.01	Summary		no information	CR
3.05.06.01.02	Full Report		no information	PCR
3.05.06.01.03	Statistical Data		no information	PCR
3.05.07	Non-Material-Mediated Pyrogenicity		no information	R
3.05.07.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.07.01.01	Summary		no information	CR
3.05.07.01.02	Full Report		no information	PCR
3.05.07.01.03	Statistical Data		no information	PCR
3.05.08	Safety of Materials of Biological Origin (human/animal)		no information	CR
3.05.08.01	Certificates		no information	O
3.05.08.02	[Study description, study identifier, date of initiation]		no information	CR
3.05.08.02.01	Summary		no information	CR
3.05.08.02.02	Full Report		no information	PCR
3.05.08.02.03	Statistical Data		no information	PCR
3.05.09	Sterilization Validation		no information	CR
3.05.09.01	End-User Sterilization		no information	CR
3.05.09.01.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.09.01.01.01	Summary		no information	CR
3.05.09.01.01.02	Full Report		no information	PCR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
3.05.09.01.01.03	Statistical Data		no information	PCR
3.05.09.02	Manufacturer Sterilization		no information	CR
3.05.09.02.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.09.02.01.01	Summary		no information	CR
3.05.09.02.01.02	Full Report		no information	PCR
3.05.09.02.01.03	Statistical Data		no information	PCR
3.05.09.03	Residual Toxicity		no information	CR
3.05.09.03.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.09.03.01.01	Summary		no information	CR
3.05.09.03.01.02	Full Report		no information	PCR
3.05.09.03.01.03	Statistical Data		no information	PCR
3.05.09.04	Cleaning and Disinfection Validation		no information	CR
3.05.09.04.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.09.04.01.01	Summary		no information	CR
3.05.09.04.01.02	Full Report		no information	PCR
3.05.09.04.01.03	Statistical Data		no information	PCR
3.05.09.05	Reprocessing of Single Use Devices, Validation Data		no information	CR
3.05.09.05.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.09.05.01.01	Summary		no information	CR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
3.05.09.05.01.02	Full Report		no information	PCR
3.05.09.05.01.03	Statistical Data		no information	PCR
3.05.10	Animal Testing		no information	R
3.05.10.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.10.01.01	Summary		no information	CR
3.05.10.01.02	Full Report		no information	PCR
3.05.10.01.03	Statistical Data		no information	PCR
3.05.11	Usability/Human Factors		no information	R
3.05.11.01	[Study description, study identifier, date of initiation]		no information	CR
3.05.11.01.01	Summary		no information	CR
3.05.11.01.02	Full Report		no information	PCR
3.05.11.01.03	Statistical Data		no information	PCR
3.06	Non-clinical Bibliography		no information	R
3.07	Expiration Period and Package Validation		no information	R
3.07.01	Product Stability		no information	R
3.07.01.01	[Study description, study identifier, date of initiation]		no information	CR
3.07.01.01.01	Summary		no information	CR
3.07.01.01.02	Full Report		no information	PCR
3.07.01.01.03	Statistical Data		no information	PCR
3.07.02	Package Validation		no information	R
3.07.02.01	[Study description, study identifier, date of initiation]		no information	CR
3.07.02.01.01	Summary		no information	CR
3.07.02.01.02	Full Report		no information	PCR
3.07.02.01.03	Statistical Data		no information	PCR
3.08	Other non-clinical Evidence		no information	O
3.08.01	[Study description, study identifier, date of initiation]		no information	CR
3.08.01.01	Summary		no information	CR
3.08.01.02	Full Report		no information	PCR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
3.08.01.03	Statistical Data		no information	PCR
Chapter 4 - Clinical Evidence				
4.01	Chapter Table of Contents		no information	R
4.02	Overall Clinical Evidence Summary		no information	R
4.02.01	Clinical Evaluation Report		no information	R
4.02.02	Device Specific Clinical Trials		no information	R
4.02.02.01	[Trial description, protocol #, date of initiation]		no information	CR
4.02.02.01.01	Clinical Trial Summary		no information	CR
4.02.02.01.02	Clinical Trial Report		no information	PCR
4.02.02.01.03	Clinical Trial Data		no information	PCR
4.02.03	Clinical Literature Review and Other Reasonable Known Information		no information	R
4.03	IRB Approved Informed Consent Forms		no information	NR
4.04	Investigators Sites and IRB Contact Information		no information	NR
4.05	Other Clinical Evidence		no information	O
Chapter 5 - Labelling and Promotional Material				
5.01	Chapter Table of Contents		no information	R
5.02	Product/Package Labels	CR	for new applications and amendments	R
5.03	Package Insert/Instructions for Use	CR	for new applications and amendments	R
5.04	e-labelling	CR	for new applications and amendments	CR
5.05	Physician Labelling	CR	for new applications and amendments	CR
5.06	Patient Labelling	CR	for new applications and amendments	CR
5.07	Technical/Operator Manual	CR	for new applications and amendments	CR
5.08	Patient File Stickers/Cards and Implant Registration Cards	CR	for new applications and amendments	CR

