Regulatory requirements of Medical Devices in MENA countries

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Vorgelegt von

Dr. Fatemeh Samadi

aus dem Iran

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Betreuer und 1. Referent: Dr. Ehrhard Anhalt

2. Referent: Dr. Birka Lehmann

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List of Abbreviations

AHWP	Asian Harmonization Working Party
AMC	Authorization for Market Commercialization
APEC	Asia Pacific Economic Cooporation
AR	Authorized representative
ASEAN	Association of East Asian Nations
CAPA	Central Administration Pharmaceutical Affairs
CAB	Conformity Assessment Body
CE	Conformité Européenne (French); English: European Conformity
CoA	Certificate of Analysis
C.O.O.	Country Of Origin
COME	Central Office for Medical Equipment
DPPC	Drug Policy and Planning Center
EIU	Economist Intelligence Unit
EP checklist	Essential Principles checklist
EU	European Union
FDA	Food and Drug Administration
FSC	Free Sales Certificates
GCC	Cooperation Council for the Arab States of the Gulf
GDP	Gross Domestic Product
GHTF	Global Harmonization Task Force on Medical Devices
GMDN	Global Medical Devices Nomenclature
GPCHE	General People's Committee for Health and Environment
HIV	Human Immunodeficiency Virus
i. e.	Id est (Latin); English: that means
IEC	International Electronical commission
IFU	Instruction for use
IMDR	Interim Medical Devices Regulations
IMDRF	International Medical Devices Regulators Forum
IMOH	Israel Ministry Of Health
ISIRI	Institute of Standards & Industrial Research of Iran
ISO	International Standardization Organization
IVD	In Vitro Diagnostic
JFDA	Jordan Food and Drug Administration
KSA	Kingdom of Saudi Arabia
LOA	Letter OF Authorization

Ltd.	Limited
MEC	Ministry of economy and Commerce
MENA	Middle East and North Africa
MD	Medical Devices
MDNR	Medical Devices National Registry
MDMA	Medical Devices Marketing authorization
MDSAP	Medical Devices Single Audit Program
MMAA	Ministry of Municipal Affairs and Agriculture
MOH	Ministry Of Health
MOPH	Ministry of Public Health
MPHP	Ministry of Public Health and Population
MS	Member State
NCDCR	National Center for Drug Control and Research
NCMDR	National Center for Medical Devices Reporting
NHRA	National Health Regulatory Authority
NODCAR	National Organization for Drug Cotrol and Research
PMA	Premarket approval
PPRO	Pharmaceutical Product Regulatory Office
QMS	Quality Management System
RA	Regulatory Authority
RPS	Regulated Product Submission
RMS	Risk Management System
SA	Saudi Arabia
SG	Study Group
SaMD	Software as a Medical Devices
SFDA	Saudi Arabia Food and Drug Authority
STED	Summary of Technichal Documentation
UAE	United Arab Emirates
UDI	Unique Devices Identification
US	United States
USD	United States Dollar
WHO	World Health Organization

Executive summary

The objective of this Master Thesis is to define the regulatory environment for Medical Devices in the Middle East and the North African countries (MENA), to show their limits and their prospects.

The Medical Devices market in this area presents unique challenges and opportunities to international manufacturers in the health care sector.

Although the Medical Devices market in the MENA region is very diverse most of the individual economies have shown sustainable growth. This growth is driven by several factors including a growing population of 400 million people, the price of oil and energy, an increase of the Gross Domestic Product (GDP) and the income per capita, an improved literacy rate, a larger middle class and also a higher disease rate.

In this market Medical Devices are one of the most important health intervention tools available for the prevention, diagnosis and treatment of diseases and for patient rehabilitation. The growth of demand for sophisticated pharmaceutical and medical products in the MENA region seen in recent years is only likely to continue.

Despite of the overall positive economic development in most of the MENA countries the regulatory environment can be challenging. Publicly accessible written legislations are limited in these countries, sometimes are only available in the local language (mostly Arabic) and leave room for interpretation. Also important to mention in this context are the barriers for the continuing evolution of the regulatory environment in some of these emerging countries due to their political instability, non-transparency and corruption.

Against this background the efforts of the Global Harmonization Task Force (GHTF) to harmonize the Medical Devices regulation, offer a valuable contribution to ease the regulatory interconnection and intercommunication between the individual countries and the international economic operators of the Medical Devices industry.

The follower of GHTF - the International Medical Devices Regulators Forum (IMDRF) - builds on the strong foundational work of the GHTF and accelerates the international Medical Devices regulatory harmonization and convergence. The impact of the EU on the harmonization in these countries is rising.

1. Introduction

1.1 Definition of MENA countries

The Middle East & North Africa (MENA) region is bordered by Morocco in the south (respectively west) to Iran in the north. There is no standard definition of the Middle East. The Word Bank defines the MENA region as Algeria, Bahrain Djibouti, Egypt, Iran, Iraq, Israel, Jordan, Kuwait Libya, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates (UAE), West bank and Gaza and Yemen[1].

The MENA countries consist of three general sub-regions [2, 4]:

- **Arabian Peninsula**: Bahrain, Kuwait, Oman, Qatar, Saudi Arabian (SA), United Arab Emirates (UAE) and Yemen. This region is also defined as Cooperation Council for the Arab States of the Gulf (GCC).
- **Western Asia:** Iran, Iraq, Israel, Jordan, Lebanon, Palestinian Territory and Syria;
- **North Africa:** Algeria, Egypt, Libya, Morocco, Tunisia.

1.2 MENA Healthcare market

As in much of the world, the 20th century brought an accelerating population growth also to MENA. The total population was 104 million by 1950—and then quadrupled, to more than 400 million, by the year 2000. In 2007, the total was 432 million. The latest population projections for the region show the total reaching nearly 700 million by the year 2050. The majority of the region's population lives in the MENA Western Asian countries, while the countries on the Arabian Peninsula have small populations [3].

MENA markets are very diverse but their economies have shown tolerable emerging markets-type growth. The several factors causing this growth include a growing population of 400 million people, the price of oil and energy, an increase in GDP/capita income, an improved literacy rate and a larger middle class.

Meanwhile, because the main diseases in the MENA region are metabolic in nature, such as obesity, hypertension, hyperlipidemia, and diabetes, demand for medical treatment for these cases is high. The amount of metabolic activities in this region is small because outdoor activities are highly constrained by hot and dry desert weather in many countries despite excessive intake of sugar and high-calorie diet [5].

Major diseases in the GCC include cardiovascular diseases, diabetes, cancer, obesity, as well as tuberculosis and other respiratory ailments. According to the WHO, up to 80% of all deaths from cardiovascular disease are preventable, with GCC countries aiming to explore this situation.

The UAE ranks second highest in the world for diabetes prevalence (20%), followed by Saudi Arabia (16.7%), Bahrain (15.2%) and Kuwait (14.4%), according to the International Diabetes Federation.

Prudery and a lack of disease awareness in the Middle East both obstruct the early diagnosis of a number of fatal diseases, such as colon cancer and breast cancer. Each year, around 5,000 Saudis are diagnosed with having cancer, which is usually discovered at an advanced stage, due to inadequate disease and health surveillance. The late identification of such diseases makes their treatment difficult. In particular, breast cancer – the most common type of cancer in the Gulf States, representing approx. 20% of all cancer patients in the GCC – is on the rise, with authorities warning of near-epidemic levels.

According to a September 2009 study by the Centre for Arab Genomic Studies, Arabs are among having the highest prevalence of genetic disorders on a global scale. The research identified around 200 such conditions as being prevalent among Arabs in the GCC alone, out of just over 900 genetic disorders reported among Arabs in total [5].

The Economist Intelligence Unit (EIU) estimates that global health care spending as a percentage of Gross Domestic Product (GDP) will average 10.5 percent in 2014 (unchanged since 2013), with regional percentages of 17.4 percent in North America, 10.7 percent in Western Europe, 8.0 percent in Latin America, 6.6 percent in Asia/Australasia, and 6.4 percent in the Middle East/Africa.

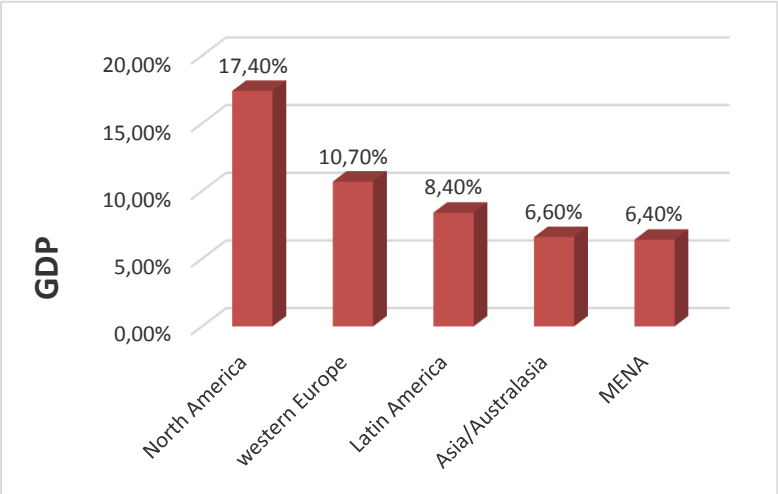

Figure 1: Healthcare expenditure as a percentage of GDP per country / region (2014 estimate) (According to the EIU) [7]

Healthcare expenditure on a per capita basis in the MENA region stands at USD 315. It is lower than that in the GCC region (USD 913) and much below developed countries such as the US (USD 7,410), Canada (USD 4,380), and the UK (USD 3,285).

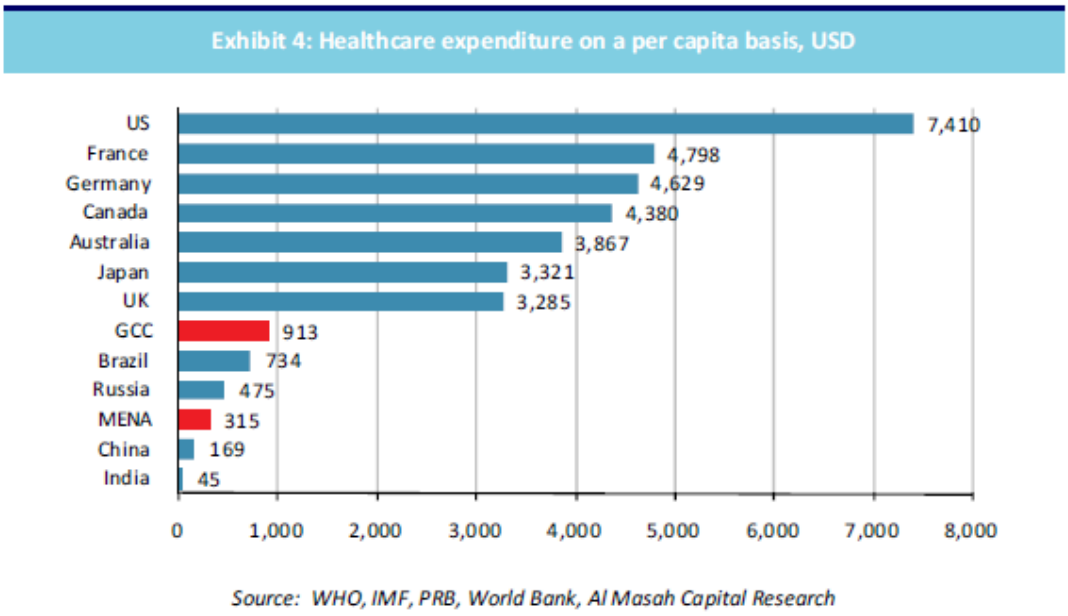

Figure 2: Healthcare expenditure on a per capita basis in different countries/regions (MENA stands at USD315) [7]

Healthcare is a large and growing market globally and one of the fastest growing sectors worldwide. The fastest-growing region in the coming years could be the Middle East and Africa, where spending is expected to rise by an average of 10 percent annually [8, 9].

1.3 MENA Medical Devices market

The Medical Devices and diagnostics market in the MENA region is displaying extraordinary growth and significant progress. In 2010, the global Medical Devices market was estimated to be worth US$ 164 billion and grew faster than the global market for medicines. It is estimated that it will reach US$ 228 billion (around 41% increasing) by 2015 [8, 10 11]. This market is growing around a pace of 5% per annum.

Despite financial limitations in some cases and the geopolitical instability in others, the overall trend is positive and sustainable political breakthroughs in countries such as Iran, Iraq, Syria, Yemen, Libya are foreseen [12].

The largest regional medical Devices market was in the Americas (representing 45% of global sales revenue), followed by Europe (31%) and Asia (21%), while the Middle East and Africa represent a combined 3% of sales revenue (Figure 3) [13].

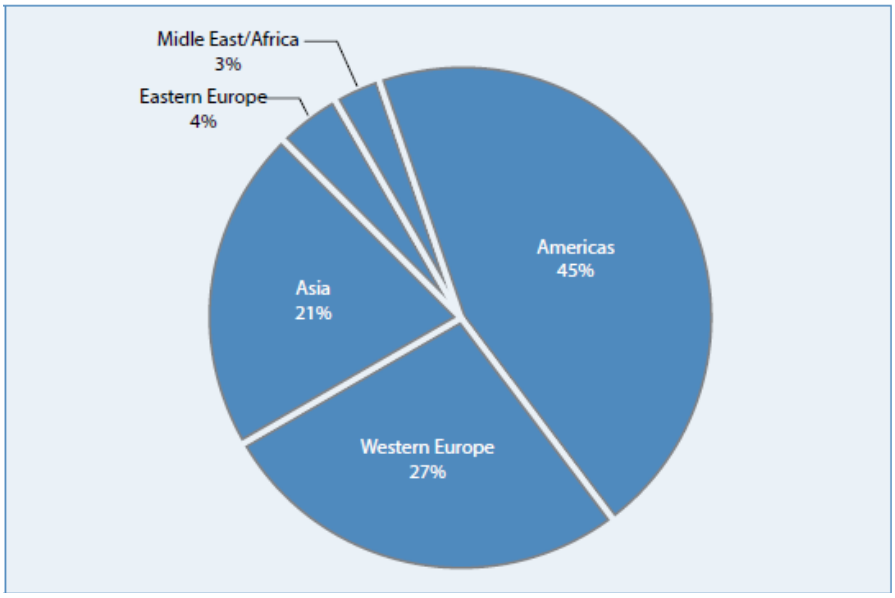

Figure 3: Medical Devices market, by region, 2010 [14]

The European market has been growing on average by 4% per annum over the past 6 years [15] (Figure 4).

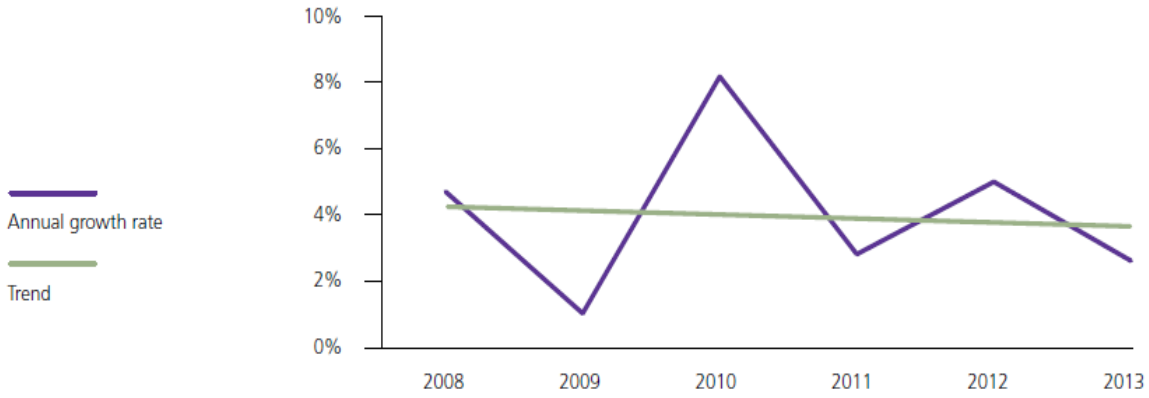

Figure 4: European medical technology market growth rates, based upon manufacturer prices, 2008-2013 [15, 16]

Europe has a positive medical technology trade balance of €15.5 billion (2012), more than a twofold increase since 2006. In comparison, US medical technology trade surplus is at €5.3 billion [15].

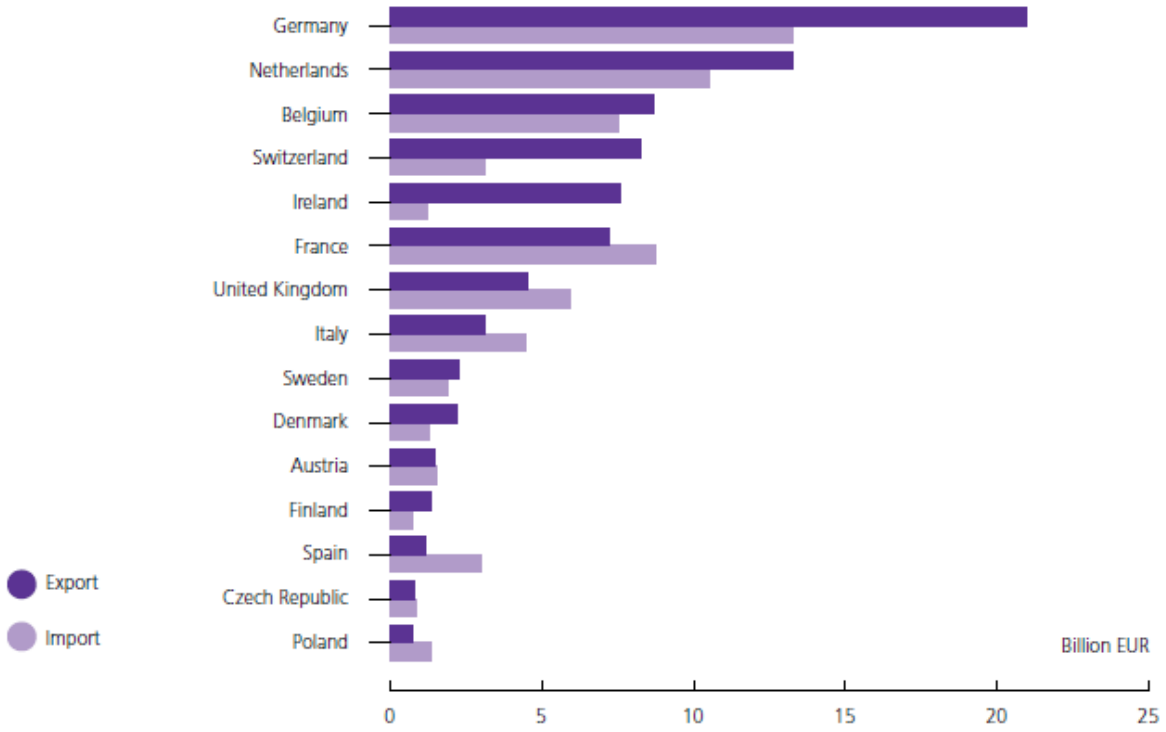

Figure 5: Exports and imports of medical technology by country, 2012 *(including European intra-trade) [15-16]*

The Medical Devices market in MENA countries is divided in three regions:

1) **The GCC region**, which has the most important market of Medical Devices in the MENA region. Table 1 describes the GCC Medical Devices market in 2013 and an estimate towards 2018.

Table 1: Medical Devices Market in GCC countries [17]

	SA	**UAE**		**Qatar**		**Oman**		**Kuwait**	**Bahrain**	**Yemen**
Total import US$ (only MD)	2013	2013	2018	2013	2018	2013	2018	NA	NA	NA
	1,864.5mn	800 mn	1,000.3 mn	200mn	400mn	108.1mn	191.4mn			
Leading supplier	EU (40%) USA (22.6%) China (7%)	EU USA China		EU USA						
Total export US$ (only MD)	19.7mn	100mn		1.5mn		7.4mn				

2) **Western Asia:** This is the second Market in the MENA region (see table 2). Table 2 describes the Western Asia Medical Devices market in 2013 and an estimate towards 2018.

