MDS-G27

Guidance on Requirements for Listing Non Sterile, Non Measuring Low Risk Medical Devices

Version Number: 1.0
Version Date: 16/7/2018

This guidance document has been published after being distributed for public comments dated on 25/4/2018 for 30 days.

Table of Content

Introduction 3
Purpose 3
Scope…… 3
Background 3

Requirements 4
Required Documents 6
Flowchart 8

Annexes 9
Annex (1): Application Form for Medical Devices Listing 10
Annex (2): Declaration of Conformity (DOC) 11
Annex (3): Essential Principles of Safety and Performance 13
Annex (4): Technical Documentation 22
Annex (5): Risk Classification Rules for Medical Devices 28
Annex (6): Definitions & Abbreviations 36

Introduction

Purpose

The purpose of this guidance is to clarify the requirements for listing non sterile, non measuring low risk medical devices in the MDNR.

Scope

This guidance applies to following parties and products:

- Importers (including healthcare providers importing for their own use) and distributers (including local manufactures involved in the distribution activity).
- Non sterile, non measuring low risk medical devices and their accessories that will be supplied to the KSA market.

This guidance does not apply to the following:

- In-vitro medical devices
- Non sterile, non measuring low risk medical devices that will be supplied to the KSA market that their manufacturer wishes to obtain MDMA instead of listing them in the MDNR.
- Custom-made medical devices.

Background

SFDA/MDS has issued this guidance document in reference to the Article four of the "Medical Devices Interim Regulation" that states that "medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization. The SFDA may exempt any medical device from market authorization, and shall announce the exempt medical devices on its website taking into consideration the public interest.

Requirements

General	1	Non sterile, non measuring low risk medical devices that may be placed on the KSA market and/or put into service are exempt from MDMA, but they shall be listed in the MDNR by any establishment importing or distributing them.
Medical Devices Listing Paths	2	One of the following paths may be selected to list Non sterile, non measuring low risk medical devices in the MDNR: A. Abridged MDNR medical devices listing path which requires the device(s) to comply with the regulations of one of the GHTF founding members (Australia, Canada, Japan, the USA and the EU/EFTA) and additionally with "National Provisions and Requirements for Medical Devices" that are specific to the KSA. B. Direct MDNR medical devices listing path which requires the following: 1. The device(s) shall conform to "Essential Principles of Safety and Performance" specified in Annex (3) through the preparation and holding of "Technical Documentation" specified in Annex (4) and additionally with the "National Provisions and Requirements for Medical Devices" that are specific to the KSA. 2. Manufacturer of the device(s) shall establish, document and maintain an effective quality management system (QMS) in accordance with the requirements specified in "The Saudi Quality Management System Requirements for Medical Devices". Note: The risk class of the medical device shall be determined in accordance with the classification rules specified in Annex (5).
Pre-requisite	3	Before listing the medical device, establishment shall have: 1. Establishment National Registry Number 2. MDEL for importation and/or distribution activities (Healthcare providers are exempt)
Submitting Documents	4	Applicant shall submit the "Application Form for Medical Devices Listing" specified in Annex (1) and the documents specified in section (A) or (B), according to selected path, of "Required Documents" electronically via section (C) of MDNR.