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
5.09	Product Brochures	CR	for new applications and amendments	R
5.10	Other Labelling and Promotional Material	CR	for new applications and amendments	O
Chapter 6A - Quality Management System Procedures				
6A.01	Cover Letter		no information	NR
6A.02	Chapter Table of Contents		no information	R
6A.03	Administrative		no information	R
6A.03.01	Product Descriptive Information		no information	R
6A.03.02	General Manufacturing Information General Manufacturing Information		no information	R
6A.03.03	Required Forms		no information	R
6A.04	Quality management system procedures		no information	NR
6A.05	Management responsibilities procedures		no information	NR
6A.06	Resource management procedures		no information	NR
6A.07	Product realization procedures		no information	R
6A.08	Design and development procedures		no information	R
6A.09	Purchasing procedures		no information	R
6A.10	Production and service controls procedures		no information	R
6A.11	Control of monitoring and measuring devices procedures		no information	R
6A.12	QMS measurement, analysis and improvement procedures		no information	R
6A.13	Other Quality System Procedures Information		no information	O
Chapter 6B - Quality Management System Device Specific Information				
6B.01	Chapter Table of Contents		no information	R
6B.02	Quality management system information		no information	NR
6B.03	Management responsibilities information		no information	NR
6B.04	Resource management information		no information	NR
6B.05	Device Specific Quality Plan		no information	CR
6B.06	Product realization information		no information	NR
6B.07	Design and development information		no information	R
6B.08	Purchasing information		no information	R
6B.09	Production and service controls information		no information	R

ToC Structure as per IMDRF/RPS WG/N9 (Edition 3) FINAL:2019		Draft of HC IMDRF Table		Evaluation done by the Author
Row ID	**Heading**	**Canadian Classification Matrix**		**Regional Content under EU-MDR**
		Classification (simplified)	**Note**	**Classification**
6B.10	Control of monitoring and measuring devices information		no information	R
6B.11	QMS measurement, analysis and improvement information		no information	R
6B.12	Other Device Specific Quality Management System Information		no information	R

8.6 Evaluation of how Requirements of different Sources are met by the Author's Proposal

Legend:

M	Must; mandatory requirement to address unaddressed requirements
opt	optional; helpful tool to ensure submission of a valid TD
Y	Yes
N	No
	Not necessary; only if requirement is fulfilled by the structure of a TD

Requirement	Source within this Thesis		Importance	Fulfilled by the Author's Proposal		Fulfilled by Using an appropriate Software	
	(Sub-) Chapter	Description	M / opt	Y / N	Justification	Y / N	Justification
Clear	3.2.1.1	Attributes per EU-MDR	M	N	Writing of documents stored in the individual chapters still is under the manufacturer's responsibility. The approach supports structuring.	N	Data entry needs to follow a strategy and terminology used should be clear. This still is under the manufacturer's responsibility.
Organised	3.2.1.1	Attributes per EU-MDR	M	Y	Clear assignment of EU-MDR requirements was possible		
Readily searchable	3.2.1.1	Attributes per EU-MDR	M	N	Provision of documents still is under the manufacturer's responsibility. Clear structure reduces the need for searching through the entire TD.	Y	Software can automatically check and transform non-searchable scans via OCR technology.
Unambiguous	3.2.1.1	Attributes per EU-MDR	M	N	Content of documents still is under the manufacturer's responsibility. Clear structure avoids redundant sections.	Y	Data-based systems can be used to completely avoid ambiguous information as the data source is only available once.
Submission in accepted language	3.2.1.1	Attributes per EU-MDR	M	N	Writing of documents stored in the individual chapters still is under the manufacturer's responsibility. As the chapter headings are provided in English, this structure supports creation of the TD in that language.	Y	Language packages can translate documents into a language needed.