Table 2: Medical Devices Market in Western Asia countries [17]

	Israel		Iran		Iraq	Jordan		Lebanon	Syria	Palestinian
Total import US$ (only MD)	2013	2018	2013	2018	2013	2013	2018	NA	NA	NA
	893mn	1,693mn	833 mn	1,28 mn	464 mn	761 mn	244 mn			
Leading supplier	EU USA		EU (67.1%)							
Total export US$ (only MD)	1,826.4mn		7.6mn		2.1mn	24.2mn				

3) **North Africa:** This is the smallest market of Medical Devices in the MENA region, but Egypt has an important place in this region (see table 3). Table 3 describes the North Africa Medical Devices market in 2013 and an estimate towards 2018.

Table 3: Medical Devices Market in Western Asia countries [17]

	Egypt		Morocco	Algeria	Libya	Tunisia
Total import US$ (only MD)	2013	2018	2013	NA	NA	NA
	541mn	1,009mn	211mn			
Leading supplier	Germany USA China Japan					
Total export US$ (only MD)	86.7mn		17.2mn			

According to information received, Israel, Saudi Arabia and UAE are the most attractive markets in the MENA region respectively [17].

The purpose of this Master Thesis is to define the regulatory environment for the MENA region. This includes regulatory provisions like registration requirements and processes, guidelines as well as predictive approval timelines. As the Medical Devices registration in most countries of the MENA

region is based on having a prior approval in one of the GHTF countries, this paper will describe briefly the regulatory environment according to the GHTF and WHO for Medical Devices regulations and its implementation in MENA countries. The medical regulation in the European Union and the United States are described in prior papers [19, 20].

2 Medical Devices regulation

2.1 Medical Devices regulation history

The regulation of Medical Devices across the world is varies a lot, ranging from comprehensive to none. Over the past two decades, the number, range, and complexity of Medical Devices and therefore regulation of these Devices has increased. In 2001 the World Health Organization (WHO) published "A model regulatory program for Medical Devices" [21].

That was an international guide to assist member states in establishing regulatory programs for Medical Devices. The aim was to provide information to nations without Medical Devices regulatory systems that would enable the production of internationally compatible regulations. In 2003 the WHO published 'Medical Devices regulations. Global overview and guiding principles' [22, 23].

This guideline emphasized the complexity of the Medical Devices industry and identified issues related to regulation. The mentioned document provided guidance to member states wishing to create or modify their regulatory systems for Medical Devices.

The WHO reported the following results from their Bangkok meeting during September 2010 about worldwide Medical Devices regulation framework.

Table 4: worldwide Medical Devices regulation framework [22, 24]

Countries %	Medical Devices regulation
30%	These countries have a developed framework for regulation of Medical Devices.
30%	These countries partially have regulation of Medical Devices
40%	These countries are either developing a framework or do not yet have any regulation

a) International Standardization Organization (ISO)

The International Standardization Organization (ISO) was set-up in 1946 to facilitate the international coordination and unification of industrial standards. ISO is a network of national standards institutes in 163 countries, and is now the world's largest developer and publisher of voluntary international standards.

ISO standards are widely adopted on a regional and national level and support the procedures and practices of Medical Devices development, manufacture, quality control and conformity assessment requirements.

b) Global Harmonization Task Force (GHTF)

In 1992 the Global Harmonization Task Force (GHTF) was founded in response to the growing need for international harmonization of Medical Devices regulation. The GHTF was a voluntary group consisting of representatives from the Medical Devices regulatory authorities of the five members: USA, European Union (EU), Japan, Australia and Canada. In 2006, the membership was expanded to include the Asian Harmonization Working Party (AHWP), the International Organization for standardization (ISO), and the International Electrotechnical Commission (IEC) [22].

The Asian Harmonization Working Party (AHWP) was established in 1996 as a non-profit organization by a group of Medical Devices regulatory authorities and the Medical Devices industry. Its aims are to study and recommend ways to harmonize Medical Devices regulations in the Asian and other regions and to work in coordination with the GHTF and other related international organizations. The aim of this cooperation is to establish harmonized requirements, procedures and standards. Membership is open to representatives from Asia and other regions that support the above stated goals. The following countries of the MENA region are members of AHWP: Abu Dhabi, Jordan, Kingdom of Saudi Arabia, Kuwait and Yemen [25].

c) International Medical Devices Regulators Forum (IMDRF)

GHTF was superseded by the International Medical Devices Regulators Forum (IMDRF), that was founded in October 2011. It is a voluntary group of Medical Devices regulators from around the world. These Medical Devices regulators have come together to build up the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aim to accelerate international Medical Devices regulatory harmonization and convergence. The current IMDRF members are Australia, Brazil, Canada, Europe, Japan, and the United States of America. The membership of China and the Russian Federation is currently being confirmed. The World Health Organization (WHO) is an official observer [26]

2.2 International Medical Devices Regulators Forum

2.2.1 Goals of the IMDRF

The goals of IMDRF are to [27]:

- accelerate international Medical Devices regulatory convergence;
- support innovation and timely access to safe and effective Medical Devices globally;
- promote open discussion and the sharing of best practices among regulatory authorities responsible for Medical Devices regulation;
- facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities;
- provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers;
- enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders; and
- establish development dialogue with other relevant organizations.

2.2.2 Technical documents

The technical documents were created by the GHTF. These are final documents and are still current. As the work of the IMDRF progresses, these documents will be reviewed and published as IMDRF documents. Until then, these documents are provided for the use of interested parties [26].

- **GHTF Study Group 1 - Pre-market Evaluation documents**

These guidance documents describe a global regulatory model for Medical Devices. They provide principles suitable for harmonization and develop harmonized guidelines. Key terms such as “Medical Devices” and “manufacture” and the essential principles of safety and performance are defined in these documents. These documents provide guidelines concerning the principles of classification and conformity assessment such as standard format for pre-market submissions and harmonized product labelling requirements [28].

- **GHTF Study Group 2 - Post-market Surveillance/Vigilance documents**

This guidance is a review of adverse event reporting, post-marketing surveillance and other forms of vigilance for Medical Devices. It is an analysis of different requirements amongst countries with

developed Devices regulatory systems. The subject of these documents is to define requirements for a common Medical Devices vigilance system on a global basis [29].

- **GHTF Study Group 3 - Quality Systems documents**

These documents are covering the implementation and integration of a risk management system within the quality management system, process validation and the control of products and services obtained from suppliers [30] [see also 2.2.6 (1)].

- **GHTF Study Group 4 - Auditing documents**

These documents give guidance regarding training requirements for auditors, regulatory auditing strategy and reports.

Recently (September 2014), the IMDRF published a guidance intended to implement the concept of a Medical Devices Single Audit Program (MDSAP). In December 2013 the IMDRF published two documents:

"Requirements for Medical Devices Auditing Organizations for Regulatory Authority Recognition"
and
"Competence and Training Requirements for Auditing Organizations".

These two documents are complementary documents and focused on requirements for an Auditing Organization and individuals performing regulatory audits and other related functions under the respective Medical Devices legislation, regulations, and procedures required in its regulatory jurisdiction [31].

- **GHTF Study Group 5 - Clinical Safety/Performance documents**

These documents focus on harmonized requirements for evidence of the clinical safety of Medical Devices and IVD Medical Devices. The subject of this guidance is a harmonized definition of clinical investigation, clinical data, clinical evaluation and clinical evidence and post-market clinical follow-up study [32].

2.2.3 Definition of 'Medical Devices' and 'In Vitro Diagnostic (IVD) Medical Devices'

The GHTF proposed the following harmonized definition of a Medical Device [33].

'Medical Devices' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article:

intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

> *diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of Medical Devices, providing information by means of in vitro examination of specimens derived from the human body;*

and

> *which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.*

'In Vitro Diagnostic (IVD) Medical Devices' means a Medical Devices, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

2.2.4 Classification System for Medical Devices

According to GHTF/IMDRF the classification of Medical Devices is the manufacturer's responsibility. The Regulatory Authorities (RA) specifies procedures to be followed by manufacturers during the design, manufacture, and marketing of each Devices. It describes the manner in which a manufacturer should demonstrate conformity to such specified procedures. Classification of a Medical Devices has to be done carefully, because the risk class establishes the correct conformity requirements. An incorrect classification would therefore lead to a conformity assessment procedure, which is not applicable to the particular Devices.

GHTF/IMDRF established a Devices classification system consisting of four classes where

Class A represents the lowest hazard and Class D the highest. The determination of class should be based on rules derived from the potential of a Medical Devices to cause harm to a patient or user and thereby on its intended use and the technology/ies it utilizes [34] (see table 5).

Table 5: Diagrammatic Representation of the Classification System

Class	Medical Devices		IVD Medical Devices	
	Level	Devices example	Level	Devices example
A	Low Hazard	Bandages / tongue depressors	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer, prepared selective culture media
B	Low-moderate Hazard	Hypodermic Needles / suction equipment	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self-testing, Anti-Nuclear Antibody, Urine test strips
C	Moderate-high Hazard	Lung ventilator / bone fixation plate	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self-testing, HLA typing, PSA screening, Rubella
D	High Hazard	Heart valves / implantable defibrillator	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

2.2.5 Essential Principles applicable to all Medical Devices including IVD Medical Devices

The worldwide adoption of fundamental design and manufacturing requirements for Medical Devices that provide assurance that the Devices is safe and performs according to its specification, offers significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities.

According to the GHTF Medical Devices regulatory framework, a Medical Devices has to meet certain essential principles regarding safety and performance before it can be placed on the market. The basic framework for these Essential Principles is described in one document for both Medical Devices and IVD Medical Devices.

This guidance describes fundamental design and manufacturing requirements, referred to 'Essential Principles of Safety and Performance', which apply to all Medical Devices. A manufacturer of a Medical Devices is expected to design and manufacture a product that is safe and performs as intended.

There is a comprehensive list of design and manufacturing requirements separate from general requirements, which are not applicable for each Medical Devices/IVD Medical Device. The responsibility of the manufacture is to decide which ones are relevant to his product. The following aspects are covered [35]:

- Chemical, physical and biological properties
- Infection and microbial contamination
- Medical Devices/IVD Medical Devices incorporating a substance considered to be a medicinal product/drug
- Medical Devices incorporating materials of biological origin
- Environmental properties
- Devices with a diagnostic or measuring function
- Protection against radiation
- Medical Devices/IVD Medical Devices that incorporate software and standalone Medical Devices software
- Active Medical Devices and Devices connected to them
- Protection against mechanical risks
- Protection against the risks posed to the patient or user by supplied energy or substances
- Protection against the risks posed by Medical Devices intended by the manufacturer for use by lay persons
- Label and Instructions for Use
- Clinical evaluation

2.2.6 Conformity Assessment Procedure

The conformity assessment is a systematic examination of evidence procedures that may be used by the manufacturer to determine that a Medical Devices is safe and its compliance with the Essential Principles as intended by the manufacturer.

Conformity assessment is primarily the responsibility of the Medical Devices manufacturer. However, a review of the process and the conclusions are conducted either by the relevant Regulatory Authority (RA) or a Conformity Assessment Body (CAB).

According to the documents of GHTF:

Conformity assessment for Medical Devices

Conformity assessment for IVD Medical Devices

the following five conformity assessment elements are applicable to all four Devices classes:

(1) Quality Management System (QMS),

The manufacturer should implement, document and maintain a QMS that ensures, that the design, manufacturing and supply to the market of the Medical Devices are safe, perform as intended and comply with the relevant requirements. Therefore, when a Medical Devices manufacturer chooses

to utilize suppliers, the manufacturer should ensure control over any product or service obtained from such suppliers as defined within the QMS [36].

The QMS can be based on international standards, such as ISO 9001 as a general management standard and ISO 13485, which include special requirements to ensure the safety and efficacy of Medical Devices. Although a full QMS is preferred, some countries or regional regulations may allow the manufacturer to choose type examination as an alternative means of demonstrating conformity with the relevant Essential Principles of safety and performance. The use of international standards is still strongly encouraged by GHTF/IMDRF, as they are generally presumed to conform to the corresponding Essential Principles and to support global convergence in regulatory system.
The requirements of a QMS have been discussed in Study Group 3 and guidance documents on the following published topics:

- Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers

This guidance document is intended for Medical Devices manufacturers and it is expected that the reader is familiar with regulatory quality management system requirements within the Medical Devices sector. This guidance document may also be useful to regulatory authorities and suppliers. This guidance document is intended for educational purposes and it is not intended to be used to assess or to audit compliance with regulatory requirements.

- Implementation of risk management principles and activities within a Quality Management System

Medical Devices manufacturers are generally required to have a QMS as well as processes for addressing Devices related risks. These processes for managing risks can evolve into a stand-alone risk management system (RMS). While manufacturers may choose to maintain these two management systems (QMS &RMS) separately, it may be advantageous to integrate them as this could reduce costs, eliminate redundancies, and lead to a more effective management system.
Manufacturers of Class A and B Devices should implement and maintain the basic elements of a QMS but have the option of eliminating the design and development controls from it. The QMS for manufacturers of Class A Devices is normally not subject to a premarket on-site audit by the RA or CAB. Manufacturers of Class C and D Devices should implement and maintain an effective QMS that includes design and development controls, and needs to be verified by the RA or CAB either by accepting existing relevant certification of the manufacturer or by carrying out an on-site audit of the facilities in question.

- Process Validation Guidance

The process validation is a requirement within a QMS and has general applicability to manufacturing processes for Medical Devices. Software validation is not covered by GHTF documents.
The degree of the assessment of the manufacturer's QMS by RA or CAB is influenced by the class of the Medical Devices [37].
Detailed guidance on auditing practice is provided in the IMDRF documents. They are intended for auditing organizations [38] and an assessment method for recognition and monitoring of Medical Devices Auditing Organizations [39].
The follow-up of corrections, corrective and improvement actions are also treated, as well as training requirements for auditors [40, 41] and the competence criteria that should be met by an audit team.

(2) a system for post-market surveillance,

The post-marketing surveillance system is part of the QMS and RA or CAB will confirm that such a process is in place, usually at the time of the QMS audit. Furthermore, the RA may require manufacturers to perform a specific post-marketing study of a particular type of Devices, and report the outcome to the RA. The RA will monitor any post-marketing study and consider whether any additional regulatory action is required after analyzing the outcome.
The post-marketing surveillance system has to include complaint handling, vigilance reporting and corrective and preventive action according to guidance documents by Study Group 2.

(3) technical documentation,

Manufacturers of all Devices classes are expected to demonstrate conformity of the Devices to the Essential Principles of Safety and Performance of Medical Devices through the preparation and holding of a technical documentation that shows how each Medical Devices was developed, designed and manufactured.
The manufacturer creates the Summary Technical Documentation (STED) for demonstrating Conformity to the Essential Principles of Safety. A subject of STED is required to be held at the manufacturers premises for inspection purposes in case of class A or B Devices or to be submitted to the RA or CAB prior to marketing of class C and D Devices. The extent of evidence to be presented depends on the risk class of the device. For future details on STDE, (see 2.2.7).

(4) a declaration of conformity,

The Medical Devices manufacturer has to prepare a Declaration of Conformity (DoC) and attest that their Medical Devices fully complies with Essential Principles.
This declaration should contain the following information:

- An attestation of compliance with the applicable Essential Principles for Safety and Performance and the applicable requirements of Label and Instructions for Use for Medical Devices,
- Sufficient information to identify the Devices/s to which the DoC applies,
- The Global Medical Devices Nomenclature (GMDN) code for the Devices,
- The risk class of the Medical Device,
- The date on which the Declaration of Conformity is issued,
- The name and address of the Device manufacturer,
- The name, position, and signature of the responsible person who has been authorized to complete the DoC on the manufacturer's behalf.

The RA or CAB may review and confirm the adequacy of the DoC and, if required, examine the supporting documents or other evidence.

(5) the registration of manufacturers and their Medical Devices by the RA.

Registration of manufacturers and their Medical Devices by the RA is considered the most basic level of regulatory control of Devices in the market. Prior to placing a Medical Devices on the market, the manufacturer, or distributor, or importer, or authorized representative should provide the RA with the information it needs in respect of registration requirements. The RA will implement and maintain the register.

The responsibility of manufacturer and RA or CAB during the conformity assessment procedure are depend on the risk class of the Devices (see tables 6, 7).

Table 6: conformity assessment elements and responsibility of manufacturer [42]

Manufacturer Responsibility				
Conformity Assessment Element	**Class A**	**Class B**	**Class C**	**Class D**
QMS	full QMS **or** QMS without design and development control	full QMS **or** QMS without design and development control	full QMS	full QMS
Post-market Surveillance	adverse event reporting procedure according to GHTF SG2 guidance	adverse event reporting procedure according to GHTF SG2 guidance	adverse event reporting procedure according to GHTF SG2 guidance.	adverse event reporting procedure according to GHTF SG2 guidance.
Technical Documentation	Compilation of STED upon request	Compilation of STED upon request	Compilation of STED upon request	Compilation of STED upon request
DoC	Preparation and maintenance	Preparation and maintenance	Preparation and maintenance	Preparation and maintenance
Registration	Provide registration requirements	Provide registration requirements	Provide registration requirements	Provide registration requirements

Table 7: conformity assessment elements and responsibility of RA or CAB [42]

RA / CAB Responsibility				
Conformity Assessment Element	**Class A**	**Class B**	**Class C**	**Class D**
QMS	Regulatory audit normally not required except where assurance of sterility or of a measuring function is required.	Verify that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	Verify that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	Verify that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.
Post-market Surveillance	May audit post-market to investigate specific safety or	Satisfy that an appropriate adverse event reporting	Satisfy that a current and appropriate adverse event	Satisfy that a current and appropriate adverse event reporting

	regulatory concerns	procedure is in place as part of the QMS	reporting procedure is in place as part of the QMS.	procedure is in place as part of the QMS
Technical Documentation	Premarket submission of STED normally not required	Premarket submission of STED normally not required	Premarket review of STED	Premarket review of STED
DoC	Submission normally not required	Review and verification	Review and verification	Review and verification
Registration	Maintain and verify as appropriate	Maintain and verify as appropriate	Maintain and verify as appropriate	Maintain and verify as appropriate

2.2.7 Summary Technical Documentation (STED)

A technical documentation of the Medical Devices has to be held by the manufacturers premises as part of the conformity assessment procedure (details in chapter 2.2.6). The technical documentation typically controlled by the manufacturer's quality management system (QMS), is often extensive and sections of it may be held in different locations. The documentation is updated to reflect any changes made during the lifecycle of the Devices.

The GHTF proposes a harmonized format for the STED for Medical Devices, in which this information should be presented. Depending on the classification of the Medical Devices, the information contained in the summary may include abstracts, summaries or existing controlled documents, as well as an Essential Principles checklist (EP checklist).

According to the GHTF guidance, the STED should contain the following sections [43]:

1) Devices Description and Product Specification, Including Variants and Accessories

A general description of the Medical Devices including its intended use, the intended patient population and medical condition to be diagnosed and treated and other considerations such as patient selection criteria should be provided here. The risk class and the applicable classification rule according to Principles of Medical Devices Classification should be described. A description of the accessories, other Medical Devices and other products that are not Medical Devices, which are intended to be used in combination with it should be exist. The product specification, which include a list of the features, dimensions and performance attributes of the medical Devices, its variants and accessories that would appear typically in the product specification must be made available to the end user.

2) Design and Manufacturing Information

Design and manufacturing information may take the form of a flow chart. The STED should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. The information include design, production, final product testing, and packaging of the finished Medical Devices.

3) Essential Principles Checklist

The EP checklist provides a tabular overview of the Essential Principles. It should be demonstrated, whether each EP applies to the Devices or not. A justification should be given if certain requirements of EP are not applicable. The method used to demonstrate compliance with each Essential Principle that applies should be described. The method used to demonstrate compliance may be:

a. conformity with recognized or other standards ;
b. conformity with a commonly accepted industry test method;
c. conformity with in-house test methods;
d. comparison to a similar Devices already available on the market.

4) Labelling

The STED should typically contain a complete set of labelling, including labels on the Devices and its packaging, instructions for use and promotional material. The required content of the labelling is detailed in separate GHTF guidance document. The labelling set should be in a language acceptable to the reviewing RA or CAB [44].

5) Risk Analysis and Control Summary

A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. This risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.

