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Review Article

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Regulatory requirements for Medical Device Registration in Kingdom of Saudi Arabia, US and European Union

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Abstract

Understanding and observing regulatory norms is essential for the development and commercialization of medical devices. To assure the operation, safety, and effectiveness of medical devices while minimizing adverse effects, strict regulatory criteria are required as their use grows. The ability to offer the essential direction for proper registration by pertinent authorities, manufacturers, and importers has been made possible by recent recommendations. Medical device rules are now being implemented in many nations. Converging rules are essential to reduce regulatory barriers and speed up access to high-quality, secure, and effective medical devices since different countries and regions have different laws governing medical devices. The Global Harmonisation Task Force (GHTF), which strives to harmonise medical device regulatory regulations, is comprised of the majority of nations. Medical device regulations that are more uniform will make high-quality products more widely available. This article discusses the definition of a medical device in each of these areas, and it does so in the order of their proportion of the global market share. In this article, we looked at how major economies throughout the world regulate medical devices. This article's objective is to give a thorough review of the legal systems that govern the registration of medical devices in the European Union, the United States, and the Kingdom of Saudi Arabia. The current article discusses the classification of medical devices in the Kingdom of Saudi Arabia, the United States, and the European Union, as well as the registration procedure for medical devices.

Keywords: Global Harmonisation Task Force (GHTF), Saudi Food and Drug Authority (SFDA), United States Food and drug Administration (USFDA), European Commission, Medical devices.

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1. Introduction

A medical device is any piece of equipment intended for medical use. Because there is a significant danger of injury when using a device for medical reasons, governing authorities must demonstrate that the device is safe and effective with adequate assurance before allowing it to be commercialized in their country. In general, the amount of testing required showing the usefulness and safety of a technology develops in direct proportion to the danger the item poses. The potential benefit to the patient grows in direct proportion to the associated risk. (1)

The intended application and indication for the use of medical devices differ. From simple, low-risk devices like tongue depressors, medical thermometers, single-use gloves, and bedpans to sophisticated, high-risk implants that provide life support, devices with embedded software that aid in the performance of medical tests, such as pacemakers, implants, and prostheses, are high-risk. Medical device design is a key topic in biomedical engineering. (2)

It is difficult to define a consistent definition because many regulatory organisations from across the world monitor medical device marketing. Even though these groups constantly debate and promote the concept as a

whole, the correct definition of a medical device varies by location. This is due to minor phrasing discrepancies that impede worldwide harmonization of medical device definitions.

1.1 Kingdom of Saudi Arabia

According to the SFDA, a "medical device" is any apparatus, instrument, implant, reagent, laboratory calibrator, piece of software, or other thing that is comparable or connected:

- It is intended for use by humans alone or in collaboration with them for one or more of the following functions: disease alleviation, monitoring, prevention, treatment, and diagnosis. All these things can be done, including diagnosis, surveillance, care, prevention, and compensation. An injury or impairment causes the study, replacement, modification, or life support, design control, and cleaning of medical equipment related to anatomy or physiological processes. (3)
- Laboratory analysis of human body sample data to offer information for therapeutic or diagnostic purposes.
- The pharmacological, immunological, and metabolic systems cannot cause it to have the desired effect on the physical body, but they can aid in it. (4)

1.2 United States

A device is described as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is:

- Recognised in the official National Formulary or the United States Pharmacopoeia, or any supplement to them," in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act. (5)
- Intended for use in treating, curing, preventing, or mitigating disease in humans or other animals, or in the diagnosis of disease or other disorders;
- Designed to alter the structure or any function of an animal's or man's body, but which does not accomplish its main goals by acting chemically on, within, or on top of an animal's or man's body and which is not dependent on metabolism to accomplish its main goals. (6)

1.3 European Union

The health of people around the world depends greatly on medical devices, which are a crucial component of contemporary infrastructure. Today's healthcare is built on a foundation of medical technology, which is essential for providing safe and effective care as well as preventing, detecting, and monitoring sickness.