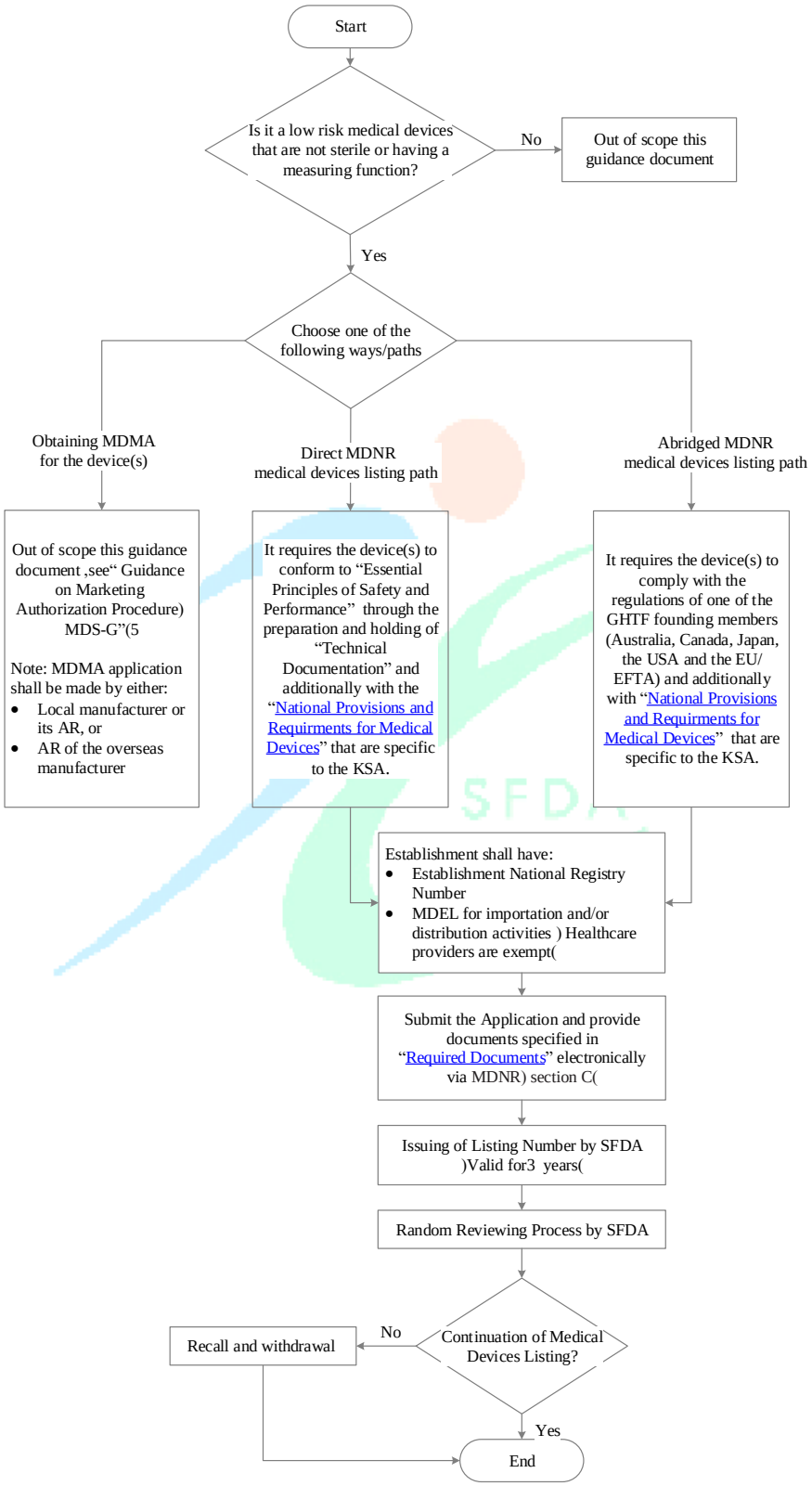
		Once satisfied, SFDA will issue Medical Device National Listing Number that approves the relevant medical device to be placed on the market of the KSA, and send it to the authorized person's email defined in MDNR system.
Processing Fees & Time	5	• Processing fees is SR 500 per application. Note: Models (differences in models may include color, quantity, range of size, number of units….etc.) may be bundled/grouped within one application only if they have same legal manufacturer; intended use/purpose and description; generic name; and risk class • Processing time is (4) working days. • Listing is valid for (3) years.

Required Documents

	Required Documents	Note
	A. Required Documents for Abridged MDNR Medical Devices Listing Path	
1	Copy of label affixed to the device and its wrappers	– It shall comply with the requirements specified in "Guidance on Labelling Requirements for Medical Devices (MDS-G10)"
2	Copy of Instructions For Use (IFU)	
3	Documentary evidence of compliance with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA. The evidence shall be as follows: - EU: o Declaration Of Conformity with European regulatory requirements (DOC), and o Medical device registration/listing evidence in one of the EU countries. o - USA: o 510k Decision Letter, or o (a) Declaration from the manufacturer that the device is 510(K) exempt, (b) Proof of the establishment registration & device listing (i.e. Screen print of US-FDA website), and (c) Relevant Code of Federal Regulations (i.e. Screen print of US-FDA website) - Canada: o Declaration Of Conformity with Canadian regulatory requirements (DOC), and o Establishment License o Manufacturer's certificate covering the medical devices exported to KSA. - Australia: Certificate of TGA Conformity Assessment - Japan: o Self-Declaration of Conformity with Japanese regulatory requirements o Medical devices marketing notification	–