6) Product Verification and Validation

The STED should contain a summary of verification and validation studies, which demonstrate conformity with the Essential Principles. This information should cover engineering tests, laboratory tests, simulated use testing, any animal tests for demonstrating feasibility or proof of concept of the finished Devices and any published literature regarding the Devices or substantially similar Devices. Additional information can be provided, where applicable on the following subjects:

- biocompatibility;
- medicinal substances incorporated into the Devices, including compatibility of the Devices with the medicinal substance;

- biological safety of Devices incorporating animal or human cells, tissues or their derivatives;
- sterilisation;
- software verification and validation;
- animal studies that provide direct evidence of safety and performance of the Devices, especially when no clinical investigation of the Devices was conducted;
- clinical evidence.

The Declaration of Conformity is not part of the STED. However, it may be annexed to the STED once the conformity assessment process has been completed.

The STED will be prepared and submitted to the RA/CAB for Class C and D Devices. For Class A and B Devices, the STED will be prepared and submitted only at the request of a RA/CAB. The structure of the technical documentation and the STED is illustrated in Figure 6.

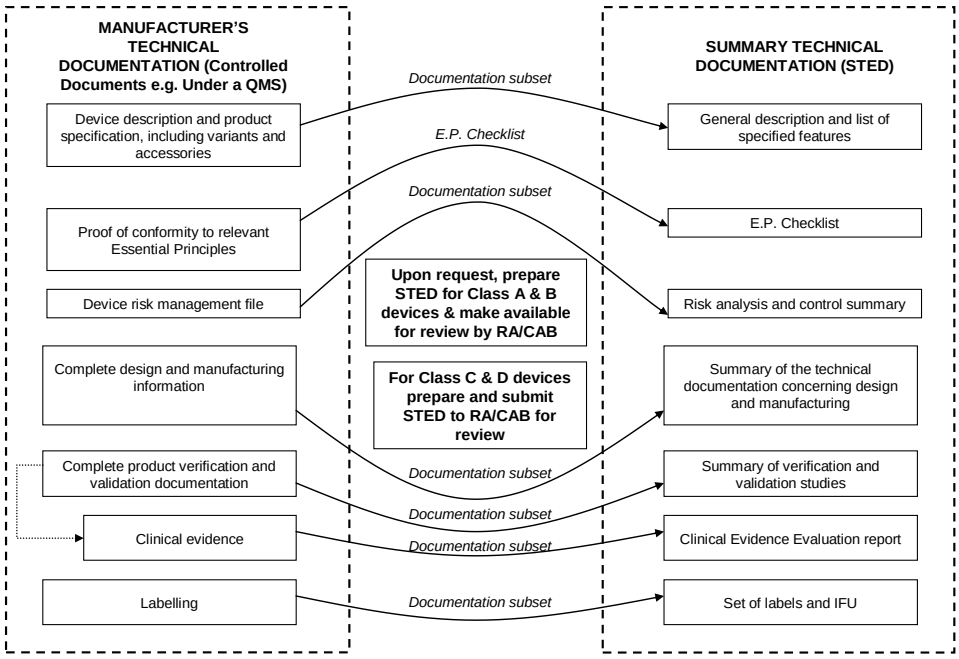

FIGURE 1: PREMARKET USE OF THE STED

Figure 6: The flow of information from the technical documentation to the STED [43]

The manufacturer should be able to gain and review experience about a Medical Devices which is already marketed by use of a post-marketing surveillance system. Information about adverse events can be obtained from various sources, e.g. expert user groups, customer surveys, customer complaints and warranty claims, service and repair information or literature reviews [45].

3. Medical Device regulation in MENA countries

The regulatory environment in these countries is very different. Publicly accessible written legislations are limited, sometimes only available in local language (most Arabic) and leave room for interpretation. In order to support the information, the author of this master thesis sent a questionnaire (Annex I) to the corresponding local Regulatory Affairs Managers (nine countries) of a globally operating Medical Devices company.

MENA region specification

Document legalization

The health ministries of foreign countries, where a company wishes to market its products, requires assurances that the products are safe, effective and in conformance with current Good Manufacturing Practices (GMP). The ministries often require copies of the company's US FDA approval certificates or ISO certification or FSC to document that the products in question are free from defects. To prove these documents are authentic, they must be certified, authenticated, legalized or apostilled depending on the national health ministry's requirements. The countries of the MENA region are divided into Apostiile and non-Apostiile countries:

a. Document legalization in Apostiile countries

The only Apostille countries in MENA region are Oman and Israel.
The mentioned certificates only need an Apostille to legalization for both countries [46, 47].

b. Document legalization in non - Apostiile countries

The remaining 17 MENA countries are non- Apostille countries. For any non- Apostille country, the document must to be sent to the chamber of commerce and the respective embassy for consular legalization.
In Germany the legalization process for these countries is different for the two following groups:

1. Iran and Palestine
   The documents for these countries must first be sent to the district court (Landgericht), then to the chamber of commerce (IHK) and finally to the Embassy of the foreign countries.
2. Algeria, Egypt, Bahrain, Iraq, Jordanian, Kuwait, Lebanon, Libya, Morocco, Qatar, Saudi Arabia, Syria, Tunisia, UAE and Yemen.

The documents for these countries must first be sent to the district court (Landgericht), then to the chamber of commerce (IHK) and the Federal Administration Office (Bundesverwaltungsamt) depending upon the national health ministry's requirements, after that to the Arab-German Chamber

of Commerce and Industry (Ghorfa) and finally to the Embassy of the foreign countries, respectively. This process is different for each country [48].

3.1 Medical Devices in GCC Countries

3.1.1 Kingdom of Saudi Arabia (KSA)

Medical Devices Definition

The Medical Devices and In Vitro Diagnostic (IVD) definitions in Saudi Arabia are based on the IMDRF definition [49] (see section 2).

a. Medical Devices Regulation

As KSA is an active member of AHWP, the most Medical Devices regulations are based on IMDRF and consequently GHTF requirements. These regulations ensure that only Medical Devices that have been authorized by one of the founding IMDRF members have access to the Saudi Arabian market. The Saudi Arabian Food and Drug authority (SFDA) was established in 2003 and is still constructing the regulatory infrastructure for Medical Devices registration. The SFDA is operating through a Medical Devices Interim Regulations (MDIR) system. The SFDA is an independent authority that reports to the council of ministers and is responsible for the regulation of Medical Devices in Saudi Arabia [50].

The MDIR is facilitated through a set of Electronic systems51 [Country Questionnaire, 2014] and solutions to enable manufacturers, Authorized Representatives, Importers, Distributors, and other parties to communicate efficiently with the SFDA. The electronic application forms (Annex V) are found on the Medical Devices Marketing Authorization (MDMA) portion of the SFDA's website [52] [Country Questionnaire, 2014].

The Medical Devices interim regulation applies to the following parties and products49:

• Manufacturers, authorized representatives, importers and distributors.

• All Medical Devices and their accessories that will be supplied to the KSA market.

• Contact lenses and laser surgical equipment for cosmetic rather than medical purposes, and their accessories.

Medical Devices may be placed on the market only if they comply with the applicable provisions of this MDIR [51, 53 54].

A local representative is required to handle the registration application on behalf of the foreign manufacturer.

b. required documentation

According to article 18 of MDIR, in order to register a Medical Devices, the applicant is asked to submit the following documentation to SFDA [52, 55-59].

- Application form (Annex V);
- Letter of Authorization (LOA);
- Manufacturer and Saudi Authorization representative details;
- GMP certificate or QM- system certificate (ISO 13485, ISO 9001);
- Recent Audit Report;
- Other Certificates as required by the Devices class;
- Documents supporting the market authorization in reference IMDRF market;
- Declaration of Conformity, written in English;

The declaration of conformity clearly identifies to which Medical Devices it applies and attests that the Medical Devices complies with the regulatory requirements of the relevant IMDRF Founding Member and also complies with the national provisions of MDIR.

- Environmental statements : Statement attesting that the Medical Devices complies with the regulatory requirements of the relevant IMDRF Founding Member jurisdiction and also complies with the national provisions of this Interim Regulation (Annex VI);
- The applicant shall indicate, which of the GHTF Founding Member(s) allows the Medical Devices that is the subject of the MDMA application, onto its market; and
- Regulatory Compliance Attestation: Statement confirming that the applicant will comply with the KSA's National Centre for Medical Devices Reporting (NCMDR) requirement and any Filed Safety Corrective Action affecting the Medical Devices be reported to KSA authorities (Annex VII).

Moreover, the following Technical documents are requested for submission:

- A copy of the Medical Devices information including labelling, Intended use, instruction for use (IFU) and marketing materials, in English and/ or Arabic language;
- Specifications or similar documents that ensure, that the Medical Devices are correctly stored, transported, installed and maintained in the KSA, and users can be trained in their proper use;
- A report of any relevant adverse event, that involves the Medical Devices, be submitted to SFDA's National Centre for Medical Devices Reporting (NCMDR) [60].

c. Pre-Owned Medical Devices

Used or refurbished medical equipment is allowed entry into Saudi Arabia. However, the Ministry of Health and other Saudi government hospitals keep away from purchasing such equipment [49, 60].

d. Post marketing surveillance

The NCMDR receives reports of suspected Medical Devices adverse events and confirmed product recalls from healthcare practitioners and Devices suppliers within the Kingdom of Saudi Arabia [62].

e. Country Specifics

Enforcement of Medical Devices Marketing Authorizations

All Medical Devices & IVDs intended to be marketed in Saudi Arabia should have a valid Medical Devices Marketing Authorization (MDMA) as per the following enforcement dates [63].

Table 8: Enforcement date of Medical Devices Marketing Authorizations KSA [63]

Class	Type	Enforcement Date
High Risk	In Vitro Diagnostics	1th October 2012
	Medical Devices	1th December 2012
Medium Risk	In Vitro Diagnostics	1th December 2012
	Medical Devices	31th December 2014
Low Risk	In Vitro Diagnostics	30th June 2015
	Medical Devices	31th December 2015

3.1.2 United Arab Emirates (UAE)

Medical Devices Definition

The Medical Devices and In Vitro Diagnostic (IVD) definition in the UAE are the same as in the KSA based on the GHTF definition [64] (see section 2.2.3).

a. Medical Devices Regulation

The UAE are like the KSA a member of the AHWP and the Medical Devices are regulated by the Ministry of Health (MOH) in the United Arab Emirates [65]. UAE Medical Devices regulations are substantially orientated towards GHTF guidelines as well as towards EU requirements.

Classification requirements and the evaluation of Devices follow international regulations and guidelines, mainly those of:

- the IMDRF for Medical Devices,
- the US Food and Drug Administration's Devices Regulation,
- the EU Medical Devices Directive 93/42/EEC,
- the EU in Vitro Diagnostic Devices Directive (IVDD) 98/79/EC and
- the EU Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC.

The similarity between the classification of medical Devices and the registration Guideline of the MOH is shown by the fact that certain definitions are very close to those provided by the EU Medical Devices Directive [66].

The guidelines provide for a simplified registration process for Devices that have received approval from recognized regulatory agencies, such as those in Europe, the US, Australia, Canada or Japan.

The Medical Devices manufacturers must be registered with the Ministry before they can market their products in the UAE. Companies who wish to export their products into the UAE must engage a local representative or distributor with a licensed medical store for registration of their products with the MOH.

In order to register a Medical Devices in the UAE, the product as well as the company must be registered there. The appointed local representative or distributor must submit a Medical Devices as well as a manufacturer's company registration application form (Annex IIX) to the Ministry's Drug Control Department.

b. Required documentation

1. Product registration

In order to register a Medical Devices, the applicant is asked to submit the following documentation in Arabic or English language to the MOH. The documentation varies depending on the Devices classification [64].

Table 9: UAE Medical Devices regulation: the required attachments per Devices Class [64]

Documentation	Class I/ General IVD A	Class II/ Class B IVD	Class III/ Class C IVD	Class IV/ Class D IVD
Application Form (Annex IIX for the company and Annex IX for the product)	√	√	√	√
CE certificate and FSC (both legalized by the chamber of commerce and the UAE embassy)	√	√	√	√
Declaration of Conformity / Evidence of Conformity to the essential principles	√ Self-Declaration	√	√	√
Company registration certificate legalized by the chamber of commerce and the UAE embassy in country of origin	√	√	√	√
Status of Devices distribution	NA	√	√	√
Declaration of prices	√	√	√	√
essential principles checklist	√	√	√	√
Post-market requirements/ vigilance system and risk assessment	NA	√	√	√
Manufacturing process: 1. Process Validation Studies 2. Software validation studies (if applicable)	NA	NA	√	√
Safety and effectiveness data, risk assessment, pre-clinical and clinical studies	NA	NA	√	√
Labeling & samples • Three copies (artwork) of each product packaging, labeling and promotional material • Sample (if applicable). • Labeling and packaging must have: the product name, name and address of the company printed in English and/or Arabic, manufacturing date and/or expiration date, Medical Devices for single use must be labeled accordingly on the outer pack	√	√	√	√
Shelf life study	NA	NA	√	√

2. Company registration

In the UAE the company registration file should be submitted at the same time as the registration files of its product/s [64].

Companies' registration requirements

- Application for the medical Devices company (Annex IIX),
- company business license,
- LoA,
- organization of the quality assurance system (flow chart),
- notarized copies of relevant certificates for Quality Accreditations from recognized notified bodies for each manufacturing facility involved in the manufacturing of the medical Devices intended for registration in the UAE,
- for classes III & IV / IVD C & D manufacturer: copies of the Design Examination, Type Examination certificates or equivalent health authority approvals issued for these Devices should be provided as a proof of compliance of the company with best practices,
- a recent audit report.
- The general profile has to include the following Information:
    a. Company name, address, including the corporate structure as well as all company names of the company and its manufacturing sites used,
    b. contact name, telephone, fax numbers and e-mail addresses,
    c. total number of employees (all shifts) covered by the scope of the audit,
    d. product range and class of Medical Devices being manufactured (the class of a medical Devices may differ from one the regulatory authority of one UAE country to another),
    e. types of Medical Devices sold and/or planned to be sold in the UAE and/or GCC regions for which the regulatory requirements will be assessed, including a complete list of authorizations (e.g. licenses) issued for those Medical Devices (where applicable),
    f. location and function of each site,
    g. a list of activities performed at each site,
    h. special manufacturing processes, e.g., software, sterilization, etc.

Furthermore, the technical documentation is required for submission, e.g. the following documents:

- Site Master File for each manufacturing site (if applicable),
- Warehousing information and general dispatch information as well as the implemented quality management system,
- validation and verification processes for sterilized products and
- the general post marketing surveillance plan.

- If the company has multiple manufacturing sites, each manufacturing location should be identified as follows indicating the manufacturing step carried out there (see application for company registration).: design, production, sterilization, packaging, labeling and final release.

c. Country Specifics

After approval of the application, a registration number is given, which is valid for five years. A registration number can be revoked [65, 67], if

• the applicant requests for it or

• upon failure to meet the standards based on assessment or monitoring proving that

- the Devices are unsafe and/or harmful,
- the quality of the Devices is substandard,
- the Devices differ from the approved label.

Importation Rules

A pre-approval for importation of the consignment is issued by Drug Registration and Control Department for importation of Medical Devices. This will be only allowed for importers with a MOH medical store license. Documents to be attached to the consignment pre-import approval application form are:

1. the legalized ISO 13485 by the UAE Embassy;
2. FSC / documentation or letters of regulatory approval / relevant CE certification/ clearance to manufacture, sale, import and export of the Medical Devices from the competent authority in the exporting country and the
3. declaration of conformity.

The control of Medical Devices will be based on an implemented risk assessment and risk management.

d. Pre-Owned Medical Devices

Used Medical Devices are not allowed for importation into and marketing in the UAE [64].

3.1.3 Qatar

a. Medical Devices Regulation

The Ministry of Public Health (MOPH) is responsible for regulation of the Healthcare Industry within Qatar. Medical Devices registration in Qatar is conducted through the Ministry of Economy and Commerce (MEC). The registration is followed by an application request to the Ministry of Municipal Affairs and Agriculture (MMAA) for an inspection of the premises, because business activities may not be undertaken in certain prohibited areas. A local agent is required and must be registered.

Since February 28, 2011, only medical Devices that have obtained a Qatar MEC marketing authorization may be sold unless they had already obtained authorization prior to that date. Moreover, after June 30, 2011, only Qatar MEC-authorized medical Devices are allowed to be used within Qatar, while Devices in use before that date may continued to be utilized.

Only Medical Devices that are authorized by one of the founding members of the Global Harmonization Task Force (GHTF) can apply for a MEC marketing authorization [68].

3.1.4 Oman

a. Medical Devices Regulation

Medical products must be registered with the MOH. Oman accepts all medical Devices classification systems. The registration procedure is conducted by submitting an application form (Annex X) and other relevant documentation through a local representative.

According to Ministerial Decision No. 109/2008, a pre-qualification of companies and factories of medical supplies is required to register a medical Devices in Oman.

The medical Devices market in Oman is organized in a form of tender system.

b. Required documentation

Regarding to Article (2) of Ministerial Decision No. 109/2008 for pre-qualification of companies and factories to participate in the Ministry's tenders, the following requirements should be fulfilled [69, 70 71]:

1. The company shall be either a manufacturer or assembler and licensed to manufacture medical devices in the country of origin (C.O.O);
2. The company shall follow the principles of GMP in the manufacturing of its products.
3. The company's products shall be in circulation in the C.O.O or marketed in one of the developed countries.

4. The company is subject to a periodical technical inspection by the concerned authorities in the C.O.O.
5. There shall not be a history of judicial verdict against the company in the C.O.O or in any other country with regard to crimes of fraudulence or forgery.
6. Payment of pre-qualification fees has to be proved.

Furthermore, according to Article (2) of Ministerial Decision No. 109/2008, the application for the pre-qualification of companies of medical devices shall be submitted by its agent or its representative to the concerned Directorate on the form prepared. All required documents should either be in English or Arabic language.

The following documents and certificates shall be attested by the concerned authorities in the C.O.O and the Embassy of the Sultanate of Oman:

1. LoA
2. Company registration certificate;
3. GMP Certificate, Good Quality Certificate such as: (ISO 9001-2000), (EN 46001), (ISO 13485) certificates.
4. A certificate for products made from plasma and blood derivatives. This certificate is required to ensure that these items are free of any component that causes any of the different types of hepatitis viruses, HI viruses and other infective viruses.
5. Supportive certificates, scientific researches and clinical studies for surgical implants manufactured by orthopedics and spine surgery devices companies,
6. a statement of the products, their trade and scientific names and catalog numbers,
7. A statement of the company capital, the date of its establishment, its type, number of the technical staff, their qualifications in addition to the details of activities of company,
8. a statement of the company branches and their activities,
9. the status of Devices distribution and
10. samples of original packing with the product name, the name of the manufacturing company, its logo, batch number, date of manufacture, expiry date, catalogue number, storage conditions and the product catalogue.

c. Pre-Owned Medical Devices

The import of used or refurbished medical equipment has no restrictions, but the MOH does not buy them. The Ministry of Health is the main buyer of medical equipment in Oman. As a matter of practice, the MOH does not purchase used or refurbished medical equipment. Normally, when the ministry decides to purchase equipment, it contacts regular suppliers and requests the latest equipment; in some cases, such purchases are conducted through tenders. Generally, equipment is purchased along with a minimum five-year maintenance contract [60].

3.1.5 Kuwait

a. Medical Devices Regulation

Kuwait is a member of AHWP. Medical Devices are registered as products ONLY within the Non-classified Products Unit of the MOH Food & Drug Control Department. The registration procedure requires to submit an application form and other relevant document through a local representative [72, 73].

b. Required documentation

Documents and materials required for registration of non-classified products and Medical Devices as per ministerial decree 201/99 are [74]:

1. the application form,
2. legalized by the Kuwait Embassy: the manufacturing license and the GMP certificate, the FSC from the C.O.O,
3. the status of registration of the product in the C.O.O.,
4. the letter of Authorization (LoA) be legalized by the Arab Chamber of Commerce and the Kuwait Embassy,
5. the list of countries where the product is registered with registration dates and numbers,
6. the Certificate of Analysis (CoA) of the finished product.
7. In addition, if the committee requests for more information of that particular product those requests have to be complied with.

Following technical documentations have to be included:

8. Information of the product on the outer and inner packs. Samples should be in English or Arabic language and satisfy the requirements of the Ministry of Commerce of the State of Kuwait.