A medical device is defined as follows in accordance with the current European regulation 93/42/EEC on medical devices, often known as the Medical Device Directive (MDD):

"Medical device" refers to any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software required for its proper application that the manufacturer intends to use for human beings for the purpose of:

- Disease detection, prevention, monitoring, treatment, or relief
- The diagnosis, monitoring, treatment, or alleviation of an injury or handicap,
- Investigate, replace, or modify the anatomy or a physiological process; control of conception, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be aided in its function by such means. (7)

2. Medical Devices Regulatory Framework in KSA

Local medical device manufacturers, legal representatives, suppliers, and distributors in the Kingdom of Saudi Arabia must follow the Saudi Food and Drug Authority's (SFDA) medical device regulations (8):

a) All foreign medical device and product manufacturers must appoint a legal representative in the Kingdom of Saudi Arabia.

b) In the Kingdom of Saudi Arabia, local manufacturers and importers of medical devices and products must follow the following guidelines:

- Medical facilities must be registered with the Food and Drug General Authority's National Register of Medical Devices.
- The Authority's national register of medical devices is where all medical items and devices intended for marketing in the Kingdom of Saudi Arabia must be declared and registered.

c) MDEL licencing authorizations must be obtained by local importers, manufacturers in charge of the distribution of medical products, and the legal representatives of manufacturers in charge of the supply and distribution of medical equipment and products.

d) A written marketing permit must be obtained in accordance with the regulation of medical devices before presenting, offering, or using a medical product or product in the Kingdom of Saudi Arabia prior to its registration with the Food and Drug General Authority.

e) The medical device must adhere to Saudi criteria relating to the specifications to

guarantee and/or use the medical device, in addition to at least one rule of the countries of the World Homogeneity Team, in order to receive a marketing licence in the Kingdom of Saudi Arabia.

f) In addition to the above-indicated circumstances as stated in the reference to the General Food Authority's recommendation for the drug MDS-ANS021 05/14 published on the authority's website, all medical devices and drugs that are to be sold in the Kingdom of Saudi Arabia must first obtain approval from the SFDA based on the device's classification and severity.

2.1 Classification of medical devices in Saudi Arabia

The Regulatory Framework for Medical Devices comprises a medical device category system based on the classification requirements provided in the Guidance Document "Guidelines for Medical Device Requirements" for Registration and Marketing Authorization (MDS-G5). (9)

Table 1. The classification levels for devices other than IVD medical devices (9,10):

Class	Medical Devices		IVD Medical Devices	
	Level	**Devices examples**	**Level**	**Devices examples**
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 Medical device regulations in Saudi Arabia

- Most medical device laws are concentrated on the IMDRF and, consequently, the Global Harmonization Task Force because Saudi Arabia is a member of the AHWP (GHTF).
- Because of these regulations, Saudi Arabia can only commercialise medical devices that have been authorised by one of the IMDRF's founding members.
- The SFDA was founded in 2003 and is still striving to build the regulatory framework for the registration of medical devices.
- The Food and Drug Administration has a temporary regulatory regime for medical devices (MDIR). Saudi Arabia's General Food and Drug Authority, which is a part of the Saudi Cabinet of Ministers, is in charge of regulating the use of medical devices there.
- A group of electronic technologies and solutions that make it feasible for producers, authorised representatives, importers, distributors, and other parties to successfully connect with the FDA enable MDIR.
- The medical device marketing authorization (MDMA) (Medical Device Marketing License) portion of the FDA website offers electronic application forms. The registration application shall be processed by a local representative on behalf of the multinational producer. (4)

2.3 Required documents

According to article 18 of MDIR, to register a medical device, the applicant is asked to submit the following documentation to SFDA (11):

a) Application form (Annex V):

b) Letter of Authorization (LOA);

c) Manufacturer and Saudi Authorization representative details;

d) GMP certificate or QM system certificate (ISO 13485, ISO 9001);

e) Recent Audit Report:

f) Other certificates as required by the devices class;

g) Documents supporting the market authorization in reference IMDRF market;

h) Declaration of Conformity, written in English;

i) Meets the legal criteria of the appropriate IMDRF Founding Member jurisdiction as

well as the national rules of this interim regulation.

j) The applicant must provide documentation proving that the device at the centre of the MDMA application conforms to the applicable medical device law in the selected GHTF Founding Member jurisdiction, as well as the compliance assessment procedure that was applied.