B. Required Documents for Direct MDNR Medical Devices Listing Path		
1	Copy of label affixed to the device and its wrappers	– It shall comply with the requirements specified in "Guidance on Labelling Requirements for Medical Devices (MDS-G10)"
2	Copy of Instructions For Use (IFU)	
3	Declaration Of Conformity with "Medical Devices Interim Regulation" (DOC)	– It shall include information specified in Annex (2) – For printable and editable version, click here

Flowchart


Start
Is it a low risk medical devices that are not sterile or having a measuring function?
No
Out of scope this guidance document
Yes
Choose one of the following ways/paths
Obtaining MDMA for the device(s)
Direct MDNR medical devices listing path
Abridged MDNR medical devices listing path
Out of scope this guidance document ,see“ Guidance on Marketing Authorization Procedure) MDS-G”(5
Note: MDMA application shall be made by either:
Local manufacturer or its AR, or
AR of the overseas manufacturer
It requires the device(s) to conform to “Essential Principles of Safety and Performance” through the preparation and holding of “Technical Documentation” and additionally with the “National Provisions and Requirments for Medical Devices” that are specific to the KSA.
It requires the device(s) to comply with the regulations of one of the GHTF founding members (Australia, Canada, Japan, the USA and the EU/ EFTA) and additionally with “National Provisions and Requirments for Medical Devices” that are specific to the KSA.
Establishment shall have:
Establishment National Registry Number
MDEL for importation and/or distribution activities) Healthcare providers are exempt(
Submit the Application and provide documents specified in “Required Documents” electronically via MDNR) section C(
Issuing of Listing Number by SFDA)Valid for3 years(
Random Reviewing Process by SFDA
Continuation of Medical Devices Listing?
No
Recall and withdrawal
Yes
End

Annexes

Annex (1): Application Form for Medical Devices Listing

(This is for reference only. Valid version is incorporated into MDNR system)

	Information of Application Form	Notes
1	Jurisdiction: – Australia – Canada – Japan, the USA – the EU/EFTA – Saudi Arabia	–
2	Manufacturer Name	– The name as it appears on the labelling.
3	Country of Origin	-
4	Manufacturer Address	– The name as it appears on the labelling.
5	Generic/Scientific name	– The name as it appears on the labelling.
6	Medical device category	-
7	Product Trade / Brand Name	– The name as it appears on the labelling.
8	Model Name/Number	-
9	Intended purpose of the medical device and Product Description	– The name as it appears on the labelling.
10	Human Readable Product Barcode Number	– Applicable only for home use medical device
11	Nomenclature Code Number	– Optional
12	GMDN Term	– Optional
13	GMDN Code	– Optional
14	Is it for homeuse (Yes/No)	-
15	Product Trade / Brand Name in Arabic	– Applicable only for home use medical device
16	Product Description in Arabic	
17	Storage Conditions	
18	Declaration Of Conformity (DOC) with the relevant regulatory requirements chosen in section (1) of this application.	– Where the Saudi Arabia has been chosen in section (1) of this application, the DOC shall include information specified in Annex (2)

Annex (2): Declaration of Conformity (DOC)
to Saudi Food and Drug Authority Medical Devices Interim Regulation
الإقرار بالمطابقة للائحة رقابة الأجهزة والمنتجات الطبية في الهيئة العامة للغذاء والدواء

[To be printed on Manufacturer Letterhead]
Click here for printable and editable version

We …… <mmanufacturer name>, <manufacturer address> and <Establishment Medical Device National Registry (MDNR) number> hereby declare that the below mentioned medical device(s) conform to the "Medical Device Interim Regulation" issued by the Board of Directors of the Food and Drug Authority (1-8-1429) dated 29/12/1429 H. and we also declare the fulfillment of the requirements of "Medical Devices Interim Regulation" and its relevant Implementing Rules and willing to make the evidence of the fulfillment of these requirments available to the SFDA, upon request.