   The information should include the name, composition, uses, batch number, manufacturing date, expiry date and the storage conditions as well as indication.
9. Safety and efficacy studies from approved international authorities (and/or clinical studies if applicable).

c. Pre-Owned Medical Devices

It is strictly forbidden to import pre-owned medical Devices into Kuwait. Kuwait's public health institutions do not buy used or refurbished medical Devices. All tenders call for new Devices and equipment. Used or refurbished equipment does not have a market in Kuwait [60, 74].

3.1.6 Bahrain

a. Medical Devices Regulation

The Ministry of Health (MOH) is responsible for the oversight and regulation of the healthcare industry within Bahrain. Medical Devices regulation in Bahrain is directed by the Pharmaceutical Product Regulatory Office (PPRO) of the National Health Regulatory Authority (NHRA). Pharmaceutical products for which the principle intended action is pharmacological, metabolic or immunological are regulated as medicines or health products; whereas where the principle intended action is physical or mechanical then the product is regulated as a medical Device [76, 77]. All medical equipment should comply with one of the international standards such as the CE mark or USA FDA standards and be approved through the NHRA Medical Devices engineering department.

Before a pharmaceutical product can be placed on the market in the Kingdom of Bahrain, an application must be made for a license to the NHRA. Such applications should contain the data necessary to support the quality, safety and efficacy for the product. These data are reviewed by the NHRA and a conclusion is reached based upon the likely balance of the benefits versus risks associated with the product. This license must be granted prior to the product being placed on the market.

According to the Law no. (18) of 1997, pharmaceutical product Importation and distribution must be done through an authorized pharmacy only (local agent).

The local agent must inform the NHRA of any agreements made with new pharmaceutical companies for review and approval before starting the licensing process[78].

b. Required documentation

According to article (64) of the Legislative Decree No (18) from 1997, a registration request must be submitted to the Directorate of Pharmacy and Drug Control in the ministry together with the following documents [79]:

1. An official certificate from the health authority in the C.O.O to proving that the drug or pharmaceutical product is registered, authorized to be used, and is already being traded with the same specifications.

2. A valid certificate proving that the manufacturer adapts a scientific approach throughout production and that the manufacturer is subject to routine health inspections.

3. A valid certification of the selling price of the imported product in the country of origin and the export prices to Bahrain neighboring countries.

4. Samples of the product to be registered.

5. Three copies of the product leaflet.

The leaflet of each product must contain the following information in both Arabic and English language (article 70):

a. a list of the active components and the scientific name of each component,
b. the quantities of active components in accordance with the required doses or regimen,
c. a list of components that may interfere or affect the use of the medicine or pharmaceutical product,
d. the internationally accredited therapeutic uses of the product,
e. the side effects and major adverse reactions of the product or pharmaceutical product,
f. the required precautionary measures, prohibitions and taboos,
g. the main interactions,
h. the product name and address and
i. a list of the scientific references used.

6. A summary report of relevant scientific studies proving effectiveness under different climate conditions and the method of analysis.

c. Country Specifics

According to article (68) of the Legislative Decree No (18) from 1997, a product registration might be revoked via a ministerial order under the following circumstances [79]:

1. If the Drug Registration Committee receive new information that indicate harmful side effects of certain products or for any other technical reasons determined by the Committee.

2. If the product is banned based on the recommendation of the World Health Organization or any other reputable global pharmaceutical authorities.

3.1.7 Yemen

a. Medical Devices Regulation

Yemen is a member of AHWP. Medical Devices in Yemen are registered through the Supreme Board for Drugs and Medical Appliances (SBDMA), part of the Ministry of Public Health and Population (MPHP). Many types of Medical Devices must be registered in Yemen, although the authorities encourage manufacturers to go through the registration process regardless.

Yemen applies a unique three-step registration process for foreign manufacturers registering medical and IVD Devices in the country [80].

1. The Appointed Agent must register as the manufacturer's representative with the Ministry of Industry and Trade.
2. The agent must register the manufacturer with the MPHP, which regulates Medical Devices through the SBDMA.
3. The agent must begin the registration of the product itself with the Yemenite authorities.

b. Required documentation

The application must be submitted by a local representative. The technical dossier submitted with the Devices license application is quite simple compared to other countries in the world, with relatively basic requirements:

- GMP certificate or ISO 13485,
- FSC.
- A CE Mark is not required, but can ease the registration process.
- In the case of invasive Devices, either USA FDA approval or certification from the Gulf Cooperation Council (GCC); in case that the registration in any of these markets has not yet been obtained, an on-site inspection must take place at the manufacturer's expense.

All documentation may be submitted in English.

c. Pre-Owned Medical Devices

There are no restrictions on the importation of used equipment, except that it is in good condition. The custom duties are excempted if the hospital is an investment project, but the used equipment must not be more than eight years old.

Public health institutions buy used or refurbished Medical Devices when priced competitively with new equipment. Yemen's Ministry of Health buys medical equipment through the tendering system [60].

GCC Country fact sheet

KSA

Table 10: Country Fact Sheet KSA (According to MDIR [49] and Country Questionnaire, 2014)

Competent authority	Saudi Arabia Food and Drug authority (SFDA)
Legal Basis	Medical Devices Interim Regulations (MDIR) from 2008
Devices classification	classification within the reference country
Time to approval	For class I & II about 2-3 weeks and for class III about 5-10 weeks
Length of license:	Licenses issued in Saudi Arabia expire when either the GHTF license expires, or after three years

UAE

Table 11: Country Fact Sheet UAE (According to Medical_Devices_Registration_Guidelin [64] and Country Questionnaire, 2014)

Competent authority	Ministry Of Health (MOH)
Legal Basis	based on IMDRF as well as EU Medical Devices Directive (93/42/EEC) and US FDA
Devices classification	Classes I, II, III, Iv IVD classes A, B, C, D
Time to approval	No fixed time. Minimum 6 months
Length of license:	Licenses issued in UAE expire when either the CE mark expires, or after three years.

Qatar

Table 12: Country Fact Sheet Qatar (According to Arazy group [68])

Competent authority	Ministry of Public Health (MOPH)
Legal Basis	based on GHTF
Devices classification	Classes I, IIa, IIb, III
Time to approval	NA
Length of license:	NA

Oman

Table 13: Country Fact Sheet Oman (According to Arazy group [69])

Competent authority	Ministry of Health (MOH)
Legal Basis	NA
Devices classification	Oman accepts all classification systems and the type of product dictates the procedure it must undergo before receiving marketing authorization.
Time to approval	NA
Length of license:	Licenses issued in Oman expire at the end of the authorization in their country of origin

Kuwait

Table 14: Country Fact Sheet Kuwait (According to Arazy group [72, 73])

Competent authority	Ministry of Health (MOH)
Legal Basis	NA
Devices classification	There are no classification requirements or special restriction for importing Medical Devices
Time to approval	within 1-2 months
Length of license:	Licenses issued in Kuwait expire with each import

Bahrain

Table 15: Country Fact Sheet Bahrain (According to HCF Guidance for Licensees on Central Decontamination of Reusable Invasive Medical Devices [77] and Arazy group [78])

Competent authority	National Health Regulatory Authority (NHRA).
Legal Basis	NA
Devices classification	Classes I, IIa, IIb, III
Time to approval	approximately six months
Length of license:	Licenses issued in Bahrain expire after two years.

Yemen

Table 16: Country Fact Sheet Yemen (According to Arazy group [80])

Competent authority	Ministry of Public Health and Population (MPHP)
Legal Basis	NA
Devices classification	Yemen follows a list classification system rather than a risk-based classification system, drawing a distinction between invasive and non-invasive devices.
Time to approval	three to six months
Length of license	Medical Devices in Yemen are valid for five years.

3.2 Medical Devices in Western Asia countries

3.2.1 Israel

Medical Devices definition

Medical Devices defined as Instrument, Devices, software, chemical, biological or biotechnological

- used in treatment; or
- needed for the activation of a Devices or apparatus

that is used for treatment and not **mainly** intended to work on the body as a drug.

a. Medical Devices Regulation

Although Israel is geographically part of the Middle East, because of political issues there is no regulatory relationship with any of the countries around it. In Israel, medical Devices are regulated by the Division of Medical Devices and Accessories under the Israel's Ministry of Health (IMOH) by the "AMAR" unit. AMAR is responsible for certification of all activities concerning medical Devices import, sale and export. In order to import or sell a Medical Device in Israel, the manufacturer shall hold an AMAR registration for the Devices concerned.

The MOH recognizes the Food and Drug Administration (FDA) certification and the European Union CE Mark, and approves products carrying such certifications without further requirements. Furthermore, MOH implements FDA's recommended indications for the Devices [81, 82].

b. Required documentation

Companies wishing to export medical equipment or Devices to Israel must have a local Israel agent or distributor who should request a Pre-Marketing Approval (PMA) from the IMOH.

The PMA request should be accompanied by one of the following documents:

• The U.S. Food and Drug Administration (FDA) 510(k) marketing authorization or PMA.
• Biological Devices fall under Medical Devices classification required FDA's Centre of Biologics Certificate.
• In most cases the CE Mark (European Union) and Canadian documentation are also accepted by IMOH.

For any imported medical Devices, the Israeli importer must submit a registration application to the MOH Department of Medical Devices. Registration of medical Devices in Israel is based on having prior approval in one of the five founding IMDRF countries: Australia, Canada, EU, Iceland, Norway, New Zealand, Switzerland, Japan or USA. If such a certificate is not available, the registration can be

processed but will take a longer period of time, and the MOH will determine what type of testing is needed.

The application should be submitted on the special form designated for this purpose and shall include the following data and documents [83, 84]:

- name and address of the manufacturer and of the importer as applicable,
- intended use of the medical Devices and of its medical indications,
- a certificate attesting the safety of the Devices, issued by a competent authority of one of the following countries: Australia, Canada, European Community (EC), Israel, Japan and USA,
- FSC,
- CE Certificates,
- ISO 9001 and ISO13485 certificates,
- description of the technical and maintenance services, including periodic checks and inspections;
- declaration of the local manufacturer/importer, and of the foreign manufacturer;
- details of the standards to which the Devices complies and
- the latest audit report.

Moreover, the following technical documentation is required for submission:

- technical details of the medical Devices and of its components,
- information on any risk which may be associated with the use of the Devices,
- IFU of the Devices,
- catalogues of and brochures for the Devices,
- labels and accompanying material.

Furthermore, the Israeli MOH – AMAR requires a checklist of information from a foreign medical Devices manufacturer for the registration or the renewal of the registration, according to the information from a local representative in 2014 (Annex XI).

c. Pre-Owned Medical Devices

The Israeli market for used medical equipment is very small and considered insignificant for US exports. There is no special tariff that applies, and the official import requirements are the same as for new equipment. However, in practice, the Ministry of Health (MOH) permits the import of used/refurbished equipment only by specified end-users, and does not issue registration certificates for imported used equipment [60].

3.2.2 Iran

Iran developed a specific Medical Devices Regulation. The objective of this regulation is to ensure the safe use of medical Devices, supplement the food and drug regulation to complete the regulatory controls in this area and to define the roles and responsibilities of those undertaking activities related to Medical Devices [85].

Medical Devices Definition

Article 2 of the Medical Devices regulation contains a definition of a Medical Devices, as follows:

Any product, Devices, equipment, tools and accessories, machinery, implant, material, reactive, laboratory calibrator, software, intended by the manufacturer to be used (alone or in conjunction with other relevant products or materials) for humans for the following purposes:

- diagnostic, monitoring, therapy or reduction of illness,
- protection or support of vital processes,
- control of conception,
- implementation of sterilization and cleanliness processes for Devices and the environment in view of medical or therapeutic objectives,
- and provision of information in view of medical objectives using laboratory techniques based on human samples.

The scope of this definition is very broad and includes some in vitro diagnostic products.
This regulation contains special rules for local manufacturers and medical Devices companies [85].
In this work, we discuss only the regulations for medical Devices importers.

a. Medical Devices Regulation

The primary regulatory authority for Medical Devices in Iran is the Central Office for Medical Equipment (COME). The COME is a specialized department of the Ministry of Health (MOH) and the decision-making center for Medical Devices in Iran. Regulatory requirements for Medical Devices are outlined in the Medical Cure and Medical Education Act. The Institute of Standards & Industrial Research of Iran (ISIRI) is the sole organization in the country that can lawfully develop and designate official standards for products [85, 86].

b. Required documentation

Require documentation for registration is similar to that required for FDA approval or EU CE marking and follows the format of the GHTF STED. According to Article 28, the following documentation should be submitted as part of an application:

1) CE or FDA certificates supported by relevant ISO standards,
2) Quality Management System (QMS),
3) test reports and certificates from the Iranian Standards Institution for those Devices subjected to mandatory local standards,
4) declaration of conformity (Annex XII),
5) application form (Annex XIII),
6) submission summary dossier;
7) technical details of the medical Devices;
8) Letter of Authorization, which to be legalized by the chamber of commerce and Iranian embassy;
9) Labeling, according to Article 42, the label on the product should carry the name of the manufacturer, the serial or batch number, the date of manufacture and the shelf-life for disposables, specifications and warnings. The compliance with the COME's labeling requirements is also mandatory.

c. Country Specifics

Registration number

After approval of the application, a registration number is given, which is valid for five years (according to the country questionnaire 2014). Medical Devices are registered at MOH where a registration number and a marketing authorization are issued. The applicant cannot manufacture or import these products unless the registration number and marketing authorization are issued [85].

After-sales service

Article 32 lists the after-sales service for a product may include: installation, putting into service, performing acceptance tests, customer training, guarantees, provision of spare parts, minor or substantial repairs, calibration, updating or upgrading, traceability, responses to customer requests, corrective actions and recall handling.

The provision of after-sales service is the responsibility of either the 'manufacturer' or the 'official representative' of the company (Article 33). All Medical Devices identified by the COME as requiring after-sales service should be handled by the official representative. According to Article 36, the provider of after-sales service should set up a quality system for this process.

Transport and Storage

Transportation of Devices across Iran needs to be carefully monitored, because Iran is a very large country. Specific transportation customs officers will be trained and work in collaboration with the MOH and universities to identify suspect products (Article 17).

According to article 19, an importer should provide details of the transportation route to customs. Deviation from this route can be considered as an illegal practice unless an acceptable justification is provided.

The transportation company and the driver of the vehicle must respect the cleaning and environmental conditions of the medical Devices they are transporting (Article 21). The storage of illegal Devices will result in prosecution, especially within the hospital/clinical environment (Article 22) [85].

d. Pre-Owned Medical Devices

The importation of refurbished Devices is forbidden (unless accepted in special cases by the committee), and importation of Devices by travelers for individual personal use is accepted (after acceptance by the COME) [85].

3.2.3 Iraq

Medical Devices definition

The definition of medical products includes such items as orthopedic Devices, hospital consumables and X-ray tubes.

a. Medical Devices Regulation

The responsible authority for registration in Iraq is the registration department of the Technical Affairs Directorate within the MOH. All medical equipment is imported through an operational arm of the Ministry of Health known as 'KIMADIA'. The State Company for Marketing Drugs and Medical Appliances (KIMADIA) is the only IRAQI company which is specialized with regard to importing, storage and distributing of the medicinal and medical appliances and equipment for all public healthcare facilities. KIMADIA has been established in 1964. Subsequent to procurement by the MOH the products are then distributed though Kimadia's own chain of warehouses and distribution centers.

According to the regulations in Iraq, a medical appliance cannot be marketed unless it is registered. Registration requires the filing of certain information concerning the safety efficacy , quality and origin of products to be marketed in Iraq. Registration should be done by manufacturers, marketing authorization holders or contract manufacturers. In Iraq, the companies are required to be registered, too [87, 88].

b. Required documentation

Requirements for the registration of medical appliances and medical equipment manufacturers are [88]:

- The company registration form (Annex XIV) should be completed, one copy signed and stamped by the person responsible in the establishment.
- Quality assurance certificate such as ISO 9001, 9002 or equivalent,
- data spread sheet of the company products (catalogue);
- a certification raw material letter clarifying that the origin of the raw material is not from Israel and the country of origin of the raw material,
- copy of the commercial invoice declaring free sales of the companies' products;

Moreover, the following documents have to be submitted for the legalization by the chamber of commerce and the Iraq embassy:

- Manufacturer registration certificate in the C.O.O, and the LoA.

c. Country Specifics

There are no regulations on the import of medical appliances and no requirements of qualification of dealers. Imported medical equipment and other technologies are subject to pre-shipment inspection by KIMADIA, a function that is currently outsourced to two foreign companies. All products are subject to quality testing by the National Centre for Drug Control and Research (NCDCR) and the Central Public Health Laboratory before they are released for distribution [89].

3.2.4 Jordan

Medical Devices definition

Every Devices, tool, material or item used separately or combined with others, including all the software needed for operating these products, which are prepared by the manufacturer for human use for the purpose of achieving any of the following:

a. diagnosis, prevention, surveillance, treatment, disease reduction of diseases;
b. diagnosis, surveillance, compensation for any injury;
c. diagnosis, replacement or amendment to the physiological situation;
d. pregnancy regulators;

and which does not accomplish its intended purpose in /on the human body through a pharmaceutical method or in an immunological or photosynthesis way, but its intended purpose could be achieved by the usage of any of these tools/Devices, and this makes it distinct to others (drugs) [90].

a. Medical Devices Regulation

Jordan is a member of the AHWP. In Jordan, Medical Devices are regulated by the Medical Devices Importation Regulations including antiseptics and disinfectants. This legislation has been issued in

accordance with Article 5 of the Drug and Pharmacy Law No. 80 of 2001, and its amendment Law No. 30 of 2003.

The Jordan Food and Drug Administration (JFDA) is responsible for the registration and approval of Medical Devices. All Medical Devices must meet certain requirements before they can be imported and used within Jordan. Medical Devices must be approved for importation by the Director General of the JFDA. Certain products (e.g. those containing a pharmaceutical) also require prior approval from the Medical Devices Committee before a final decision on importation is made by the Director General of the JFDA.

The Medical Devices Committee will evaluate a registration request and issue a decision within 30 working days of the date of the registration request. The applicant has the right to submit an objection to the Medical Devices Committee within 30 working days from being notified in writing of the Committee's decision. Following receipt of an objection, the Medical Devices Committee will re-evaluate its decision and issue a final decision within 30 working days from the date of receipt of the objection.

The Director General of the JFDA has the right to prohibit (based on the decisions and recommendations of the Medical Devices Committee) the importation or marketing of Medical Devices. The Director General may also cancel previous approvals or request recalls of Medical Devices. Any changes/updates to approved Medical Devices must be approved by the Medical Devices Committee before implementation.

The Director General of the JFDA issues special inspection instructions for manufacturers, importers and distributors of Medical Devices as well as for locations where Medical Devices are used (e.g. hospitals) [90, 91].

b. Required documentations

The applicant should submit all of the following documents to the JFDA:

- The Applicant Commercial Registry Certificate issued by the Ministry of Industry and Trade;
- Notarized the following certificates (these certificates should be valid at the time of shipping):
    a. FDA Certificate (Certificate to Foreign Government);
    b. CE Certificate and
    c. FSC
- The following technical documents should be submitted:
    - original catalogue containing full information about the medical Devices (e.g. its composition, indications, contraindications, precautions for use);
    - declaration from the manufacturer clarifying the validity period of the medical Devices, its storage conditions, a stability statement guarantee regarding these conditions, and a stability study for one batch to cover the whole shelf-life;
    - samples of the outer pack, inner pack and insert leaflet (if available);

- finished product specifications and method of analysis of the medical Devices.

• For Medical Devices containing ingredients of animal origin, a Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE) Certificate should be submitted.

• The outer packs of single-use Medical Devices should clearly indicate:

- the batch or lot number,
- the expiry date
- the name of the manufacturer or the marketing authorization holder;
- C.O.O;
- storage conditions and
- the sterilization method.
- If the Medical Devices is CE-marked, the CE mark should be present on the label.

• Medical Devices should pass analysis testing by the JFDA Laboratory if they contain a pharmaceutical or are a solution used to preserve human body parts. The Medical Devices Committee will decide which products should be analyzed.

• Two copies of the invoice showing the following:

- name of the manufacturer or the Marketing Authorization Holder,
- C.O.O,
- names of the Medical Devices requested for importation, their models and catalogue numbers;
- batch number and expiry date for each item requested to pass the JFDA Laboratory Department analysis.

• CoA for each imported batch of in vitro fertilization media or materials used in dentistry (e.g. fillings).