Requirement	Source within this Thesis		Importance	Fulfilled by the Author's Proposal		Fulfilled by Using an appropriate Software	
	(Sub-) Chapter	Description	M / opt	Y / N	Justification	Y / N	Justification
Existent	3.2.1.2	Administrative per EU-MDR	M	Y	Using the classification matrix, an easy completeness check can be done		
Most recent released versions ("up to date")	3.2.1.2	Administrative per EU-MDR	M	N	Updating of documents stored in the individual chapters still is under the manufacturer's responsibility. Maintaining documentation is positively impacted as there is no redundant information.	Y	Document management software automatically replaces archived documents by currently approved versions.
Archiving and possibility to attribute produced products to outdated versions	3.2.1.2	Administrative per EU-MDR	M	N	Updating of documents stored in the individual chapters still is under the manufacturer's responsibility	Y	Document management software archives outdated documents and enable reconstitution of a TD that was released at a certain date.
Permanent availability	3.2.1.2	Administrative per EU-MDR	M	N	Updating of documents stored in the individual chapters still is under the manufacturer's responsibility	Y	Documents can be accessed remotely.
Third-party permanent access (e.g. reviewers, consultants, PRRC, authorised representative)	3.2.1.2	Administrative per EU-MDR	M	N	Providing access to individual documents still is under the manufacturer's responsibility. Following the ToC structure, there is only limited information within one document, which supports the idea of confidential data.	Y	Hyperlinks to documents located in the system can be shared with third parties.
Complete list of articles	3.2.1.3	Content per EU-MDR	M	Y	Chapter 2.04.01 covers this aspect.		
Harmonised standards	3.2.1.3	Content per EU-MDR	M	Y	Chapter 3.04.01 covers this aspect.		
Common Specifications	3.2.1.3	Content per EU-MDR	M	Y	Chapter 3.04.01 covers this aspect.		
Elements of Annex II	3.2.1.3	Content per EU-MDR	M	Y	Completeness check was done within this thesis.		
Elements of Annex III	3.2.1.3	Content per EU-MDR	M	Y	Completeness check was done within this thesis.		

Requirement	Source within this Thesis		Importance	Fulfilled by the Author's Proposal		Fulfilled by Using an appropriate Software	
	(Sub-) Chapter	Description	M / opt	Y / N	Justification	Y / N	Justification
Class IIa and specific class IIb: Representative device per generic device group to be covered FOR REVIEW PURPOSES	3.2.2	Review related documentation	M	N	Structure of documentation is given, but content still is under the manufacturer's responsibility.	N	Completeness check can be done, but representative device approach still is under the manufacturer's responsibility.
Easy compilation of documentation for each article number (for class IIb; review purposes)	3.2.2	Review related documentation	M	N	Structure of documentation is given, but content still is under the manufacturer's responsibility.	Y	Automatic check for completeness of documents can be programmed.
Class Is/m/r: Only evidence about aspects related to special conditions to be covered FOR REVIEW PURPOSES	3.2.2	Review related documentation	M	Y	Only chapters 3.05.09.01 and 3.05.09.04 need to be provided. Chapter 1 would be necessary for the basic understanding of the devices.		
Possibility of sampling of portions of a Technical Documentation	3.2.3	Sampling	M	Y	Clear assignment of EU-MDR requirements to individual chapters is possible. Extraction of certain chapters of interest is easily possible.		
Wise determination of product groups and devices covered under one TD (balancing the financial risk of maintaining too many TDs for similar products and too many products covered within one TD whenever there is a risk of a negative review outcome)	3.2.4	Portfolio availability risk vs. Financial interest	opt	N	Determination of product groups still is under the manufacturer's responsibility.	N	Determination of product groups still is under the manufacturer's responsibility.
Supporting lean processes	3.2.4	Data consistency	opt	N	Content of documents still is under the manufacturer's responsibility. Clear structure avoids redundant sections.	Y	Data-based systems can be used to completely avoid ambiguous information as the data source is only available once.
Logical structure without duplicate information	3.2.4	Data consistency	M	N	Content of documents still is under the manufacturer's responsibility. Clear structure avoids redundant sections.	Y	Data-based systems can be used to completely avoid ambiguous information as the data source is only available once.