نقر نحن ..... <اسم المصنّع> و<عنوان المصنّع> و<رقم السجل الوطني للمنشأة> (عندما ينطبق ذلك) ..... أن الأجهزة والمنتجات الطبية المذكورة أدناه تتوافق مع "لائحة رقابة الأجهزة الطبية" الصادرة بقرار مجلس إدارة الهيئة العامة للغذاء والدواء رقم (١-٨-١٤٢٩) وتاريخ ١٤٢٩/١٢/٢٩ هـ، كما نقر استيفائنا جميع المتطلبات المشار إليها في "لائحة رقابة الأجهزة والمنتجات الطبية" وقواعدها الإجرائية ذات العلاقة وعلى استعداد لتقديم ما يثبت ذلك للهيئة عند الطلب.

Information of Medical Device(s)	معلومات الأجهزة والمنتجات الطبية
Generic Name:	الاسم العام/الجنيس:
Trade/Brand Name:	الاسم التجاري/العلامة التجارية:
Model Name/Number:	رقم/اسم الطراز:
Intended Purpose:	الغرض من الاستخدام:
Risk Class:	درجة الخطورة:
Classification Rule Number:	رقم قاعدة تصنيف الخطورة:
Manufacturing Site:	موقع التصنيع:
Applied Standards:	المواصفات المطبقة:

Authorized Signatory	المخول بالتوقيع
Name:	الاسم:
Position:	المنصب:
Date:	التاريخ:
Signature:	التوقيع:

SFDA

Annex (3): Essential Principles of Safety and Performance

A. General Requirements

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art

2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

    a) establish and document a risk management plan for each device;

    b) identify and analyse the known and foreseeable hazards associated with each device;

    c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

    d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

    e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

    f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

    a) eliminate or reduce risks as far as possible through safe design and manufacture;

    b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

    c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

    (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

    (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

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B. Design and Manufacturing Requirements

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:

a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;

b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;

c) the compatibility between the different parts of a device which consists of more than one implantable part;

d) the impact of processes on material properties;

e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;

f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;

g) surface properties; and

h) the confirmation that the device meets any defined chemical and/or physical specifications.

10.2. Devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

10.3. The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

10.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.

10.5. The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.

10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.

11. Infection and microbial contamination

11.1. The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should:

- allow easy handling, and, where necessary:
- reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,
- prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.

11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation

11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities..

11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

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13. Devices incorporating materials of biological origin

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14. Construction of devices and interaction with their environment.

14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

e) the risks of accidental ingress of substances into the device;

f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and

g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6. Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

15. Devices with a diagnostic or measuring function

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16. Protection against radiation

16.1. General:

a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance

16.2. Intended radiation

a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

16.4. Ionising radiation

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17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

18. Active devices and devices connected to them

18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.

18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.

19. Particular requirements for active implantable devices

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20. Protection against mechanical and thermal risks

20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance

20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

21. Protection against the risks posed to the patient or user by devices supplying energy or substances

21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.

21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

21.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:

- ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,
- reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and
- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:

- can verify that, at the time of use, the device will perform as intended by the manufacturer, and
- if applicable, is warned if the device has failed to provide a valid result.

Annex (4): Technical Documentation

Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of Medical Devices Interim Regulation to be assessed.

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in this annex.

The Technical Documentation comprises eight major sections, which are:

1. Device Description and Specification, Including Variants and Accessories
   1.1. Device Description:
      1.1.1. Product or trade name and a general description of the device including its intended purpose and intended users;
      1.1.2. A clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
      1.1.3. The intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;
      1.1.4. Principles of operation of the device and its mode of action, scientifically demonstrated if necessary;
      1.1.5. The rationale for the qualification of the product as a device
      1.1.6. The risk class of the device and the justification for the classification rule(s) applied in accordance with “Risk Classification Rules for Medical Devices”;
      1.1.7. An explanation of any novel features;
      1.1.8. 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 the device, if applicable;
      1.1.9. A description or complete list of the various configurations/variants of the device that will be made available, if applicable;
      1.1.10. A general description of the key functional elements of the device, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this will include: labelled pictorial representations of the device (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;
      1.1.11. A description of the materials incorporated into key functional elements of the device and those making either direct or indirect contact with a human body. e.g., during extracorporeal circulation of body fluids Technical specifications, such as

features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications

1.2. Reference to previous and similar generations of the device

1.2.1. An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist.

1.2.2. An overview of identified similar devices available in KSA or on international markets, where such devices exist

2. Information to be supplied by the manufacturer shall be in accordance with "Guidance on Labelling Requirements for Medical Devices (MDS-G10)"

3. Design and manufacturing information

3.1. Information to allow the design stages applied to the device to be understood.

3.2. Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation.