• Quality Control Release Certificate for each imported lot of a medical Devices that contains a pharmaceutical as one of its components.

• For Medical Devices containing human albumin, a certificate issued in accordance with the current regulations is required. For imported batches, the lot numbers should be submitted.

• For Medical Devices containing ingredients of animal origin, a TSE/BSE Certificate should be submitted for the imported batches/lots.

c. Pre-Owned Medical Devices

Used or refurbished Medical Devices are not permitted to be used in Jordan [90].

3.2.5 Lebanon

Medical Devices definition

The Medical Devices and In Vito Diagnostic (IVD) definitions in Lebanon are based on the GHTF definition [91] (see section 2).

a. Medical Devices Regulation

The Ministry of Public Health (MOPH) is responsible for the registration and approval of Medical Devices in Lebanon. MOPH adopted a national strategy with an approach that confirms [92]:

- Establishing and implementation of a regulatory framework focusing on quality and security through products' compliance with international standards to reduce the risks associated with the use of non-compliant products.
- Post-marketing surveillance in accordance with recent international guidelines, the establishment of a traceability and vigilance system for implantable high-risk products (class IIb and III)
- Supporting development of quality management systems covering the procurement process: The pre-qualification of suppliers, identifying the need, selection, purchase and use.
- Capacity building and promotion of appropriate use of Medical Devices: Development and dissemination of information, educational and communication programs.

All Medical Devices would require a CE certificate or a FDA certificate before being placed on the market in Lebanon [91, 92].

b. Required documentation

The registration procedure requires the following documents [93]:

1. FSC legalized by Lebanon embassy in C.O.O,
2. CE certificate copy,
3. Original GMP legalized from ministry of heath of C.O.O. or ISO 13485,
4. CoA,
5. 2 samples of the product,
6. Stability data of one batch beginning from the day of its manufacture date till its expiry Date,
7. storage conditions,
8. summary of product characteristics or leaflet,
9. distribution agreement covering the Territory of Lebanon signed by both parties and then notarized and then legalized by Lebanese Embassy in C.O.O,
10. The company profile (Annex XV).

3.2.6 Syria

a. Medical Devices Regulation

The Ministry of Health (MOH) is responsible for the registration and approval of Medical Devices in Syria.

b. Required documentation

The registration procedure requires the following documents, which have to be legalized by the chamber of commerce and the Syrian embassy in the C.O.O [95, 96]:

- Manufactured company registration certificate,
- CE-Mark or FDA clearance,
- FSC from the C.O.O,
- ISO 13485 certificate or any equivalent attested certificate.
-

c. Pre-Owned Medical Devices

According to Syrian laws and regulations, the import of use of refurbished medical equipment is not permitted. Syrian regulations prohibit the importation of used or refurbished medical equipment. The import licenses for medical equipment issued by the Ministry of Economy and Foreign Trade requires the importer to acknowledge that the medical equipment being purchased is new equipment and not refurbished [60].

3.2.7 West Bank and Gaza (Palestine)

Medical Devices Regulation

The regulation of Medical Devices in Palestine is coordinated by the General Administration of Pharmacy and the Drug Registration Department under the Ministry of Health (MOH). The MOH has not yet approved the regulations of Medical Devices. There is no need for any product registration in Palestine. However, an import license is required [97].

Country fact sheet Western Asia courtiers

Israel

Table 17: Country Fact Sheet Israel (According to Arazy group [81] and Country Questionnaire, 2014)

Competent authority	Israel's Ministry of Health (IMOH) by "AMAR" unit
Legal Basis	AMAR
Devices classification	According to CE and FDA standards, with the exception of Devices such as cardiovascular stents and implants
Time to approval	120 working days from submission
Length of license:	Licenses issued in Israel expire in accordance with the CE expiration date, and are subjected to the CE and/or FDA clearance terms.

Iran

Table 18: Country Fact Sheet Iran (According to Espicom [86] and Country Questionnaire, 2014*)*

Competent authority	Ministry of Health (MoH).
Legal Basis	Based on EU regulation
Devices classification	Classes A, B, C and D
Time to approval	2 to 3 Months but for implantation Devices it is longer (Class D)
Length of license	NA

Iraq

Table 19: Country Fact Sheet Iraq (According to KIMADIA [87, 88] and Country Questionnaire, 2014)

Competent authority	Ministry of Health known as 'KIMADIA'
Legal Basis	NA
Devices classification	NA
Time to approval	For Company Registration Less than one month if all the documents is completed and accepted, but for items registration it will take longtime for testing ,and lab sterilization testing
Length of license:	NA

Jordan

Table 20: Country Fact Sheet Jordan (According to Arazy group [90, 91] and Country Questionnaire, 2014)

Competent authority	Jordan Food and Drug Administration (JFDA)
Legal Basis	Based on Article 5 of the Drug and Pharmacy Law No 80 of 2001, and its amendment Law No 30 of 2003.
Devices classification	Classes I, IIA, IIB, III and Active Implants Class.
Time to approval	Some classes it takes 2 to 3 days and other classes that does not mention exactly by code or article need to get additional approval and time
Length of license:	Licenses issued in Jordan expire when the Device's previously obtained license (from the USA, EU, or Japan) expires

Lebanon

Table 21: Country Fact Sheet Lebanon [93, 94] (Country Questionnaire, 2014)

Competent authority	Ministry of Public Health (MoPH)
Legal Basis	NA
Devices classification	Classes I, II, III and Custom Devices REF: Medical Devices maha [Compatibility Mode]
Time to approval	between 3-6 months depending on conformity of documents with requirements
Length of license	unlimited

Syria

Table 22: Country Fact Sheet Syria (According to Arazy group [96] and Country Questionnaire, 2014)

Competent authority	Ministry of Health (MoH).
Legal Basis	NA
Devices classification	Syria follows the European model of classification.
Time to approval	NA
Length of license	Licenses issued in Syria expire at the end of the authorization from their C.O.O.

Palestine

Table 23: Country Fact Sheet Palestine (According to Arazy group [97])

Competent authority	Ministry of Health (MoH).
Legal Basis	Based on US FDA regulation.
Devices classification	Palestine follows the European model of classification.
Time to approval	NA
Length of license	Licenses issued in Palestine expire after five years.

3.3 Medical Devices in North Africa and the Maghreb countries

3.3.1 Egypt

Medical Devices definition

Egypt has adopted the definition and classification of Medical Devices according to European Medical Devices Directive (Directive 93/42/EEC), also:

"Any instrument, apparatus, appliance, material or other Article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [98, 99].

a. Medical Devices Regulation

The Egyptian Ministry of Health (MOH) is responsible for the standardization and coordination of the registration and approval, and importation and manufacturing of Medical Devices. MOH does this through the Drug Policy and Planning Center (DPPC) and the Central Administration of Pharmaceutical Affairs (CAPA). The DPPC controls and sets the strategic rules for drug policy but it also regulates the importation and manufacture of medical Devices and instruments.

The DPPC controls the registration of medical Devices through a specialized committee for the study of manufactured and imported medical Devices and equipment. This committee includes pharmacist managers from CAPA, DPPC and the National Organization for Drug Control and Research (NODCAR).

This committee is responsible for reviewing and approving applications for the manufacture or importation of Medical Devices and equipment in Egypt.

The Egyptian regulatory system for Medical Devices is highly similar to the system in the European Union.

b. Required documentation

The only requirement for Class I non-sterile Devices is a declaration of conformity. For all other medical Devices, the following documents are required [98]:

1. the Declaration of Conformity;

2. The original technical file, signed and stamped by the company of origin, which contains:
    - a certificate detailing the full composition of the product, mentioning the specifications and role of each of the raw materials;
    - the test method of the finished product;
    - the sterilization certificate or the method of sterilization for sterile products;
    - description of the product parts with a sketch diagram;
    - inner and outer labels signed and stamped by the manufacturer for all codes under registration;
    - the CoA of the finished product conforming with the finished product specifications, issued by the quality control department at the manufacturing foreign company;
    - the certificate for the stability data (validity time);
    - packaging configuration (inner and outer package description, raw materials used and the number of the units per box etc.);
    - product IFU and catalog;
    - internal and external label(s) of the product;
    - the shelf life letter and certificate for the stability data.

Moreover, the following documents are to be submitted for the act of legalization by the chamber of commerce and the Egypt embassy in the C.O.O.:

- Distribution /Agency Agreement between the importing Egyptian and the exporting foreign company (LoA);
- Free Sale Certificate;
- CE Certificate or FDA approval; and
- GMP certificate or QM-system certificates (ISO 13485, ISO 9001).

3. One sample from each product under registration, and if the product has more than one design or one package, one sample for each is needed.

c. Country Specifics

The class and type of Devices will determine which registration procedure will apply:

• Class I, Class IIa and Class IIb Devices are registered at the DPPC where an import approval or manufacturing approval is issued at the end of the procedure. The company can start importing or manufacturing before the issue of the approval.

• Class III Devices are registered at CAPA where a registration number and a marketing authorization are issued. The applicant cannot manufacture or import these products unless the registration number and marketing authorization are issued.

• Single-use sterile medical Devices are registered at CAPA (any class) where a registration number and a marketing authorization are issued.

As a general rule, all invasive items (sterile consumables or disposables) need to be registered at CAPA [98, 100].

d. Pre-Owned Medical Devices

According to the 1997 Ministry of Health (MOH) Technical Committee Decree, the importation of used and refurbished medical equipment and supplies to Egypt is banned without the prior approval of the MOH. The importer must submit a form requesting the MOH's approval to import used medical equipment and all documents required are the same as with the import of new Medical Devices [60].

3.3.2 Morocco

a. Medical Devices regulation

The Moroccan Ministry of Health (MOH) regulates the importation and registration of Medical Devices through the Medical Devices Advisory Committee. Medical Devices can be registered in Morocco in a short period at low cost, particularly for Devices of lower risk. Morocco recognizes certification from the EU and the USA FDA [100].

b. Required documentations

Medical equipment and Devices other than radiation equipment requires approval from the MOH that the equipment meets Moroccan health standards. Morocco recognizes certifications provided by the FDA.

A commercial invoice is required. The commercial invoice should fully describe the goods in French.

Certification from the country of origin is required. Payments are made through bank-to-bank and irrevocable letters of credit. Pro-forma invoices must be provided in most cases. Invoices, which should be on company letterhead, are required for both import licenses and foreign exchange transfers. "To order" bills are acceptable as bills of lading. For medical Devices registration in Morocco the following documents are required [60]:

- FSC and QMS certificates,
- a commercial invoice witch should fully describe the goods in French,
- a compliance certificate,
- FDA authorization.
- Payments are made through bank-to-bank irrevocable letters of credit.

- Pro-forma invoices must be provided in most cases. Invoices, which should be on company letterhead, are required for both import licenses and foreign exchange transfers. "To order" bills are acceptable as bills of lading.

Labeling Requirements

No special regulations apply to the exterior marking of containers for shipments to Morocco.

c. Pre-Owned Medical Devices

Approximately 20 percent of the total imported medical equipment is used or reconditioned.

For used equipment, the exporters must provide Moroccan buyers with the following:

• Compliance certificate,

• FDA authorization,

• the technical documentation and directions for use of the product,

• certification of electro-technical and radiological working order,

• documentation on previous maintenance.

When a manufacturer or its agent has registered a medical Devices in Morocco, a third party cannot legally import the same Devices in used or refurbished condition without the used Devices being subjected to new safety inspections. For any piece of used or refurbished medical equipment that enters the country, the third party must provide the same documentation as described above [60].

3.3.3 Algeria

a. Medical Devices Regulation

Registration of Medical Devices for sale in Algeria requires approval from the Ministry of Health and Population (MOHP). Additionally, all documentation submitted to Algeria regulators must be translated into either French or Arabic language.

Regulation of Medical Devices in Algeria is conducted by the Directorate of Pharmacy and by the National Laboratory for the Control of Pharmaceutical Products (LNCPP), which are both under the supervision of the Ministry of Health and Population. Registration documents must be submitted to both bodies [102].

3.3.4 Libya

a. Medical Devices Regulation

The General People's Committee for Health and Environment (GPCHE) is responsible for the regulation and monitoring of all health services in Libya. As a general rule, the importation of medical equipment and supplies into Libya is permissible as long as the manufacturer of the imported equipment is registered with and recognized by the Ministry of Health (MOH).

The registration procedure is conducted as part of an annual purchasing program for imported medical Devices. The registration process must be carried out by a local representative [103].

The Medical Devices market in Libya is a form of tender system.

b. Required documentation

The importer should submit an application including the following [103]:

1. Annex No. (5) of Tender No. 17 - 2011 (Annex XVI), data to be filled in except the price,
2. ISO- and GMP certificates for sterile medical Devices,
   certificate and methods of analysis for the final product,
3. stability study for the final product,
4. accompanied sample's CoA to include the scientific name, the trade name , the batch number, the production and expiry date in the form of day/month/year,
5. a sufficient number of samples of the final product to carry out three complete tests.

c. Country Specifics

Packaging

According to Article 12 of Tender No. 17 – 2011, all products must be packed in such a way that, the inner and the outer pack ensures the safety of handling, transport and storage conditions, adequate with the nature of the product taking into consideration the following points [103]:

1. Products that are affected by heat and humidity shall be kept in temperature and humidity appropriate to the nature of the product. All packs must have attached to them monitors and special cards in Arabic or English, clearly showing change in temperature that may have occurred in any packets during transport and storage.

2. Light-sensitive materials must be packed in opaque containers, and

3. supplied materials must arrive to the recipient in good condition. The products sent in containers and must be closed in a manner to ensure detection of any attempt of unauthorized opening.

Labelling

In accordance with Article 14 of Tender No. 17 – 2011, each box and parcel must carry the necessary data, which should be clearly written with indelible ink or non-erasable in both Arabic and or English language as follows [103]:

- name and address of the supplier, manufacturer and C.O.O,
- name and address of the buyer in boldface,
- application number and code of each item as appearing in the tender documents,
- number of boxes or parcels conform to the packing list (shipping data),
- the logo of the producing company,
- the number of the items and their names contained in each box,
- the batch number,
- the Red Crescent logo.
- Each box or pack must show clearly the manufacturing and expiry date of the products and the instructions necessary for handling and storing;.
- Each pack or box must carry the sign: MOH - NOT FOR SALE).
- The generic name must be written on the box outside and on the inside pack.

3.3.5 Tunisia

a. Medical Devices Regulation

All medical Devices require to obtain an Authorization for Market Commercialization (AMC), issued by the Directorate of Pharmacy and Pharmaceuticals (DPM) of the Republic of Tunisia. Heavy medical equipment, such as CT or MRI scanners, must also obtain a separate license from the Ministry of Health (MOH).

The registration process is conducted through a local agent, and documents should be submitted directly to the DPM office in Tunis. Due to trade agreements with the European Union, Medical Devices that carry a CE mark benefit from an expedited registration process [104].

Required documentation

Before initiating the application, the importer must submit several documents including:

- a purchasing invoice,
- a transport title;
- an analysis report and
- a certificate of conformity.

Documents must be submitted in either Arabic, French or English.

b. Pre-Owned Medical Devices

According to the Tunisian Ministry of Commerce, there are no statutory prohibitions on the import of used or refurbished equipment. While regulations are minimal, importation of used equipment into Tunisia is difficult as there is a strong preference for guarantees and after-sales service, which comes with new equipment. The purchase of used equipment for government-funded projects is permitted only in exceptional circumstances [60].

Country fact sheet North Africa and the Maghreb countries

Egypt

Table 24: Country Fact Sheet Egypt [98-100] (Country Questionnaire, 2014)

Competent authority	Ministry of Health (MOH).
Legal Basis	Egyptian Regulation for Medical Devices. Regulations based on the EC directives
Devices classification	Class I, IIa, IIb and III
Time to approval	5-8 months for all classes
Length of license	validity of the registration license is ten years

Morocco

Table 25: Country Fact Sheet Morocco (According to Arazy group [101])

Competent authority	Ministry of Health (MOH).
Legal Basis	Morocco Regulation for Medical Devices.
Devices classification	There is no special requirement for a specific classification system or previous foreign marketing approvals.
Time to approval	Approximately one month.
Length of license	NA

Algeria

Table 26: Country Fact Sheet Algeria (According to Arazy group [102])

Competent authority	Ministry of Health and Population (MoHP).
Legal Basis	NA
Devices classification	Class I, IIa, IIb and III
Time to approval	30 days
Length of license	NA

Libya

Table 27: Country Fact Sheet Libya [103, 104]

Competent authority	Ministry of Health (MOH).
Legal Basis	Libyan Regulation for Medical Devices.
Devices classification	The Libyan authorities accept all classification systems.
Time to approval	NA
Length of license	NA

Tunisia

Table 28: Country Fact Sheet Tunisia (According to Arazy group [105])

Competent authority	Ministry of Health (MOH).
Legal Basis	NA
Devices classification	NA
Time to approval	Approximately one month.
Length of license	NA

4. Summary – Integration of Medical Devices regulation in MENA region

During the development and registration process, several parties need to interact with each other. Local authorized representatives or agents play a key role in medical Devices registration in all MENA countries. They are required as per the regulations and they help to overcome barriers for foreign companies, like language issues and the know-how of local requirements and processes as well. Often websites and local regulations are only available in local language (mostly Arabic) and local agents can benefit from participation in local regulatory or industry networks.

As the requirements for Medical Devices are not homogeneous throughout the MENA countries, different types of dossiers will have to be prepared. The technical documentation will cover the requirements of the majority of countries, however not internationally named as 'design dossier' or STED.

Beside the technical documentation, the main requirements are usually GMP or QM-System certificates, a FSC from the Country of Origin, a Letter of Authorization, EC certificates, and Declaration of Conformity, a Certificate of Analysis the finished product, a statement about the status of Devices distribution, a local application form and country specific declarations.

The FSC is a key document in the registration process of Medical Devices in most MENA countries, which must be legalized by the chamber of commerce and the embassy of the foreign importing country in C.O.O. (see Annexes II, III and IV)). Annex II-IV illustrate which countries need a FSC for submission and which countries do not required a FSC.

The Devices needs to be classified very early in the development process in order to determine the path forward.

Medical Devices in general usually are divided into three groups as in the USA (class I, II and III) or four groups as in the EU (class I, IIa, IIb and III) or according to the GHTF guidelines (class A, B, C and D). The main MENA countries accept both EU and FDA definitions. In vitro diagnostic Devices are seen as a separate group and the classification of these products vary a lot.

Good manufacturing practice is required in all countries (Annex II-IV). An ISO 13485 certificate is in most countries the way to demonstrate compliance with the quality system requirements.

In some countries like Egypt, an ISO 13485 certificate - issued by EU notified bodies or USA/Australian bodies - might be enough to demonstrate compliance with the quality requirements but it must be approved by the local certification body.

The requirements for the risk management report for Medical Devices vary depending on the classification of the Devices e.g. Iran requires risk assessment for class C and D Medical Devices, while the UAE only asks the risk assessment for class III Medical Devices.

Clinical studies are required mostly for high risk Medical Devices. Most MENA countries require clinical evaluation and not clinical trials.

Labeling requirements are generally the same. The language shall be adjusted to the country where the product is sold. Instructions for use are not always necessary depending on the class of the Devices. Class I Devices and sometimes class II Devices (depending on the classification system) do not always require instructions for use if the Devices can be used safely without it.

In some countries of the MENA region such as UAE, Jordan and Kuwait the importation of pre-owned Medical Devices is strictly forbidden, while in other countries such as Yemen and Morocco there are no restrictions on the importation of used equipment. The entry of pre-owned Devices in other countries such as KSA and Qatar is allowed, but the Ministry of Health and government hospitals keep away from purchasing such equipment.

Main requirements for registration are a local representative, a Certificate of Free Sale from the C.O.O, an import license from the competent authority in the importing country and the registration of the company and the product in the importing country.

The use of quality management systems and risk management systems within development, manufacturing, quality control and post market surveillance of the Medical Devices in question are required in most countries, except for medical Devices class I. Certificates of ISO 13485 and ISO 9001 are required or recommended.

5. Discussion

In comparison to medicinal products, the registration process of Medical Devices in the MENA countries is much more unregulated. Most countries have on the first look more or less similar requirements for registration of Medical Devices and they are striving to harmonize their regulations with the regulations of the most important exporting economies such as EU and US/Australia and their international regulatory organizations.