k) The National Center for Medical Device Reporting (NCMDR) mandates that any safety-related corrective action involving medical devices be reported to the authorities in the Kingdom of Saudi Arabia (KSA).

l) In addition, the following technical documents must be submitted: In English and/or Arabic, a copy of the Medical Devices information, including labelling, intended use, instruction for use (IFU), and marketing materials; Specifications or other documentation that ensure that Medical Devices are processed, transported, assembled, and maintained correctly in the KSA, and users should be educated on how to use them properly; any relevant adverse events involving Medical Devices should be reported to the SFDA's National Centre for Medical Devices Reporting (NCMDR).

2.4 Medical device technical documentation

The following components must be contained in the technical documentation in a clear, organised, easily searchable, and unambiguous manner (11,12):

I. A description and specification of the device This section defines the device and related accessories, including variants. The following details, which must include details on the variations and accessories covered by the technical documentation, must be documented:

a) The product or brand name of the apparatus (list all products or variants that are covered by the technical file, including any accessories).

b) An unambiguous means of clearly identifying the gadget, such as a product code, model number, catalogue number, etc.

c) Description of the device, including:

i. What the device looks like (physical description);

ii. What parts it comprises of (components/parts/spares/accessories);

iii. What it is made of (materials and which of these have direct or indirect contact with the human body);

iv. Principles of operation/mode of action (how it works/operates);

v. Any specific performance characteristics it has (and how they different between models); and

vi. What options/configurations/sizes.

d) Picture or drawing of the device (this should also be detailed enough to aid understanding of the device operation and include sufficient explanation to understand the drawing).

e) Intended purpose of the device, including:

i. Key indications;

ii. Medical conditions;

iii. Patient populations; and

iv. Contraindications (e.g., age, gender, parts of the body, if suffering from another disease, pregnant, or breast feeding).

f) Intended users of the device:

i. Patient/clinician/career and

ii. Any user restrictions.

g) The basis for the device's qualification (i.e.., why is it being regulated as a medical device this applies also to devices which have no medical purpose but are regulated as devices).

h) The device's categorization in line with the rules for classification (this should include the device's class and all applicable rules, along with a justification of the class/rule selection for the device and any accessories).

i) A description of any novel elements (examples of novel features include new to market technology, new types of materials used, or new application of existing technology).

j) A more thorough explanation of any accessories (if not completely described previously). Description of any devices required to operate the device that are not included (e.g., IT infrastructure, laptop, and mobile "smart" phone).

k) configurations, (detail what configurations are available for the market if applicable).

l) Device history: provide an overview of the previous generation or generations of the device, if applicable.

m) Device market share (Are there similar devices in Saudi Arabia or other international markets)?

n) Declarations (does the product require any special disclosures to be made, such as whether it contains derivatives of human blood, animal tissue, or medications?)

II. Information to be provided by the Manufacturer

Information provided by the manufacturer conveys information to the user or clinician and is a key part of the technical documentation. The technical documentation shall include a full set of labels for the device and packaging which includes the instructions for use (IFU) and any promotional mate rial as applicable. Where the manufacturer has placed information on their website, this should also be identified.

2.5 The approval process for medical devices in Saudi Arabia

a) The provisional medical device regulation (MDIR), decree no 1-8-1429/2008, states that before being distributed in the KSA, medical devices must receive marketing permission from the SFDA. Your product must have acquired prior market approval in one of the following relevant markets: Australia, Canada, the European Union, Japan, or the United States. Your device's KSA categorization will be determined by how it is categorised in your reference market.

b) Choose a Saudi Approved Representative (AR) to manage the registration of your device in the Kingdom of Saudi Arabia. Your representative must be accepted by the SFDA. Your contract with your AR must also be approved by the SFDA.

c) In order to represent you in the Kingdom of Saudi Arabia, your Saudi AR must submit an authenticated AR contract to the SFDA for inspection and approval. The AR contract and licence may be in effect for a period of one to ten years, but neither may outlive the other.

d) Create an MDMA request and send it to your AR. The application also includes information on device marking, IFUS, marketing materials, regulatory approval documentation for your reference market, and certification of your quality system (if applicable). Labelling, promotional materials, and IFUS must be in Arabic and English; English should only be used for technical devices.