Requirement	Source within this Thesis		Importance	Fulfilled by the Author's Proposal		Fulfilled by Using an appropriate Software	
	(Sub-) Chapter	Description	M / opt	Y / N	Justification	Y / N	Justification
Restricted access to a specific part of the system (e.g. OEM/PLM)	3.2.4	Proprietary issues	M	N	Providing access to individual documents still is under the manufacturer's responsibility. Following the ToC structure, there is only limited information within one document, which supports the idea of confidential data.	Y	Hyperlinks to documents located in the system can be shared with third parties.
Chinese translations (in addition to original documents)	3.2.5	Decree No. 4 of China Food and Drug Administration	opt	N	Writing of documents stored in the individual chapters still is under the manufacturer's responsibility. As the chapter headings are provided in English, this structure supports creation of the TD in that language.	Y	Language packages can translate documents into a language needed.
Follow ToC format	3.2.5	Chinese ePRS portal; US RPS pilot program	opt	Y	This format was followed		
Electronic submission	3.2.5	Chinese ePRS portal; US RPS pilot program	opt	Y	Following an internationally harmonised structure supports electronic submissions.		

8.7 Evaluation of how Requirements for IT Aspects could be met by Using Software Tools

Legend:

M Must; mandatory requirement to address unaddressed requirements

opt Optional; beneficial tool to ensure submission of a valid TD

Feature	Description	Source within this Thesis	Importance	Software Solution	
			M / opt	Solution	Software Tool
XML backbone	Metadata visibility	Chapter 3.2.6	opt	XML backbone	Document Submission
Directory folder structure	Harmonisation	Chapter 3.2.6	M	Defined harmonised structure	Submission
User interface	ease of navigation	Chapter 3.2.6	M	Creation of user interface	Content Management, Submission, Validator
Only used folders	Canadian validation rules: no empty folders allowed	Chapter 3.2.6	M	Automatic folder deletion	Validator
File size limitation	Canadian validation rules: maximum file and transaction sizes	Chapter 3.2.6	M	File size verification	Validator
File type restrictions	Canadian validation rules: Only accepted data formats, no dynamic content	Chapter 3.2.6	M	Automatic conversion to accepted formats in latest versions	Validator
Document readability	Canadian validation rules: corrupt or protected files	Chapter 3.2.6	M	Verification of accessibility to documents	Validator
Bookmarks within long documents	Canadian validation rules: bookmarks	Chapter 3.2.6	M	Automatic creation of bookmarks	Content Management
Functional hyperlinks and bookmarks	Canadian validation rules: No dead links	Chapter 3.2.6	M	Verification of living links	Validator
Copying and printing of documents	Canadian validation rules: Copies and printing of documents	Chapter 3.2.6	M	Automatically enable copy and printing	Validator
Naming syntax of files	Canadian validation rules: maximum path length	Chapter 3.2.6	M	Path length verification	Validator
Searchable documents	Scanned documents	Chapter 3.2.6	M	Automatic OCR function	Validator
Electronically searchable documents	Scanned documents	Annex 8.6	M	Automatic OCR function	Validator

Feature	Description	Source within this Thesis	Importance	Software Solution	
			M / opt	Solution	Software Tool
Unambiguous information	redundancies, discrepancies	Annex 8.6	M	Information dependency trees for information	Validator
Submission in accepted language	-	Annex 8.6	opt	Language package	Document Submission
Most recent released versions ("up to date")	-	Annex 8.6	M	Archiving function	Content Management
Archiving and possibility to attribute produced products to outdated versions	-	Annex 8.6	M	Archiving function	Content Management
Permanent availability	Accessible upon request	Annex 8.6	M	Online access	Content Management
Third-party permanent access (e.g. reviewers, consultants, PRRC, authorised representative)	Accessible upon request or whenever needed	Annex 8.6	M	Online access	Content Management
Easy compilation of documentation for each article number	For class IIb; review purposes	Annex 8.6	opt	Data relationship setting	Content Management
Supporting lean processes	logical data and document gathering flows	Annex 8.6	opt	Data entry flow	Content Management
Logical structure without duplicate information	Harmonisation	Annex 8.6	M	Defined harmonised structure	Submission
Restricted access to a specific part of the system (e.g. OEM/PLM)	Protection of proprietary information	Annex 8.6	M	User settings	Content Management
Chinese translations (in addition to original documents)	Requirement for Chinese market	Annex 8.6	opt	Language package	Document Submission

8.8 Notified Body Survey Results

Legend:	
Contacted NBs:	26 (5 already designated while survey was running)
Contact methods:	Private email, LinkedIn message
Survey tool:	Typeform (www.typeform.com)
Survey period:	26.01.2020 – 22.03.2020
Received responses:	8

Question 1
- Mandatory, one answer possible -
Are you as a notified body already designated under regulation 2017/745 (EU-MDR)?