The common denominator is:

- A local representative,
- an US- or EU oriented QM-system documented with related certificates,
- a Devices classification,
- labeling requirements.

Apart from those items the requirements for achieving a marketing authorization differ from country to country. A good example is the submission dossier that is only asked by some health authorities like the MOH of the Iran.

The fact that some countries like UAE and Saudi Arabia have a highly developed MD regulation whereas other countries like Palestine or Algeria only require an import license or do not have a special regulation for MD, does not make things easier for exporting companies that make efforts in this region. Because the regulatory basis is limited, some countries like UAE implement stricter legal conditions than asked by the internationally harmonized regulation, which makes the registration process a laborious, time-consuming and expensive operation. This also explains why local agents in these countries are indispensable.

The further harmonization of the standards within the region would therefore have a positive impact on the co-operation between these countries as well as on the relation between these countries and the exporting nations.

6. Conclusion, Outlook

Some countries have similar requirements for registration of medical Devices and are striving to harmonize with the IMDRF guidelines, in others the MD regulation is still in its infancy.

Although the US are still the dominating regulator, the EU regulation becomes continually more impact on harmonization. This corresponds to the growing exports of EU countries in the MENA region.

In the authors opinion the fundamental demand to be solve in the future is the approximation of the existing individual regulations in these countries to promote a uniform commercial basis, because the relatively small amount of population in each country bears not relationship to the costs generated by such individual requirements (different in almost each country).

At least documents to be prepared for EU or USA, such as technical documentation with risk analysis, clinical evaluation, etc., can also be used for a registration of products in MENA countries, however only in English language.

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Declaration – Erklärung

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

Darmstadt, 02.02.2015

Dr. Fatemeh Samadi

Annex I: Results from country questionnaire

Questions sent to local Regulatory Affairs Managers of the respective countries:

	KSA
1	What is the name of competent authority responsible for Medical Devices? Saudi Food Drug Authority http://www.sfda.gov.sa/en/medicalDevices/Pages/default.aspx
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) For class I & II it takes 2-3 weeks and 5-10 weeks for class III
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? There is online electronic system for submission and certification
6	Do you Required local clinical studies for submission of a Medical Devices? No
7	Are there any regulations regarding pricing and reimbursement? There are fees published in the SFDA ELECTONIC WEBSITE.
8	Does your authority accept a CE mark? Yes they do
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? No
10	Would you rank your Medical Devices regulations rather EU or US-oriented? They equally accept Australia, Canada, Japan the USA and the EU/EFTA

UAE

1	What is the name of competent authority responsible for Medical Devices? MOH UAE
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? Yes
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) No Fixed time. Minimum 6 months
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? Yes
6	Do you Required local clinical studies for submission of a Medical Devices? Sometimes
7	Are there any regulations regarding pricing and reimbursement? Yes
8	Does your authority accept a CE mark? Yes
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes
10	Would you rank your Medical Devices regulations rather EU or US-oriented? Both

Israel

1	What is the name of competent authority responsible for Medical Devices? Ministry of health -AMAR
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) 120 days, no matter what class is the Devices.
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? Yes, there is a special format in the MOH website. The following documents needs to be attached to the submission: Regulatory approvals Technical documents Catalogs

	Manufacturer and importer statements Devices description Clinical reports
6	Do you Required local clinical studies for submission of a Medical Devices? Not necessarily
7	Are there any regulations regarding pricing and reimbursement? No
8	Does your authority accept a CE mark? Yes, but Devices with CE needs to get AMAR approval for selling the Devices in Israel
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes
10	Would you rank your Medical Devices regulations rather EU or US-oriented? Neither EU nor US-oriented

Iran

1	What is the name of competent authority responsible for Medical Devices? MOH Ministry of Health http://www.imed.ir/
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? Medical Equipment Department
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) 2 to 3 Months but for implantation devices it is longer (Class D)
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? There is no special format but in the beginning we need international certificates and global standards.
6	Do you Required local clinical studies for submission of a Medical Devices? Sometime yes, if there is some missing certification and documental approval related to this Devices
7	Are there any regulations regarding pricing and reimbursement? Yes by MOH
8	Does your authority accept a CE mark? Yes
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? No
10	Would you rank your Medical Devices regulations rather EU or US-oriented? A mixture of EU, US and Australian regulation

Iraq

1	What is the name of competent authority responsible for Medical Devices? Ministry of Health
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) For Company Registration Less than one month if all the documents is completed and accepted, but for items registration it will take longtime for testing ,and lab sterilization testing
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? lot Reference of item, sterilization date and validity ,manufacture name , made in Germany, CE Number, and all the information Required must be printed on the box and internal sterilized pack not on the sticker directly on the paper of the pack.
6	Do you Required local clinical studies for submission of a Medical Devices? Yes
7	Are there any regulations regarding pricing and reimbursement? No
8	Does your authority accept a CE mark? Yes
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes
10	Would you rank your Medical Devices regulations rather EU or US-oriented? EU

Jordan

1	What is the name of competent authority responsible for Medical Devices? Jordan food and drug administration " JFDA "
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) Some classes it takes 2 to 3 days and other classes that does not mention exactly by code or article need to get additional approval and time
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? Paper format only for Devices and other paper format for Instruments and disposables
6	Do you Required local clinical studies for submission of a Medical Devices? Sometime yes, if there is some missing certification and documental approval related to this Devices
7	Are there any regulations regarding pricing and reimbursement? No
8	Does your authority accept a CE mark? Yes
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes
10	Would you rank your Medical Devices regulations rather EU or US-oriented? Neither EU nor US-oriented.

Lebanon

1	What is the name of competent authority responsible for Medical Devices? Ministry of Health
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No.
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) Anywhere between 3-6 months depending on conformity of documents with requirements

5	Is there any special format (e.g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? a. Free sales certificates of the product showing also his medical classification by your government (as shown on the CE certificate: annex III : Medical Devices …) legalized by your ministry of health and our Lebanese embassy (each page should be stamped) b. CE or FDA certificate copy if available c. original GMP legalized from your ministry of health or original copy of the ISO 13485 (or copy of this ISO legalized by notary and Lebanese embassy) d. certificate of analysis(stamped and signed by the company) e. 2 samples of the product. f. Stability data of one batch beginning from the day of its manufacture date till its expiry date (stamped and signed by the company). Batch size should be mentioned (qty manufactured of the related batch) and the packaging also. g. storage conditions (stamped and signed) h. Summary of product characteristics or leaflet (stamped and signed) i. Plant profile to be legalized by the chamber of commerce and Lebanese embassy as mentioned on the last paper j. Distribution agreement (official paper from the company stating that we are their exclusive distributor in Lebanon)
6	Do you Required local clinical studies for submission of a Medical Devices? No.
7	Are there any regulations regarding pricing and reimbursement? No pricing regulations for Medical Devices. As for reimbursement, it is handled by National Social Security Fund. Not all registered Devices are covered. For those covered, they will set a price ceiling.
8	Does your authority accept a CE mark? Yes.
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes.
10	Would you rank your Medical Devices regulations rather EU or US-oriented? I would say both

Syria

1	What is the name of competent authority responsible for Medical Devices? Ministry of Health
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? No.
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) For Company Registration Less than one month if all the documents is completed and accepted. but for items registration it will take longtime for testing ,and lab sterilization testing
5	Is there any special format (e.g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? lot Reference of item, sterilization date and validity ,manufacture name , made in Germany, CE Number, and all the information required must be printed on the box and internal sterilized pack not on the sticker directly on the paper of the pack
6	Do you Required local clinical studies for submission of a Medical Devices? Yes
7	Are there any regulations regarding pricing and reimbursement? No
8	Does your authority accept a CE mark? Yes.
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes.
10	Would you rank your Medical Devices regulations rather EU or US-oriented? EU

Egypt

1	What is the name of competent authority responsible for Medical Devices? Ministry of Health Central Administration for Pharmaceutical Affairs Medical Devices Regulatory Unit
2	Do you have a Medical Devices regulation? Yes
3	Do you involve other organizations / institutions (like the notified bodies in the European Union) into the assessment of Medical Devices? If yes, which are they? Yes. Notified bodies, and ministries of health which issues the Free sale Certificates
4	How long does the health authority review from submission to approval for a Medical Devices take? (Please separate by different Medical Devices classes, if applicable.) 5-8 months for all classes
5	Is there any special format (e. g. STED format) for the submission dossier? Which essential documentation do you need to submit for a Medical Devices? First, Documents should be Original, fresh validity, approved by the chamber of commerce & legalized by the Egyptian Consulate: a. (Agency Agreement) Recommended form attached (This form is recommended by our Ministry of Economy & trade to permit us to participate in the Government tenders). b. FDA (if available) c. CE Mark Annex II Section 3 & Annex II Section 4. d. ISO Certificate 13485 e. FSC with mentioning the manufacturer site and the products has freely sold inside Europe. f. Declaration Certificate of conformity with mentioning the CE Certificate number, ISO number, product name, classification and the statement that the declaration is issued under the responsibility of the manufacture. g. Shelf Life & Sterilization Certificate. Second, Documents should be original, printed over your company letterhead & sealed by your company stamp: a. Product Raw Materials composition Certificate b. Product Components Certificate.

	c. Product Stability Study. d. Product Analysis Certificate., in which the manufacturer have full responsibility for the analysis and quality control of product e. Product Design (Drawing) and specification. f. Product Packaging Certificate. g. Pattern of Label Inner & outer. h. Samples (1pcs per item) i. Catalogs
6	Do you Required local clinical studies for submission of a Medical Devices? Yes for the products that are not from reference countries (EU countries, and USA, Canada, Australia, Japan)
7	Are there any regulations regarding pricing and reimbursement? For some items only
8	Does your authority accept a CE mark? Of course, It is the most important certificate
9	Would you need a Free Sales Certificate for submission of a Medical Devices in your country? Yes must be from reference countries (EU countries, and USA, Canada, Australia, Japan)
10	Would you rank your Medical Devices regulations rather EU or US-oriented? EU oriented

Annex II: Medical Devices registration requirements in GCC

	Application form	FSC	CE certificate or FDA-approved	Technical documentation*	Status of Devices distribution	DOC	GMP certificate or QM-system certificate (ISO 13485, ISO 9001)	LoA	CoA	Company registration certificate	Additional requirement
KSA	√		√	√		√	√	√			-Attestation accompanying application for marketing authorization - Environmental statement -Latest Audit report
UAE	√	√	√	√	√	√	√	√	√	√	-Essential principles checklist - storage conditions -Declaration of price - Process validation study -Latest Audit report
Qatar			√				√				
Oman	√		√		√		√	√		√	pre-qualification of Companies and Factories of Medical supplies
Kuwait	√	√		√	√		√	√	√		
Bahrain			√	√			√				
Yemen		√					√				In the case of invasive Devices, either USA FDA approval or certification from Gulf Cooperation Council (GCC) countries

Technical documentation*: Post market requirement& Risk assessment, Devices information, Labelling & samples, Safety and effectiveness data, Stability studies Shelf life

Annex III: Medical Devices registration requirements in West Asia

	Application form	FSC	CE certificate or FDA-approved	Technical documentation*	Status of Devices distribution	DOC	GMP certificate or QM-system certificate (ISO 13485, ISO 9001)	LoA	CoA	Company registration certificate	Additional requirement
Israel		√	√	√		√	√				-Description of the technical and maintenance services, including periodic checks and inspections. -Latest Audit report
Iran	√		√	√	√	√	√	√			-Submission summary dossier - test reports and certificates from the Iranian Standards Institution (if applicable)
Iraq							√	√		√	- Raw material Certification -Company registration form - manufacturer registration certificate
Jordan		√	√	√			√		√		-For Medical Devices containing ingredients of animal origin, a Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE) Certificate should be submitted
Lebanon	√	√	√	√			√	√	√		storage conditions Company profile
Syria		√		√			√			√	Sterilization certificate
Palestine											Importer license

Technical documentation*: Post market requirement& Risk assessment, Devices information, Labelling & samples, Safety and effectiveness data, Stability studies Shelf life

Annex IV: Medical Devices registration requirements in North Africa

	Application form	FSC	CE certificate or FDA-approved	Technical documentation *	Status of Devices distribution	DOC	GMP certificate or QM-system certificate (ISO 13485, ISO 9001)	LoA	CoA	Additional requirement
Egypt		√	√	√		√	√		√	-Company license - Sterilization certificate -Product specification certificate -certificate for the stability data
Morocco		√	√				√			-Compliance certificate, -FDA Authorization, -commercial invoice
Algeria			√				√			
Libya				√			√		√	Packaging & Labelling
Tunisia			√			√			√	-Purchasing invoice -transport title

Technical documentation*: Post market requirement& Risk assessment, Devices information, Labelling & samples, Safety and effectiveness data, Stability studies Shelf life

Annex V: On-line MDMA Application form

KSA

A Practical Guide to completing the SFDA USA On-line MDMA Application form	Revision: 11-July-2013 (v1)

1. Manufacturer

No	SFDA Question	DO CHECK WARNING	Task
1.1	Manufacturer	*DO*	*Insert the name of the Manufacturer*
1.2	Legal Manufacturer	*DO*	*Insert the name and address of the Legal Manufacturer (Registered Device Manufacturer)*
		CHECK	*The name and address of the Legal Manufacturer of the devices in this application. It must concur with sections:* *2.1.10 Labelling* *2.1.11 IFU,* *2.3 A/C power supply statement – if applicable* *2.4 Environmental statements* *5.3 PMA,510(k) or declaration of conformity* *5.4 The amendment letter –if applicable-* *5.7 Establishment registration and device listing evidence* *6.4 Recent EIR* *6.6 The most recent audit report – if applicable-* *7.1 Regulatory Compliance Attestation*
		WARNING	*A common error is to insert the device manufacturers site address, rather than the Legal Manufacturer address* *If the Legal Manufacturer has two addresses, a Postal Address and a Site Address, please provide an attested letter from the Legal Manufacturer explaining that there are two addresses. – Insert the letter in section 5.3*
1.3	Medical Device Category	*DO*	*Use SFDA drop-down list of 17 categories*
		CHECK	*That all the devices in the application fall under the selected category.* ***Note on SFDA BUNDLING Rules*** *Devices must have the same:* *1. Purpose* *2. Technical Performance* *3. Classification*
		WARNING	*A common error is to insert one or more devices in section 2.1 that do not fall under the category selected in 1.3.*

2. General Info.

No	SFDA Question	DO CHECK WARNING	Task
2.1	Details of the medical devices applying for market authorisation (open the list below)	*DO*	*Insert the list of devices in the application*
		CHECK	*Cross check the list of devices against* *2.1.10 Labels* *2.1.11 IFU* *5.3 PMA,510(k) or declaration of conformity*

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td></td><td>5.4 The amendment letter –if applicable-
5.7 Establishment registration and device listing evidence

Note on SFDA BUNDLING Rules
Devices must have the same:
1. Purpose
2. Technical Performance
3. Classification

If a device has multiple models (with the same brand name), for example Male Urinary Catheters of different sizes, the applicant should include these in one line.

<table><tr><td>Product Description</td><td>Intended Purpose</td><td>Trade/Brand Name</td><td>Model Number</td></tr><tr><td>Male Urinary Catheters</td><td>Drain urine from the bladder</td><td>XYZ</td><td>123-40
123-50
123-60</td></tr></table></td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is to insert the wrong devices that appear in other sections of the applications</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is to omit devices that appear in other sections of the applications</td></tr>
<tr><td>2.1.1</td><td>Product Brief Description</td><td>DO</td><td>Insert the Product Description

Note: The Product Description will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The Product Description must be precise and informative (maximum of 100 characters).
In English only.
No spelling or typing errors
No Brand Names or Company Names
No measurement unit (examples: 50ml or 100mm)
No comma (,).</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>“Catheter, Urinary” will be rejected whereas “Urinary Catheter” is acceptable

Classification from FDA used as product description is not accepted. i.e. “Respirator, mask, surgical”

Do Not include Brand Names or Company Names</td></tr>
<tr><td>2.1.2</td><td>Intended purpose of the medical device type (mandatory)</td><td>DO</td><td>Insert the intended purpose.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Typically this is an extract from the IFU</td></tr>
<tr><td>2.1.3</td><td>Trade/Brand Name (as it appears on the label)</td><td>DO</td><td>Insert the device Trade/Brand Name

Note: The device Trade/Brand Name will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The device Trade/Brand Name must be IDENTICAL to the Trade/Brand Name as it appears on the device Label</td></tr>
</table>

No	SFDA Question	*DO CHECK WARNING*	*Task*
		WARNING	*The Trade/Brand Name inserted in section 2.1.3 will be printed on the MDMA License issued by the SFDA. If it does not match the Trade/Brand Name on the label, it may cause delays at the Port of Entry or complete refusal*
		WARNING	*The combination of the Product Description and Trade/Brand Name must be unique for every device listed in the application.*
2.1.4	Model Number (as it appears on the label)	*DO*	*Insert the Model Number*
		CHECK	*If more than one Model Number is listed in a window, these models should only differ in either colour, size, weight or dimensions.* *Check it concurs with the product model number as it appears on the product Label*
2.1.5	Manufacturer's Device Identifier Number (mandatory)	*DO*	*Insert the Manufacturers Device Identifier Number(s)*
		CHECK	*Typically this is the REF number, or Product catalogue number* *Check it concurs with the product ID number as it appears on the product Label*
		CHECK	*If a device has multiple models with the same Product Description, Intended Purpose and Brand Name, for example Male Urinary Catheters of different sizes, the applicant should include these here.*
		WARNING	*The SFDA will is issue the MDMA License only for the models/sizes listed in section 2.1.5*
2.1.6	Format of medical device identifier number(s) that will appear on labelling for traceability purposes	*DO*	*Insert the Format of medical device identifier number(s) that will appear on labelling for traceability purposes*
		CHECK	*Typically this is the LOT number, or Serial number* *Provide a brief description of how the number is formatted* *Eg LOT YYYY-MM-DD (year-month-day)* *It is indicated on the provided label*
2.1.7	GMDN	*DO*	*Insert the GMDN code number if available*
2.1.8	UMDNS	*DO*	*Insert the UMDNS code number if available*
2.1.9	Other (e.g. FDA identification number, JMDN)	*DO*	*Insert the Other code numbers if available*
2.1.10	Provide the label(s) affixed to the device or its wrappers when it is	*DO*	*Attach the device labels for ALL the devices listed in this section*

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td>supplied to the KSA.</td><td></td><td>Example labels with “xxx” for variable data is acceptable

A/C Power Supply
If the product is connected to an A/C power supply, the applicant must provide images of the power supply label, so it can be cross-checked with the A/C Power Supply signed declaration provided in section 2.3

This is a USA submission therefore the labels must be compliant with US-FDA Regulations</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Labels are provide for ALL the devices listed in this section

Including each of the model numbers/REF/Part No./etc

When the device has a range (eg sizes) then
a representative label is acceptable provided there is also a table provided that clearly links one product-size to one product ID number.

Example (Acceptable)
<table>
<tr><td>Trade Name</td><td>REF
(Product ID Number)</td><td>Size
(product variable)</td></tr>
<tr><td>Medical Device</td><td>1234</td><td>5x5cm</td></tr>
<tr><td>Medical Device</td><td>1236</td><td>10x10cm</td></tr>
</table>
The applicant has provided a clear link between each of the product ID numbers and the product sizes/dimensions

The table must be from the Legal Manufacturer and must be signed, job title & dated

The Labels must contain:
Device Trade Name (see 2.1.3)
Device model Number (see sec 2.1.4)
Device ID Number (REF) (see 2.1.5)
Legal Manufacturers Name & Address (see 1.1 & 1.2)

In addition it may also contain:
LOT or Serial Number
Power Supply – if applicable
Storage Temperature
Expiry Date
Date of Manufacture
Sterile & Method – if applicable
Single Use – if applicable
The term “Made in.....” with country of origin.
IVD – if applicable
IVD Self Test – if applicable
Rx only, if applicable

Note: If the device is for Professional Use only
The label in English only is acceptable
Reference: SFDA MDS-IR6 Article 9 (C)

Note: If the device is for Home Use / Self Test IVD
The label must be in both English & Arabic
Reference: SFDA MDS-IR6 Article 9 (C)</td></tr>
</table>

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is wrong or missing labels</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>Tables-
Example (Not Acceptable)<table><tr><td>Trade Name</td><td>REF
(Product ID Number)</td></tr><tr><td>Medical Device</td><td>1234
1236
etc</td></tr></table>The applicant has provided no link between the product ID numbers and the product sizes/dimensions.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1.11</td><td>Provide the ‘instructions for use’ document intended for KSA users of the medical device.
- If NOT RELEVANT provide a justification.
(See below)</td><td>DO</td><td>Attach the IFU for ALL the devices listed in this section

This is a USA submission therefore the IFU must be compliant with the US-FDA Regulations.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>IFU cover ALL the devices Trade/Brand Names listed in this section
Legal Manufacturers name and address are printed on the IFU and concurs with section 1.1 & 1.2
Electrical rating –if applicable-.