e) The SFDA examines the MDMA filing to finish it. A third-party conformity assessment body (CAB) performs a thorough technical investigation when the application fee is paid.

f) The SFDA bases its final decision on the CAB's recommendations. The distributor or importer may use the MDMA certificate that the SFDA issues when a device is certified to put it on the market.

g) The device registration is valid for three years, or for as long as the reference nation is still in effect (if less than three years). (12,13)

2.6 Post marketing surveillance of medical device

a) Monitoring medical devices is a procedure in which an incident involving a medical device that has been approved to be sold and used in Saudi Arabia and of which the manufacturer has been notified is investigated by the manufacturer and reported to the SFDA as necessary.

b) Where warranted, the manufacturer and/or the SFDA should take all necessary steps to minimize or eliminate the risk of a repeat incident. (13)

3. Medical Devices Regulatory Framework in US

The Federal F, D, and C Acts govern medical device regulation in the United States. Before a medical device can be commercialised in the United States, a marketing application must be submitted to the Food and Drug Administration (FDA) and approved. The FDA's Centre for Devices and Radiological Health (CDRH) is primarily responsible for pre- and post-market surveillance of medical devices in the United States. Medical devices in the United States are categorised based on the risk associated with their use, using a method known as "risk-based categorization." Device classification is accomplished in three stages. (14,15) (Table no. 2).

- Class I, the least risk
- Class III—highest risk
- Class II: Intermediate Risk

3.1 Class I devices

These are medical devices that do not endanger the health or safety of patients. Class I (lowest risk) devices are subject to general controls, which are broadly accepted criteria for labelling, manufacture, post-market surveillance, and reporting. When there is a reasonable likelihood that general controls alone will be sufficient to ensure safety and efficacy, a device is classified as class I. Furthermore, the FDA has been given authority to take countermeasures such as seizures and the right to recall items. Most class I devices are not subject to a formal FDA examination before they are placed on the market. There is no necessity for the FDA to independently analyse a product's safety and efficacy prior to its introduction. Examples of class I items include handheld surgical instruments, tongue depressors, crutches, and other items. (15)

3.2 Class II devices

Class II medical devices are more dangerous because generic controls are insufficient to ensure efficacy and safety, and there is sufficient evidence to recommend the need for particular controls. Because they pose a higher risk of injury than class I devices, these devices are subject to stricter examination and certain restrictions, which the FDA may approve. Furthermore, before being marketed, most class II devices require FDA approval via the 510(k) premarket notification process. During the 510(k) process, medical device manufacturers must demonstrate that the new product is an identical reproduction of an item that has been legally marketed.

Simply put, a small proportion of 510(k) submissions require clinical data, which is frequently supported by bench and animal research. (16,17)

3.3 Class III devices

Class III medical equipment either supports or sustains life or minimises the danger of harm to a person's health significantly. Pacemakers, heart valves, coronary stents, and other class III devices are examples. Because they are regarded as posing the greatest risk of illness or harm, general and control procedures are deemed insufficient to ensure safety and efficacy. As a result, many class III medical devices require FDA premarket approval (PMA) before they can be used.

Table 2. Medical Device Classification System (14)

Device Class	Risk Level	Examples
Class I	Low	Elastic bandages, examination gloves
Class II	Moderate	Powered wheelchairs, Infusion pump
Class III	High-risk	Heart valves, Silicone gel-filled breast implants

3.4 Premarket notification 510(k) process

A 510(k) is a premarket file submitted to the FDA to demonstrate the safety and efficacy of a commercially available device. Most class II devices (termed 510k) require pre-market entry notification. In essence, this is a less stringent regulatory evaluation method than the PMA approach. The 510(k) application must establish the new product's resemblance to an existing US market product. (16,17)

3.5 PMA process

All Class III devices are evaluated for efficacy and safety during the PMA process. This is one of the most stringent systems for regulating medical equipment. Before marketing approval, clinical trials demonstrating the product's safety and effectiveness are required under the PMA process. Due to the high degree of risk associated with these products, the FDA has determined that general and special controls alone are insufficient to assure the safety and efficacy of Class III devices. (17–19)

3.6 Registration process

- ***US FDA Registration Process for Medical Devices and IVDs (20–24):***

Step 1: Search the FDA classification database for another (predicate) device that has the same technology and intended application as the medical device or in vitro diagnostic (IVD) device. The three-letter product code and seven-digit regulation number of the predicate devices should be given special consideration. If the categorization cannot be determined, use the 513(g) method to contact the FDA for classification.