Responding options	**Responses**
No, but working on it	7 (87.5%)
Yes	1 (12.5%)
No, and not planning to	0 (0.0%)

Question 2
- Optional, manual entries of responses by participants -
Would you mind sharing the name of the notified body you're answering these questions for?

Responding options	**Responses**
MTIC Intercert	1 (12.5%)
HTCERT	1 (12.5%)
No response	6 (75.0%)

Question 3
- Mandatory, one answer possible -
In case every manufacturer follows the same structure, do you feel the following aspect will be changing?
Efficiency of internal processes for notified bodies

Responding options	**Responses**
This aspect will be improved	6 (75.0%)
No changes to the aspect are expected	1 (12.5%)
The aspect will suffer	1 (12.5%)

Question 4 **- Mandatory, one answer possible -** In case every manufacturer follows the same structure, do you feel the following aspect will be changing? Covering varieties of products that need to be covered	
Responding options	**Responses**
This aspect will be improved	5 (62.5%)
No changes to the aspect are expected	2 (25.0%)
The aspect will suffer	1 (12.5%)

Question 5 **- Mandatory, one answer possible -** In case every manufacturer follows the same structure, do you feel the following aspect will be changing? Occurrence of mistakes and data errors	
Responding options	**Responses**
This aspect will be improved	4 (50.0%)
No changes to the aspect are expected	3 (37.5%)
The aspect will suffer	1 (12.5%)

Question 6 **- Mandatory, one answer possible -** In case every manufacturer follows the same structure, do you feel the following aspect will be changing? Usage of automatization (e.g. via software) for activities related to technical documentation	
Responding options	**Responses**
This aspect will be improved	7 (87.5%)
No changes to the aspect are expected	0 (0.0%)
The aspect will suffer	1 (12.5%)

Question 7 **- Mandatory, one answer possible -** In case every manufacturer follows the same structure, do you feel the following aspect will be changing? Employee onboarding	
Responding options	**Responses**
This aspect will be improved	4 (50.0%)
No changes to the aspect are expected	4 (50.0%)
The aspect will suffer	0 (0.0%)

Question 8 **- Optional, manual entries of responses by participants -** Do you see any additional advantages or disadvantages in case every manufacturer would follow the same structure?	
Responding options	**Responses**
“Advantage: better understanding of requirements by using the same terminologies”	1 (12.5%)
“Easier to review, clear which data needs to be provided, evaluation of KPIs much easier... Overall a common structure like STED would improve the work for everyone significantly, a little bit more complexity for simple medical devices is the only downside I see at the moment.”	1 (12.5%)
“It would be easier to evaluate the technical documentation and discuss any rising concerns with the manufacturer. At the same time it would be easier to mapping the process/documents need to prove conformity and control it”	1 (12.5%)
“Advantage: improved communication between manufacturers and NBs during TD assessment. Disadvantage: risk of "copy-paste" approach by manufacturer with decreased attention to specific risks management”	1 (12.5%)
“It must differ”	1 (12.5%)
No responses	3 (37.5%)

Question 9 **- Mandatory, multiple answers possible -** Some notified bodies split complete Technical Documentations up into individual sections for expert groups. Which expert groups did you define internally?	
Responding options	**Responses**
Clinical	7 (87.5%)
Sterilization	7 (87.5%)
Biocompatibility	5 (62.5%)
General information	3 (37.5%)
Quality	2 (25.0%)
Risk Management	7 (87.5%)
We do not use the system of expert groups	1 (12.5%)
Other (to be entered manually): - "Software" - "Biomechanical software electrical"	2 (25.0%) - 1 (12.5%) - 1 (12.5%)

Question 10a) **- Mandatory, one answer possible -** Receiving only Technical Documentation structured in the same way would... … safe how much time regarding the review process only?	
Rating	**Responses**
1 (saves no time)	1 (12.5%)
2	1 (12.5%)
3	1 (12.5%)
4	0 (0.0%)
5 (saves 50% of the time)	1 (12.5%)
6	0 (0.0%)
7	1 (12.5%)
8	0 (0.0%)
9	0 (0.0%)
10 (saves 100% of the time)	1 (12.5%)

Question 10b)

- Mandatory, one answer possible -

Receiving only Technical Documentation structured in the same way would...