Note: If the device is for Professional Use only
The IFU in English only is acceptable
Reference: SFDA MDS-IR6 Article 9 (C)

Note: If the device is for Home Use / Self Test IVD
The IFU must be in both English & Arabic
Reference: SFDA MDS-IR6 Article 9 (C)

The IFU must have Date of Issue or the latest Revision Number</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is a wrong or missing IFU</td></tr>
<tr><td></td><td>If NOT RELEVANT provide a justification</td><td>DO</td><td>If its NOT RELEVANT to have an IFU for the device, then the applicant MUST provide a justification.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The justification must be from the Legal Manufacturer and must be signed, job title & dated</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>The justification must be from the Legal Manufacturer and must be signed, job title & dated</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1.12</td><td>List of Accessories</td><td>DO</td><td>List the Accessories for this device</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Definition: Accessories are devices specifically intended by its Legal Manufacturer to be used together with the medical device to achieve its intended purpose.</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>If the Accessory can be used as a stand-alone medical device, the SFDA do NOT consider it an Accessory. It</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			must be listed as a Medical Device
2.2	Jurisdiction(s) where this medical device may be placed on the market. • Australia • Canada • Europe • Japan • USA	*DO*	*Make the selections as appropriate.*
		CHECK	*USA must be selected because this is a USA submission*
2.3	If the device is connected to an a/c power supply, provide a statement that confirms it is: 1. designed to operate with a 60 Herz supply at nominal values of either 230 or 400 volts; 2. is fitted with the appropriate a/c power connector; 3. maintains the required electrical safety conditions 4. continues to perform to specification.	*DO*	*Complete the statement Template provided* *Leave this section blank if it is not applicable and move to the next section.* *If the device is connected to an a/c power supply, complete the statement Template provided* ***Printed on the <u>Legal Manufacturers</u> Letterhead*** *Only list of the devices in the application (see 2.1).* *Do NOT alter the wording of the SFDA Template provided. Adding statements to the SFDA Template may be acceptable*
		CHECK	*The statement must be from the Legal Manufacturer and must be signed, job title & dated* *Only the devices in section 2.1 have been listed.*
		WARNING	*If the voltage or Hz values on the labels submitted in section 2.1.10 are outside those listed in the SFDA template provided in this section (2.3) a justification will be required.* *The statement must be from the Legal Manufacturer and must be signed, job title & dated* *Only the devices in section 2.1 that are connected to a power supply have been listed.* *Do NOT alter the wording of the SFDA Template provided. Adding statements to the SFDA Template may be acceptable*
2.4	Provide a statement that the device will perform as intended when subjected to other environmental factors encountered within the	*DO*	*Complete the statement Template provided* ***Printed on the <u>Legal Manufacturers</u> Letterhead*** *Only list of the devices in the application (see 2.1):*

4. Product Categories (Europe)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
4.1	Device Type • Medical Device • IVD	*Do*	*Select one option*
		CHECK	*The selected Device Type complies with the devices listed in section 2.1*
4.2	Device Classification Medical Devices • Class I • Class II • Class III • Unclassified devices IVD • Class I • Class II • Class III • Unclassified devices	*DO*	*Select one option*
		CHECK	*The selected Device Classification complies with the devices listed in section 2.1* *The Device Classification concurs with the provided evidence(s) in section 5.*

5. Product Verification (USA)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
5.1	Indicate pre-market submission status of the medical device • PMA • 510(k) • Class I Exempt • Class II Exempt	*DO*	*Please tick the appropriate pre-market submission status*
		CHECK	*The selected pre-market status is correct for the specific device(s) in this application*
5.2	Provide the product code allocated by the FDA	*DO*	*Provide the product code allocated by the FDA*
		CHECK	*Confirm the selected product code is correct for the specific device(s) in this application* *See the FDA webpage:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
5.3	Provide the current 510(k) or PMA approval letter authorising the marketing of the device, where relevant	*DO*	*Provide the current 510(K) or PMA approval letter authorising the marketing of the device, where relevant*
		CHECK	*Confirm the 510(k) or PMA letter has been provided (if required), or the declaration of conformity if the device Exempt.* *Check the FDA webpage to confirm the 510(k) or PMA is correct for the specific device(s) in this application* *For 510(k) see:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm* *For PMA see:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm* *Check the FDA webpage to confirm the 510(k) or PMA is correct for the Legal Manufacturer (name & address)* *If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide an attested justification from the Legal Manufacturer, signed, job title and dated.*
		WARNING	*If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide a justification from the Legal Manufacturer, signed, job title and dated.*
5.4	Provide the amendment letter(s) where CDRH has issued amendments to the original 510(k) or PMA approval letter.	*DO*	*Provide the amendment letter(s) where CDRH has issued amendments to the original 510(k) or PMA approval letter.*
		CHECK	*Confirm that the letters have been provided (if required)* *Confirm that the letters are for the specific device(s) in this application*
5.5	Provide the name and affiliation of the Accredited Person under the Accredited Person Programme responsible for reviewing the 510(k), if such was involved	*DO*	*Ignore this questions if an Accredited Person was NOT involved in 510(k) review* *Provide the name and affiliation of the Accredited Person under the Accredited Person Programme responsible for reviewing the 510(k), if such was involved.*
		CHECK	*Confirm that the name and affiliation of the Accredited Person has been provided* *See:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm*

No	SFDA Question	DO CHECK WARNING	Task
5.6	If the device is Class I exempt or Class II exempt, indicate the location of the technical information that demonstrates that the device is safe and performs as intended by the manufacturer	*DO*	*Confirm the device is Class I exempt or Class II exempt* *Confirm that the location is provided*
		CHECK	*Confirm that the technical information is stored at the location provided to the SFDA*
5.7	Provide evidence that the manufacturer has complied with FDA's 1- Establishment Registration 2- Device Listing.	*DO*	*Provide evidence of Establishment Registration and Device Listing*
		CHECK	*Confirm that the evidence has been provided* *Confirm that the data is for the current year.* *Confirm the data provided concurs with the information on the FDA database* *See:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm* *If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide an attested justification from the Legal Manufacturer, signed, job title and dated.*
		WARNING	*If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide an attested justification from the Legal Manufacturer, signed, job title and dated.*

6. Manufacturers QMS Status (EUROPE)

No	SFDA Question	DO CHECK WARNING	Task
6.1	Indicate whether the manufacturer of the medical device operates an establishment quality management system (QMS) that is acceptable to the FDA • Yes • No	*DO*	*Select one answer*
6.2	Indicate the type of QMS used	*DO*	*Insert the Quality Management Standard*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		CHECK	*This application is under the US-FDA Regulations. Therefore the FDA 21 CFR 820 Quality System Regulations are applicable unless QSR is exempted for the device(s)*
6.3	Indicate the procedure(s) that are included within the Manufacturers QMS • Design and development • Manufacturing • Manufacture of sterile devices	*DO*	*Select one or more*
		CHECK	*Confirm that one or more has been selected* *Confirm the data provided against the FDA database* *See:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm*
6.4	Where the QMS has been audited by the FDA, provide evidence of the most recent audit	*DO*	*Confirm a full copy of the Establishment Inspection Report (EIR) has been provided (redactions are acceptable)* *Confirm the Manufactures name and address are correct*
		CHECK	*Confirm that the Establishment Inspection Report is for the Legal Manufacturer*
6.5	Provide the date of the most recent audit by either the FDA or Accredited Person	*DO*	*Provide the date of the most recent audit by either the FDA or Accredited Person*
		CHECK	*Confirm the date has been provided* *Confirm that it tallies with the date provide in 6.4 (if available)* *Confirm that the date is the latest one issued by either FDA (section 6.4) or Accreditation Person (section 6.6)*
6.6	Where the QMS has been audited by an Accredited Person, provide the evidence of the most recent audit	*DO*	If the QMS has been audited by an Accredited Person, provide the evidence of the most recent audit. *If the most recent EIR is not provided, provide evidence from the FDA that the most recent audit report issued by the* Accredited Person is accepted.
		CHECK	*Confirm the evidence has been provided* *(not required if 6.4 & 6.5 completed)* *Confirm the Legal Manufactures name and address are correct*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
6.7	Name of the Accredited Person responsible for the QMS audit	*DO*	*Provide the name of the Accredited Person responsible for the QMS audit*
		CHECK	*Confirm the name has been provided*

7. Other National Provisions (KSA)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
7.1	Provide an attestation written in English, to declare that each clearly identified medical device covered in this application complies with the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application and with the specific KSA national provisions within the Medical Devices Interim Regulation. (SFDA Template provided)	*DO*	*Complete the attestation using the template provided* *The attestation must be printed on the **Legal Manufacturers Letterhead*** *GHTF Regulation: Select USA* *Devices: as listed in section 2.1* *Manufacturer name & address* *Signed:* *Job Title:* *Dated:*
		CHECK	*Only USA has been selected as the GHTF Regulation.* *The attestation must be from the Legal Manufacturer and must be signed, job title & dated* *Only the devices in section 2.1 have been listed.*
		WARNING	*This is a USA submission, therefore only USA must be selected.* *The attestation must be from the Legal Manufacturer and must be signed, job title & dated* *Only the devices in section 2.1 have been listed.*
7.2	Provide the address of the location where the manufacturer holds technical information to support this attestation.	*DO*	*Provide the address of the location where the Legal Manufacturer holds technical information to support this attestation.*
		CHECK	*It must be a full postal address*
7.3	Signature of the person responsible for completing this	*DO*	*Complete the attestation using the SFDA template provided* *The attestation must be printed on the **Authorised***

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	application (A)		***Representative (AR)/ Local Manufacturers (LM) Letterhead*** *Application Number:* *AR/LM Company name & address:* *Signed:* *Job Title:* *Dated:* *AR ID Number:*
		CHECK	*The correct application number has been provided.* *The name & address of the AR or LM has been provided* *And the attestation signed, job title and dated*

Annex VI: Statement for KSA Environmental Factors

Date:

Statement for KSA Environmental Factors

Name and Full Address of Manufacturer including country:

I hereby confirm that the medical device(s) and accessory(ies) in this application (No. 15185), will perform as intended when subject to the other environmental factors encountered within the KSA.

Authorised Signatory:

Name:

Job Title:

Signature:

Date:

Annex VII: Attestation accompanying Application for Marketing Authorization KSA

[To be printed on Manufacturer Letterhead]

Name and Address of Manufacturer:

I hereby declare that the Medical Devices(s) listed below complies with:-

1. The provisions of the Medical Devices regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application.
2. The specific KSA national provisions within the MEDICAL DEVICES INTERIM REGULATION.

GHTF Founding Member jurisdiction that has been selected as the basis of the application, selected from:

AUSTRALIA / CANADA / EU / JAPAN / USA.

List of Devices :

1. *(Trade Brand name)*
2. *(Trade Brand name)*
3. *.....*

Authorized Signatory:

Name:

Job Title:

Signature:

Date:

Annex IIX: Company registration form UAE

1. Detail of Medical Devices Company	
Company Name:	
City:	Country of origin:
Street:	
Web site:(*if available*)	Post Code:
Contact Name:	Email:
Telephone:	Fax:
Business registration number in country of origin:	Validity:
Name of the competent authority that issued the business License :	
Contact person:	Telephone:
Fax:	
Email:	

Please Indicate the nature of the Applicant? (click the appropriate boxes)

□ **Manufacturer** □ **Marketing Authorization Holder in Country of origin**

(for pharmaceutical products)

□ **Authorized Product rights owner in Country of origin**

□ **Others, Please specify _____**

Please tick the type of products manufactured by your company

□ ***Active Implantable Medical Devices***	□ ***In-Vitro Diagnostic Medical Devices***
☐ ***Non Invasive Medical Devices***	☐ ***Electro Mechanical Devices***
☐ ***Invasive Medical Devices***	☐ ***Single Use Devices***
☐ ***Non Active Implantable Devices***	☐ ***Ophthalmic and Optical Devices***
☐ ***Dental Devices***	☐ ***Tissues of Animal Origin***
☐ ***Lab Reagent***	☐ ***Accessories***

☐ **Others , Please specify_____**

2. Manufacturing Facility

Please complete the following information about each facility / location included in this assessment.

Main Manufacturing sites

City: Country:

Address:

Post Code:

Tel: Fax:

Email:

No. of employees (for Medical Devices) at the manufacturing site

Brief description of the facility and principal activities occurring at this site:

(Further details may be attached on a separate sheet, In case of Pharmaceutical Dosage Form please specify the production line according to the dosage form (solution, injection, cream …..etc).

List of other Manufacturing site (s) subsidiary/contracted with the company

S.N.	Name of Site	City/ Country	activities occurring at this site	Type of Quality
1				
2				
3				
4				
5				

3. Details of the Local Distributor

Name of Medical Store:

Address

Emirate: City:

Postal Code:

Contact person:

Tel: Fax:

Email:

Medical Store License No.:

Expiry Date :

Is the Local distributor different than local authorized representative? □ ***YES*** □ ***No***

If YES, please fill the below mentioned detail of local authorized representative

A. Details of the Local Authorized Representative

Name of establishment :

Business Registration No.

Is your Establishment registered with Ministry of Health (Scientific Office)

☐ ***YES*** ☐ ***No***

Address

Emirate: City:

Postal Code:

Contact person qualified (please attach his qualifications according to the guideline):

Tel:	Fax:

Email:

Power of Attorney authorizing the Local authorization Holder is enclosed ?

☐ ***YES*** ☐ ***No***

B. Quality Management System (QMS)

1. Please tick below the standards with which the QMS complies:

☐ **ISO 9001: 2000**

☐ ***ISO 13485:1996***

☐ ***ISO 13485:2003***

☐ ***Good Manufacturing Practice***

☐ ***Others, please specify…….***

Name of certification body & its validity :

2. Type of an established Quality Management System?

☐ ***Full Quality Management System (design, production post production process,…etc)*** ☐ ***Partial quality management system***

If full management quality system please mention the name and type of certification, & if partial quality management system, please specify the scope.

3. Does the manufacturer outsource any process (e.g., design & Development, manufacturing, warehousing, sterilization, etc.)

☐ **Yes** ☐ **No**

If yes please fill the information mentioned below:

Name of Facility

Address

City: Country:

Postal Code:

Enter the details of Conformity Assessment Body approval of quality system for sterilization or measuring function relevant to the Devices(s)

***Please list any Certifications currently held by company**

	Type Certification	**Certified by:**
1.		
2.		
3.		
4.		

C. Countries that Devices are approved and sold

	Country	***Devices Name*** *(Please list five Devices from different authorities if available)*	***Authority that issued the approval for marketing***
1.			
2.			
3.			
4.			

D. Documentation Procedures

Describe briefly the content of each selected procedure. A copy of the documented (Glob SOP) procedures shall be enclosed	
Distribution Record	
Complaint Handling	
Adverse Event Report	
Recall	
Alert and Modification	

E. Products

Please give some 2-3 examples of Family Devices manufactured and/marketed by your company

Please attach products list with their main description (use, and general lay name)

F. Declaration

I hereby declare that all the information I have provided is correct and all the attached documents are genuine; I will inform the Ministry about any changes to this information.

Name of company:

Name of Authorized person

Position

Signature:

Date:

Stamp of Local Authorized Representative

Stamp of legal manufacturer

Annex IX: Product registration application form UAE

UAE			
Application For Medical Devices / IVD			
1. DETAIL OF LOCAL DISTRIBUTOR			
Authorized Distributor			
Contact person			
Address /Street			
City:			
Email::		Tel:	
Detail of Drug Store License			
No. Of License		Date of Renewal	
2. DETAIL OF THE LOCAL AUTHORIZED REPRESENTATIVE			
Name			
Address /Street			
City		Emirate:	
Postal Code			
Email:		Tel:	
3. DETAIL OF THE AUTHORIZED REPRESENTATIVE (product's rights owner) IN COO / MANUFACTURER			
Name			
Address /Street			
City		Country	
Postal Code			
Email:		Tel:	

4. DETAIL OF MANUFACTURING FACTILITY INVOLOVED IN THE MAUFACTURING			
Name of Manufacturing Site	**Address /Street**	**City/Country**	**Activities occurring at this site**

Is the manufacturing facility registered in Registration and Drug Control Department ?

Yes **No**

If yes, copy of certificates is Requiredd If No, the local authorized representative should submit all related documents along with this application

5. DETAIL OF THE DEVICES / IN VITRO DIGNOSTIC KIT	
Brand Name / Family Devices	

Description **Of the Devices**				
Qualitative and Quantitative composition *(In case of Dosage Form)*				
S.N	Name of Substance	**Quantity**	**Unit**	**Reference**
1				
2				
3				
4				
5				
6				
7				
8				
Class of the Devices **According to the UAE Classification**		**Class 1** **Class 2** **class 3** **Class 4**		
Class of the In Vitro Diagnostic		**Class A** **Class B** **Class C** **Class D**		
Type of Devices		**Active Devices** **Non Active Devices** **Invasive Devices** **Non Invasive Devices** **In Vitro Diagnostic Kit**		
Description of the rule				
Intended use of the Devices/IVD				
Contraindication against use of the Devices /IVD				
User precaution				
Disposal/ **Environmental Precaution**				
Cleaning /or Sterilization procedures ***(if Applicable)***				
Performance & Safety ***Type summary of risk analysis conducted*** ***(applicable for class 3,& 4)***				
Type of Test Performance				
Storage Conditions				

Detail for Safe Handling	
Condition to avoid ***If applicable***	
Summary of Clinical Evaluation ***(If applicable)***	

Please tick √ the appreciate box if YES or NO	**YES**	**NO**
The Devices incorporates, as an integral part, a medicinal product which act on the human body with action ancillary to that of the Devices		
The Devices is manufactured from or incorporating human cells/tissues/ derivatives		
The Devices is manufactured from or incorporating animal cells/tissues/ derivatives		

Please specify the classification system of the above mentioned Devices / In vitro diagnostic Medical Devices in other competent authorities if applicable

In case of not applicable, please tick √

GHTF	**□ Class A □ Class B □ Class C □ Class D**	**Not Applicable**
EU	**□ Class 1 □ Class 2a □ Class 2b □ Class 3**	
Australia	**□ Class 1 □ Class 2a □ Class 2b □ Class AIMD**	
Japan	**□ Class 1 □ Class 2 □ Class 3 □ Class 4**	
Canada	**□ Class 1 □ Class 2 □ Class 3 □ Class 4**	
USA	**□ Class 1 □ Class 2 □ Class 3**	
Singapore	**□ Class 1 □ Class 2a □ Class 2b □ Class 3**	
China	**□ Class 1 □ Class 2 □ Class 3**	
Taiwan	**□ Class 1 □ Class 2 □ Class 3**	
Malaysia	**□ Class 1 □ Class 2 □ Class 3 □ Class 4**	

In vitro diagnostic Medical Devices

EU	**□ List A □ List B □ Self Testing Devices**	**Not Applicable**
USA	**□ Class 1 □ Class 2 □ Class 3**	
Canada	**□ Class 1 □ Class 2 □ Class 3 □ Class 4**	
Japan	**□ Class 1 □ Class 2 □ Class 3 □ Class 4**	

Others, Please specify:

……
…….