Step 2: The majority of QSR criteria are waived for a few Class I devices. Create a quality management system (QMS) that meets the FDA Quality System Regulation (QSR) for Class II and III devices, as defined in 21 CFR Part 820.

Step 3: All innovative Class II and Class III devices will undoubtedly require clinical studies. Obtain FDA "pre-submission (pre-sub)" comments.

Step 4: If clinical trials are required, submit an investigational device exemption (IDE) application. Create a clinical trial protocol, then carry out the research. With IRB permission, non-significant-risk research can be conducted.

Step 5: Prepare and submit an application for a 510(k) Premarket Notification for a Class II device, as well as pay the requisite cost. Create and submit a premarket approval (PMA) application for a Class III device. Make payment for the PMA submission cost.

Step 6: The FDA inspects the manufacturer and any significant suppliers who contributed to the design and production of your Class III device. The FDA QSR must be followed by all parties.

Step 7: For Class II devices, the FDA issues 510(k) approval letters, which are made available online.

Step 8: The application must be totally compliant with QSRs at this time. The FDA will not examine Class I or II device producers' compliance before registering a device, but after registering a device, the FDA may conduct arbitrary inspections and issue a Form 483 for noncompliance.

Step 9: If the applicant does not have a physical presence in the United States, select an FDA US agent representative to act as your local point of contact with the FDA.

Step 10: Using the FURLS system, register the organisation and list the device on the FDA website. In addition, you must pay annual costs for establishment registration and listing.

Step 11: The applicant is now free to promote and sell their goods in the United States. The FDA website will include information on the company as well as the progress of the device registration. The applicant's authorization remains valid as long as the device's

intended purpose, design, or other specifications are not changed.

The FDA automatically classifies devices with a novel intended use or cutting-edge technology as Class III. A De Novo classification proposal allows for the investigation and marketing of a novel device as a Class I or II device if its minimal risk is demonstrated. This diagram does not depict the De Novo process. Class I devices, despite being exempt from FDA QSR implementation, must nonetheless comply with some aspects of FDA 21 CFR Part 820, such as the recordkeeping and complaint file requirements (24-27) (21 CFR 820.180).

Table 3. Legal procedures for different classes of medical devices in US (16,17)

Class	Necessary procedures for the medical device marketing
Class I	Registration 510(k) clearance may be required
Class II	510(k) clearance Investigational device exemption is possible
Class III	Premarket approval application 510(k) clearance Investigational device exemption is probable

4. Medical Devices Regulatory Framework in European Union

Three EC Directives govern the use of medical devices in the European Union:

- Directive 93/42/EEC on medical devices,
- Directive 98/79/EC on in vitro medical devices and
- Directive 90/385/EEC on active implantable medical devices

These directives established criteria for the marketing of medical devices in all European Union member countries. (28)

According to Annex IX of Directive 93/42/EEC, the "risk-based" system is used to classify medical devices. It was classified into four product classes: Class I, Class IIa, Class IIb, and Class III. Class I and IIa devices are considered low-risk, and the manufacturer may claim conformity with the essential standards solely based on self-evaluation without consulting the Notified Body (NB). Notified bodies must be involved in Class IIb and Class III. (29)

The way that devices are regulated in the EU and the US varies significantly from one another, particularly with regard to the clinical evidence required for premarket authorization. A medical device must be CE-labelled in order to be marketed in the EU, and the manufacturer must follow EU directives in order to receive a CE certificate. The inspection will be carried out by the relevant body, which is in charge of overseeing device certification in each country, to confirm manufacturing standards and technical information. High-risk equipment is directly managed by the Notified Bodies, which are determined by the manufacturer in any EU country. For items in higher-risk classes, competing authorities should receive design assessments and CE certificates from notified organization. (30)