… safe how much time regarding the entire process of desk review, starting from submission to certificate issuing?

Rating	Responses
1 (saves no time)	0 (0.0%)
2	2 (25.0%)
3	3 (37.5%)
4	1 (12.5%)
5 (saves 50% of the time)	1 (12.5%)
6	0 (0.0%)
7	0 (0.0%)
8	1 (12.5%)
9	0 (0.0%)
10 (saves 100% of the time)	0 (0.0%)

Question 11

- Mandatory, multiple answers possible -

Which statements would you consider being true regarding a harmonised structure for Technical Documentation?

Responding options	Responses
Documents from critical suppliers need to be aligned to the structure.	6 (75.0%)
The harmonised structure should lead to a fewer individual documents, covering more required elements at the same time.	5 (62.5%)
The harmonised structure should lead to a higher number of individual documents, covering less required elements at the same time.	3 (37.5%)
A summary (e.g. a STED) should be available at any case.	3 (37.5%)
Whenever a report or information is not applicable, the rationale should be provided using an individual document rather than a summary or a plan.	2 (25.0%)
Whenever a report or information is not applicable, the rationale should be provided in a summary or a plan; no need to create an individual document.	2 (25.0%)

Question 12 **- Mandatory, multiple answers possible -** Is there already a preferred method of structuring Technical Documentation that you ask customers to follow?	
Responding options	**Responses**
EU-MDR Annexes II and III	6 (75.0%)
GHTF: STED	2 (25.0%)
IMDRF: ToC	1 (12.5%)
Team-NB: NB-MED/2.5.1/Rec5	1 (12.5%)
Internal notified body checklists provided to the customers	7 (87.5%)
Other	0 (0.0%)

Question 13 **- Mandatory, one answer possible -** Would you generally support the idea of manufacturers using a harmonised Technical Documentation structure, no matter which devices and what company size?	
Responding options	**Responses**
Yes	5 (62.5%)
Yes, but with certain limitations	2 (25.0%)
No	1 (12.5%)

Question 14 **- Mandatory if question 13 was answered with "Yes, but with certain limitation", manual entries of responses by participants -** Which limitations would that be?	
Responding options	**Responses**
"It's not always possible to consider all medical devices in a general way. Consideration need to be done case by case."	1 (12.5%)
"Harmonized structures should account for differences in device classes (e.g., a Class III harmonized document should be different by a Class IIa one) or peculiarities (e.g., if SW is present)"	1 (12.5%)

Question 15 **- Mandatory if question 13 was answered with "No", manual entries of responses by participants -** Which limitations would that be?	
Responding options	**Responses**
"unclear how deviation from such mandatory format would be handled resp. evaluated"	1 (12.5%)

Question 16 **- Mandatory, multiple answers possible -** Is there already a preferred method of structuring Technical Documentation that you ask customers to follow?	
Responding options	**Responses**
Multiple files and one reference matrix for navigation	6 (75.0%)
Electronic submission via an e-mail/upload	5 (62.5%)
One complete file that covers all required elements in prose (e.g. pdf)	2 (25.0%)
Submission using the online-submission software (provided by the notified body)	2 (25.0%)
One complete file that covers information rather than prose (e.g. a checklist)	1 (12.5%)
Paper submission via mail	0 (0.0%)
Other	0 (0.0%)

Question 17

- Mandatory, multiple answers possible -

If there would be an electronic document review software that you would use for Technical Documentation assessment, what would be functions you would consider being must-haves?

Responding options	**Responses**
Electronic application inbox for document review requests	4 (50.0%)
Electronic submission inbox for documents to be reviewed	5 (62.5%)
Automated document completeness check (document validation; e.g.: Is a GSPR checklist available?)	7 (87.5%)
Automated extended content check for logical aspects (e.g. in case it is a sterile device, sterilization validation availability is checked)	7 (87.5%)
Possibility to add a comment or a finding to the reviewed document itself	6 (75.0%)
Automated report draft creation based on comments/findings entered	4 (50.0%)
Project management (e.g. setting up expert groups and internal collaborations)	4 (50.0%)
Automated send-out of audit reports, as soon as approved internally	3 (37.5%)
Automated creation of certificate drafts, based on electronic submission information	4 (50.0%)
Other (to be entered manually): - “Document management for various review circles on the same project”	1 (12.5%) -

Hiermit erkläre ich an Eides statt, die Arbeit selbstständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

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