Marketing Approval Status in other countries (please tick *√ the appropriate boxes if applicable)*

Please attach evidence in registration file

□ US FDA

- **○ Pre market Approval**
- **○ Supplementary**
- **○ Investigational Devices Exemption**
- **○ 510(k) Clearance**
- **○ Certification for Foreign Government**

□ EU Medical Devices Directive(CE Marking)

- **○ EC Design Examination Certificate**
- **○ EC Type Examination Certificate**
- **○ EC Certificate for quality System/GMP**
- **○ Full Quality Assurance system**
- **○ Production Quality Assurance**
- **○ EC Declarations of Conformity**

□ Australia TGA Clearance/Approval

□ Canada TTP Clearance/Approval

□ Japan MHLW Clearance/ Approval

Others, Please Specify

……

please tick *√ the appropriate boxes*

History	**Yes**	**No**
The Devices has been recalled in the C.O.O or any country product marketed or in progress?		
The Devices has been revoked/ banned in the C.O.O or any country Devices marketed ?		
Has there been any reportable adverse incidents bearing implications to the advice?		
Pro-active post market surveillance studies?		
Repair & Servicing	**Yes**	**No**
The Devices is intended for single use and non repairable		
The Devices Requireds regular servicing/testing/checking/calibration		
Repairs and servicing provided by local authorized representative or by contracted other party in UAE (if by other party please		

Technical support provided by the manufacturer		

Declaration Of Conformity (check list)

Submit a written Declaration of conformity states the following:

1. **That Devices complies with Conformity assessment elements that include quality, safety and effectiveness Requiredments.**
2. **conformity to appropriate quality systems in production and design**
3. **Information sufficient to identify the Devices including its nomenclature**
4. **The name and address of the Devices manufacturer**

6. Declaration

We confirm that the information contained in our application is true and correct and that our Devices are merchantable quality and fir for the purposes for which they are commonly bought.

Signature	
Name	
Position	
Contact telephone	
Date	

Stamp of Company

Annex X: Application Form for Pre-qualification of Manufacturers of Medical Supplies to Participate in Ministry of Health Tenders Oman

Sultanate of Oman

Ministry of Health

Directorate General of Medical Supplies

Directives:

- This application form should be filled by the manufacturer electronically in MOH website www.moh.gov.om
- All Requiredd documents should either be in English or Arabic.
- Arrangement of original hard copy should follow the same sequence in this form and to be submitted to Department of Specifications & Supplies in the Directorate General of Medical Supplies.

PART - I :

1- Type of Application:

- New ☐

- Re-qualification ☐

2-Payment of pre-qualification fee:

- Cash receipt No: ……

- Receipt date: ……

Note: Original payment receipt to be submitted by the Local Agent in Oman along with the original pre-qualification documents.

3- Details of the local Agent in Oman: -

Agent Name:	
Post Box:	
Code No:	
Tel. No:	
Fax No:	
Email Address:	
Authorised person	

4 – Authorization letter from manufacturer for local agent confirming:

- Full Authorization for all products ☐

- Authorisation for specific products ☐

(List of products to be attached)

PART - II :

1- Factory Details

- Factory Name	
- Date of Establishment	

2- Address of Factory in the country of origin

Street No.	
City:	
P.O. Box:	
Postal Code:	
Country:	
Tel No.	
Fax No.	
E-mail address:	

3. The Manufacturer is specialized in :

- Medical laboratory & blood bank Products ☐

- Hospital sundries supplies ☐

- Renal Dialysis supplies ☐

- Oral Dental Health Care products ☐

- Orthopaedic products ☐

- Medical Rehabilitation Supplies ☐

- Cardiovascular Surgery Supplies ☐

- Surgical Instruments ☐

- Other Medical products ☐

4- Number of Factory Branches: ☐

5- Locations of Factory Branches:

Sr. No	City Name	Country Name
1.		
2.		
3.		
4.		
5.		

6- Statement of Manufacture's capital assets and date of establishment and its type.

7. Number of Employees

Departments	Executive	Engineers	Specialists	Technicians	Others	Total
Research						
Production						
Quality Control						
Packaging						
Total Number of Employees =						

8 – Requiredd Documents

The certificates shall be attested by the concerned Authorities in the Country of Origin and Embassy of Sultanate of Oman or its representatives

	YES	NO
A. A Certificate issued from Manufacturer nominating a Local Agent or deputed body to submit the prequalification Requiredments to MOH.	☐	☐
B. A Certificate issued by Concerned Authorities in the country of origin indicating that the company is a Manufacturer or Assembler licensed to manufacture medical supplies in the country of origin, and subjected to periodical technical inspection and its products are sold in country of origin.	☐	☐
C. Quality Assurance Certificate from the concerned authority ensuring that the manufacturer fulfills the GMPGMP) Requiredments in accordance with FDA/CE/ISO, etc.	☐	☐
D. A Quality Certificate issued by Concerned Authorities for its manufactured products i.e. equipment, Medical diagnostic reagents and other Medical Products such as ISO 9001: 2000/ ISO 13485: EN 46001, FDA.	☐	☐
E. A Certificate issued by Concerned Authorities in the country of origin for products made from Plasma or blood derivatives confirming that they are free from any causative agents like HIV, Hepatitis and all other types of infective viruses.	☐	☐
F. Site Master Plan File.	☐	☐
G. For surgical implants like orthopaedic or cardiovascular, supportive Certificates, scientific researches and clinical studies carried out in the Country of Origin and developed countries should be submitted to ensure the quality, efficacy and safety of their use.	☐	☐
H. List of all products manufactured by the Company with their generic names, trade names, catalogue numbers with set of catalogue.	☐	☐
I. Statement of the branches and their activists with Legal, Technical and Financial responsibility of the parent company towards its affiliated branch.	☐	☐

J. List of countries where manufacturer products are marketed along with documentary evidence proving marketing of these in at least 3 of these countries: -

Sr. No	Country
1.	
2.	
3.	
4.	
5.	

We ……

Certify that we have never been convicted due to forgery or commercial fraud in the country of origin or in any other country.

Auth. Name: . …….

Job Title: ……

Signature/Stamp…….

Date: ……

For official use only (by MOH, Oman)

Request No	
Date	
Staff Name	
Concerned department	
Signature	

Annex XI: Checklist for foreign manufacturers

Israel

CHECKLIST FOR FOREIGN MANUFACTURERS

Manufacturer Name:_____

Devices/Product Name: _____

List of Attachments/Information	Attached YES / NO	BioMedical's Comments	Manufacturer's Comments	FILENAME of Applicable Document
• Devices Class • Indicated population – adults/Children/neomates	☐**YES** **NO** ☐			
• Worldwide List of Sales - Per Country	☐**YES** **NO** ☐			
• Worldwide reimbursement Status - Per Country	☐**YES** **NO** ☐			
Regulatory Approvals (based on the Israeli MOH list of Recognized Countries) If **Yes**, Please attach the formal approval by the specific authority				
1. EuropeanCE MARKING EC Design Examination	☐**YES** **NO** ☐ **N/A** ☐			
2. Declaration of Conformity (DOC)	☐**YES** **NO** ☐ **N/A** ☐			
3. US FDA Clearance/Approval	☐**YES** **NO** ☐ **N/A** ☐			
4. MOH Australia New Zealand – TGA **Registration Only**	☐**YES** **NO** ☐ **N/A** ☐			
5. Health Canada	☐**YES** **NO** ☐ **N/A** ☐			
ISO 13485 Certificate (QA)	☐**YES** **NO** ☐			
ISO 9001	☐**YES** **NO** ☐ **N/A** ☐			

CHECKLIST FOR FOREIGN MANUFACTURERS

Manufacturer Name:_____

Devices/Product Name: _____

List of Attachments/Information	Attached YES / NO	BioMedical's Comments	Manufacturer's Comments	FILENAME of Applicable Document
CATALOGUE	☐**YES** **NO** ☐ **N/A** ☐	IFU, Product brochure, User Manual		
Risk Analysis (**For Each Product)**	☐**YES** **NO** ☐ **N/A** ☐	To be provided for CLASS IIB (OR CLASS II –FDA) and CLASS products as submitted to the regulatory authority		
Clinical File **up-to-date** (**For Each Product)**	☐**YES** **NO** ☐ **N/A** ☐	Such as the Clinical Evaluation Report included in the Technical File for CE To be provided for CLASS IIB (OR CLASS II –FDA) and CLASS products as submitted to the regulatory authority		
Declaration of Foreign Manufacturer	☐**YES** **NO** ☐	Please fill **attached** declaration using Company letterhead		
Subcontractor Manufacturer for final product release	☐**YES** **NO** ☐	If **Yes,** please provide Regulatory Approvals		

Annex XII: Declaration of Conformity IRAN

Manufacture Letter head

We

Name of manufacture:

Country of origin:

Address/Tel/Fax:

Facility/ies (address):

European representative:

Declare under our sole responsibility that quality of

Name of product/s:

Model or Catalogue number:

UMDNS code: Classification:

IRAN Classification (Rule:---------)	A		EU Classification (Rule:---------)	I		US FDA Classification	I	
	B			I*			II	
				IIa				
	C			IIb			III	
	D			III				

Complies with all relevant Requiredments of:

FDA Regulation

(Registration number: ……, Establishment number :……

510 (k)number: k…… PMA number: P ……..)

Directive 93/42/EEC

(Annex: ……..)

Notified Body: Applied standard(s):

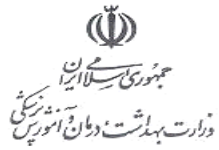
Standard No	Title	Description

Valid until:

Date/Signature/position/Stamp manufacture:

Date/ Signature/position / Stamp representative in Iran:

Annex XIII: Application for a medical Devices registration



ISLAMIC REPUBLIC OF IRAN
MINISTRY OF HEALTH AND MEDICAL EDUCATION
MEDICAL EQUIPMENT QUALITY AND PRICE REGULATORY DEPARTMENT

APPLICATION FOR A MEDICAL DEVICES REGISTRATION

Devices Registration Number

(Official use only)

Date (dd/mm/yy)

1. DEVICES NAME

Devices Name as it appears on label	
UMDNS Code	
UMDNS Term	

2. NAME AND ADDRESS OF MANUFACTURER AS IT APPEARS ON THE LABEL

Company Name
Street Address/P.O Box : City: Province/Stat e: Postal/Zip Code: Country:
Contact Name and Title :
Telephone No.: Fax No.
E-Mail Address :

3. NAME AND ADDRESS OF ORIGINAL EQUIPMENT MANUFACTURER (OEM) (if applicable)

Company Name
Street Address/P.O Box : City: Province/Stat e: Postal/Zip Code: Country:
Contact Name and Title :
Telephone No.: Fax No.
E-Mail Address :

4. DEVICES CLASSIFICATION

IRAN Classification	A		EU Classification	I		US FDA Classification	I	
	B			IIa			II	
	C			IIb			III	
	D			III				

5. DEVICES CATEGORY

Anesthesiology		Neurology	
Cardiovascular		Obstetrics & Gynecology	
Dental		Ophthalmology	
Ear, Nose & Throat		Orthopedics	
Gastroenterology & Urology		Physical Medicine	
General & Plastic Surgery		Radiology/Imaging	
General Hospital			

6. DOES THIS DEVICES CONTAIN A DRUG?

Yes _____

No _____

IF YES

Generic Name of Drug:

Brand / Trade Name of

Drug: Drug Manufacturer:

7. PURPOSE/INTENDED USE

A description of the medical conditions, purposes and uses for which the Devices is manufactured, sold or represented*: [Note: Failure to supply an appropriate level of detail may result in the application being rejected.]*

8. CONTRA-INDICATIONS

Details informing the users and/or patient and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken (where appropriate):

[Note: Failure to supply an appropriate level of detail may result in the application being rejected.]

9. DEVICES DETAIL

Please provide the following information, as applicable to registration application type, and where applicable for each component Devices, part or accessory. (Add Additional Copy if necessary)

Name of Devices, Components, Parts and/or Accessories as per product label	UMDNS Code	Model or catalogue number	Unit Price

10. In addition to items 1 to 9, of the Devices Registration Application following information is requested, please indicate (X) which of the relevant information Requiredments listed below are included as attachments to this

application. For details regarding content and format please refer to the GUIDANCE FOR "APPLICATION FOR A MEDICAL DEVICES REGISTRATION"

Cover Page	
Executive summary	
Table of contents	
Devices Description (principles of operation & materials used in construction and packaging, describing each of the functional components of the Devices, with labeled pictorial representation of the Devices in the form of diagrams, photographs or drawings.)	
Design Philosophy	
Marketing History	
List of Standards	
Method of Sterilization (if applicable)	
Summary of Safety and Effectiveness Studies (for class C and D only)	
Risk Management Report (for class C and D only)	
Material Specifications (for class C and D only)	
Labeling material	
Quality Management Certificate (ISO 13485)	
FDA Approval	
CE Approval	

We, the manufacturer, signed and stamped all documents which are attached and hereby certify that the information provided on this application and in any attached documentation is correct, complete and guarantee the quality of the products are exported to Iran. If any false data are found, we assume legal responsibility, and hold responsibility for all the consequences arising thereafter and this is grounds for refusal to issue registration certificate.

Name of Signing Official:

Title:	Managing Director		Sales Manager	
	Regulatory Affairs Manager		Other(Specify):_____	

Signed: _____

Date:_____

Annex XIV: Registration form For Medical Appliances & Lab Diagnostic kits Iraq

Appendix 4

First:- General Information

A	Name of company	
B	Main address	
C	Nature of activities (contract manufacturer , market authorize holder , etc	
D	Number of various working branches inside country of origin	
E	Number of various working branches outside country of origin	
F	Name and address of branch supplying the Iraqi market. N.B. if the branch supplying the Iraqi market is not the mother company. Pleas fill separate application for the mother company.	
G	Name and addresses of other companies that cooperate or share in its activities in the field of medical appliences, what sort of relation	
H	Year of foundation	
I 1)	Registered annual capital	
2)	Working annual capital (optional)	
3)	Sales annual capital – (optional)	
J	Total number of employees	
K	Product list	
L-1	Are these preparations totally or partially manufactured by the firm itself?	
L-2	If partially manufactured, what are these products, where manufactured, and why?	
M	Other activities besides	
N	Names other countries where products are marketed	

Second: Production Division

A	Origin of all raw materials	
	self manufacturing	
	Under license	
	Other sources	
B	Number and qualification of personnel working in the production division.	
C	Number of square meters assigned for production area	
D	Name, qualification and signature of the head of the dept.	

Third: Control Laboratories

A	Do you have control laboratories	
	For testing raw materials	
	For in process control	
	For testing final products	
B	what type of laboratory tests you perform?	
C	What type of laboratory equipments used for quality control?(may be submitted separately).	
D	Number and qualification of personnel working these labs?	
E	Do you revert to the aid of other laboratories for control purposes? Name these labs & indicate what sort of assistance.	
F	Number of square meters assigned for these labs.	
G	Give in details the activities performed by the competent authorities for controlling your establishment and production.(provide details & documentation)	
H	Name, qualification and signature of the head of the dept.	
I	I, the undersigned: (Full name of the person responsible for the establishment). Hereby declare that all information are given above is true, and I assume full responsibility for this declaration with all consequences, which might arise from false or erroneous information.	
	Date	
	Name of the establishment	
	Signature and Stamp:	

N.B.

Please sign and stamp each page of this form

Annex XV: Company Profile Lebanon

MINISTRY OF PUBLIC HEALTH - LEBANON -

MINISTERE DE LA SANTE - LIBAN -

PLANT PROFILE

A - GENERALITIES

A - GENERALITES

1. Name :

1. Nom :

2. Year of Foundation :

2. Année de fondation :

3. Responsible Person (s) :

3. Responsable (s) :

4. Main Office, Adress :

4. Siège Social, Adresse :

5. Factory: Location :

5. Usine: Adresse :

6. Total Number of Employees :

6. Nombre Total des employés :

B - ORGANISATION AND MANUFACTURING FACILITIES

B - ORGANISATION ET FACILITES DE FABRICATION

1. Number of pharmaceutical specialities manufactured

(Including all dosage forms of each Product.)

1. Nombre des Spécialités Pharmaceutiques fabriquées

(Y compris toutes présentations de chaque produit.)

2. Origin of raw materials. (Principal Active Ingredients.)

2. Provenance des matières premières (Principaux produits actifs.)

Origin Provenance No. No.

a) Your Manufacturing :

a) Propre fabrication :

b) Under Licence:

b) Accord de licence:

c) Other Sources :

c) Autres sources :

3. Do you have Control Laboratories ?
3. Possédez - vous des Laboratoires de Contrôle ?
a) For the raw materials used in manufacturing your specialities.
a) Pour les matières premières utilisées dans la fabrication de vos Spécialités.
YES OUI NO NON
b) For the manufactured Specialities.
b) Pour les Spécialités fabriquées.
YES OUI NO NON

4. Indicate the Control Laboratories you have.
4. Indiquer les Laboratoires de Contrôle que vous possédez.
a) Pharmacological Control
a) Contrôle Pharmacologique
b) Microbiological Control
b) Contrôle microbiologique
٢/٤
c) Toxicological Control
c) Contrôle toxicologique
d) Physico - Chemical Control
d) Contrôle physico - chimique
e) Others
e) Autres

5. What are the Registers (Records) kept for each Batch manufactured ?
Also what are the reference Samples kept in the Laboratory ?
Give details.
5. Quels sont les registres utilisés pour chaque lot de fabrication ?
Quels sont les échantillons de référence gardés au Laboratoire ?
Donner des détails.

6. For how long are these Records (Registers) and reference Samples kept ?
6. Pour combien de temps sont gardés les registres et les échantillons de référence ?

7. Number of Specialized Personnel working in the manufacturing of your
Specialities?
(Excluding Administrative Personnel)
7. Nombre du personnel spécialisé travaillant dans les laboratoires de fabrication?
(à exclure de ce nombre le personnel administratif)

8. Do you obtain the aid of official or governmental laboratories for control
purposes?
8. Obtenez-vous l'aide de Laboratoires officiels ou gouvernementaux pour le contrôle?
YES OUI ☐ NO NON ☐
a) Name Nom ……

b) Address Adresse ……
a) Name Nom ……
b) Address Adresse ……
a) Name Nom ……
b) Address Adresse ……

9. Do you obtain the aid of private laboratories (other than your own) for Control Purposes?
9. Obtenez-vous l'aide de Laboratoires privés (différent des vôtres) pour le contrôle?
YES OUI Í NO NON Í
a) Name Nom …….
b) Address Adresse …….
a) Name Nom …….
b) Address Adresse …….
a) Name Nom …….
b) Nom Adresse …….

10. What are the Specialities you export to Lebanon?
10. Quelles sont les Spécialités que vous exportez au Liban?

11. Are the same conditions and specifications imposed on Specialities manufactured for consumption in your country being enforced likewise on specialities intended for export?
11. Est - ce que les mêmes conditions et spécifications imposées aux Spécialités fabriquées pour la consommation locale, sont appliquées aux spécialités destinées à l'exportation ?

12. Explain in detail the type of control your government enforces on your establishment and on your products.
12. Expliquer en détail le mode de contrôle exigé par votre Gouvernement sur vos produits et sur votre établissement.
N.B: Use extra sheets when necessary.
Employer des pages additionnelles si nécessaire.

I the undersigned, (Full name of the person responsible for the manufacturer)
.....
.....
Hereby declare that all the information given above is true, and I assume full responsibility for this declaration with all consequences which might arise from false or erroneous information.
Date ..... Name of manufacturer, Signature and Stamp.
We hereby certify that the information given is true and that it comnplies with the reality and that the manufacturer concerned fulfils the Requiredments of the local regulations. Legalization of the Chamber of Commerce or similar Organization.
Legalization of the Lebanese Consulate/Embassy.
(Please sign and stamp each page of this document)

Je soussigné (Nom et prénom de la personne responsable du Laboratoire)

.....

.....

Déclare que les informations données ci-dessus correspondent à la réalité et assume l'entière responsabilité de cette déclaration avec toutes les conséquences qui découlent d'une déclaration fausse ou erronée.

Date ..... Nom du Laboratoire, Cachet et Signature.

Nous certifions que les informations données sont exactes et conformes à la réalité et que le Laboratoire en question répond aux exigences des lois du Pays. Légalisation de la Chambre de Commerce ou de son similaire.

Légalisation du Consulat du Liban/Ambassade.

(Prière de signer et tamponner chaque page de ce questionnaire

Annex XVI: Annex No. (5) of Tender No. 17 – 2011 Libya

Annex (5)

Tender (2011/17)

Item Code	Item Specifications	Quantity Required	Unit Pack	Piece/price	Total Price	Manufacturer	Site of Production	Shelf Life	Unit/Pack	Delivery Time

Name : .....

Signature : .....

Position : .....

Date : / / 2011

Stamp : .....