4.1 CE marking

Medical device manufacturers are required to CE-mark their products to ensure that they are safe and suitable for their intended usage. The English abbreviation for "Conformité Européenne" in French is "CE". A manufacturer can certify that a product complies with the key requirements of any applicable European regulations on health, safety, and environmental protection by placing the CE Marking on it. Additionally, it guarantees the product's unrestricted access to the EFTA and EU single markets. The CE marking is handled by the notified bodies. (31)

4.2 Notified Bodies (NBs)

A private or public entity that has been accredited certifies the device's compliance with the European Directive. Manufacturers are able to choose their preferred NBs from among the EU members. The competent authorities in each state will select the notifying bodies, and the NBs will have the power to grant the CE mark. (32)

4.3 The European CE medical device approval process

Step 1: Choose the EU Medical Device Directive that applies to your device. Active Implantable Medical Devices Directive (AIMDD) or Medical Devices Directive (MDD) 93/42/EEC:

Step 2: According to Annex IX of the Medical Devices Directive (MDD), your equipment should be classified as either Class I (non-sterile, non-measuring), Class I (sterile, measuring), Class IIa, Class IIb, or Class III/AIMD. The same regulatory requirements that apply to active implanted medical devices also apply to class III devices.

Step 3: Put a Quality Management System (QMS) in place for all devices except Class I (non-sterile, non-measuring) devices in line with Annex II or V of the MDD. Businesses often employ the ISO 13485 standard to achieve QMS compliance.

Officially, Class I (non-sterile, non-measuring) products are exempt from the need for a QMS. The PMS method is required (NB), even though it is not audited by a notified organisation.

Step 4: Create a technical file for Classes I through IIb that details your medical device in detail and proves compliance with 93/42/EEC. All devices will require clinical data. Most of these facts ought to be relevant to the gadget in question. A design dossier for Class III/AIMD devices should be prepared. Clinical studies are necessary for Class IIb and Class III implants, but pre-existing clinical data may be acceptable. Clinical research carried out in Europe must first have pre-approval from a competent European authority.

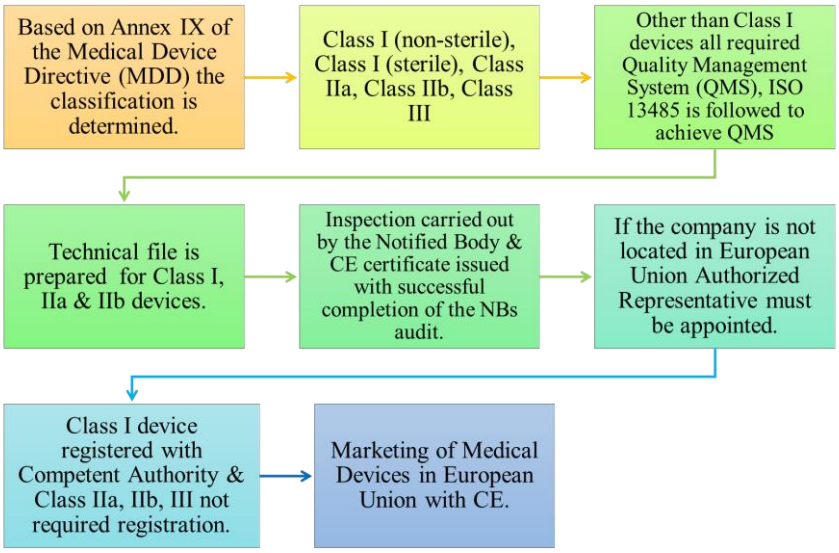

Figure 1. Registration Process of Medical Devices in EU (33)

Step 5: If you don't already have one, choose an authorised representative (EC Rep) with a presence in Europe. The EC Representative should be qualified to handle regulatory issues. On the label, packing, or usage instructions for the device, provide the name and address of the EC REP.

Step 6: For all devices other than Class I (non-sterile, non-measuring) devices, your QMS and technical file, or design dossier, must be inspected by a recognised body, a third party authorised by European authorities to assess medical device enterprises and products.

Step 7: Following a successful Notified Body audit, you will receive an ISO 13485 certificate for your facility as well as a European CE Marking Certificate for any devices other than Class I (non-sterile, non-measuring) equipment. The ISO 13485 certification needs to be renewed annually. A CE marking certificate typically lasts for three years.

Step 8: Produce a Declaration of Conformity, which is a document the manufacturer creates to certify the item conforms to the pertinent directive. You may now request the CE marking.

Step 9: You or your EC REP must register all Class I devices with the competent authority where you are headquartered. Some EU nations require additional registration before Class IIa, IIb, or III devices can be marketed there.

Step 10: Class I (non-sterile, non-measuring) products do not require annual NB audits. However, you are required to complete PMS chores and CER updates.

A Notified Body will audit you yearly for all other classes to make sure you are still in compliance with Regulation (EC) No. 93/42/EEC or Regulation (EC) No. 90/385/EEC. If you don't pass the audit, your CE marking certificate will no longer be valid. CER updates and PMS duties need to be finished. (34,35)

The Medical Device Directive (MDD) has governed the safety and marketing of medical devices in Europe since the 1990s. In contrast to the United States, the European Union (EU) has a four-tiered system. Class I devices, which include Is and Im, are classified as IIa, IIb, and III. Class III is the highest classification, and the higher the classification, the more scrutiny is applied. Medical equipment cannot be marketed in the European Union unless it meets the EU's stringent requirements, one of which is the use of the CE (Conformity with Europe) designation. (34-36)

Table 4. Medical Device Classification system for EU (35)

Class	Risk Level	Examples
Class I	Low	Chemistry analyzer
Class IIa	Low - Moderate	Urine test strips
Class IIb	High - Moderate	Blood Glucose self-testing
Class III	High	HIV blood analyzer

Table 5. Points of comparison for medical device registration processes in KSA, US and EU (7,32,37-46)

Sr No	Points of comparison	KSA	US	EU
1.	Regulation Authority	SFDA	USFDA	EMA and RA of Member State
2.	Classification Categories	Class A Class B Class C Class D	Class I Class II Class III	Class I Class IIa Class IIb Class III
3.	Fees for available pathways	$4000-$7000 USD per product	510 (K) $ 4,690 PMA $ 234, 495	Fee varies for Members State
4.	Quality Management Systems requirement	ISO 13485, ISO 9001	21 CFR Part 820	ISO 13485 or as per applicable annex of 93/42/EEC
5.	Assessment of Technical Data performed by	SFDA	USFDA	National Regulatory Authority
6.	Medical Device Regulations	IMDRF	From 21 CFR Part 800 – 21 CFR Part 861	Medical Device Directive (MDD 93/42/EEC), Active Implantable Medical Device Directive (AIMDD 90/42/EE), In vitro Diagnostic Medical Device Directive (IVDMDD 98/79/ EC).
7.	Validity of License	licenses are valid for 3-5 years	Indefinite, unless revoked or product recalled Annual Establishment Registration is required	Validity of CE marking is Indefinite for Class I 3 years for Class IIa, IIb and III
8.	Labelling Requirements	As per MDIR	As per 21 CFR Part 801	As per annex I 93/42/EEC
9.	Data Presentation (Electronic / Paper)	(Electronic/ Paper)	(Electronic/ Paper)	(Electronic/ Paper)
10.	Timelines for Approval(months)	Approval typically takes between 35 and 120 working days after files have been submitted to the authorities	Class I –varies, Class II- 6 to 12 months, Class III-more than 12 months.	Class I – approval is not required, Class IIa-1 to 3 months, Class IIb- 3 to 6 months, Class III- 6 to 9 months.

5. Conclusion

The registration, categorization, and conformity assessment processes are all governed by the laws of their respective countries, including the European Union, the United States of America, and the Kingdom of Saudi Arabia. Comparing the three nations reveals that each has unique benefits in terms of regulatory requirements.

A legal requirement for medical device registration in the aforementioned nations, providing assurance that medical devices sold or imported into these nations comply with the safety standards spelled out in the Medical Devices Regulations and that protocols are in place to protect the public in the event that a problem with a device is discovered.

Regular evaluations of policies and regulations are necessary so that the right adjustments can be made in response to technological advancements.

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Conflict of Interest

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