3.3. Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed

4. Essential Principles of Safety and Performance:

The documentation shall contain information for the demonstration of conformity with the "Essential Principles of Safety and Performance" that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

The applicant must make available to the SFDA, upon request, the following information:

4.1. EPs checklist

4.2. Applicability of each essential principle to the device.

4.3. Method of compliance with each essential principles of safety and performance which should done in one of the following ways:

4.3.1. Recognized or other standards.

4.3.2. Comparison to a similar/equivalent device already available on the market as below:

The manufacturer must conduct a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device to demonstrate equivalence. The data generated must demonstrate compliance with the relevant "Essential Principles of Safety and Performance". The Comparison shall be drawn to a legally marketed device in Saudi Arabia, Australia, Canada, Japan, the USA or the EU/EFTA,

In drawing the comparison, the manufacturer must consider the following three factors:

4.3.2.1. Clinical characteristics:

- used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication),
- used for the same intended purpose,
- used at the same site in the body, and
- used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects), and not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.).

4.3.2.2. Technical characteristics:

- be of similar design,
- used under the same conditions of use,
- have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability),
- use similar deployment methods (if relevant), and
- have similar principles of operation and critical performance requirements.

4.3.2.3. Biological characteristics: Use the same materials or substances in contact with the same human tissue or body fluids

4.4. A reference to the actual technical documentation that offers evidence of conformity with each method used.

5. Benefit-Risk Analysis and risk management.

The documentation shall contain information on:

5.1. The benefit-risk analysis referred to in sections 1 to 8 of "Essential Principles of Safety and Performance".

5.2. The solutions adopted and the results of the risk management referred to in section 3 of "Essential Principles of Safety and Performance".

6. Product Verification and Validation

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of Interim Medical device regulations and the applicable Essential Principles in this guidance.

6.1. Pre-clinical and clinical data

6.1.1. Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its

intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications.

6.1.2. Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

6.1.3. The biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user

6.1.4. Physical, chemical and microbiological characterisation

6.1.5. Electrical safety and electromagnetic compatibility

6.1.6. Software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer)

6.1.7. Stability, including shelf life

6.1.8. Performance and safety

6.1.9. The clinical evaluation report and its updates and the clinical evaluation plan

6.1.10. The Post-Market Clinical Follow-up (PMCF) plan and PMCF evaluation report or a justification why a PMCF is not applicable

6.2. Additional information required in specific cases

6.2.1. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of "Law of Pharmaceutical Establishments and Preparations", including a medicinal product derived from human blood or human plasma, a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device

6.2.2. Where a device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of "Essential Principles of Safety and Performance".

6.2.3. In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

6.2.3.1. Absorption, distribution, metabolism and excretion

6.2.3.2. Possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other

substances, considering the target population, and its associated medical conditions

6.2.3.3. Local tolerance

6.2.3.4. Toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device

6.2.3.5. In the absence of such studies, a justification shall be provided

6.2.3.6. In the case of devices containing substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) or endocrine-disrupting substances referred to in Section 10.4.1 of "Essential Principles of Safety and Performance", the justification referred to in Section 10.4.2 of "Essential Principles of Safety and Performance".

6.2.4. In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilization and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues

6.2.5. In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications

6.2.6. If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

7. Post-market surveillance plan:

7.1. A proactive and systematic process to collect and utilize available information, in particular:

7.1.1. Information concerning serious incidents, including information from PSURs, and field safety corrective actions

7.1.2. Records referring to non-serious incidents and data on any undesirable side-effects

7.1.3. Information from trend reporting

7.1.4. Relevant specialist or technical literature, databases and/or registers

7.1.5. Information, including feedbacks and complaints, provided by users, distributors and importers

7.1.6. Publicly-available information about similar medical devices

The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market.

7.2. Effective and appropriate methods and processes to assess the collected data

7.3. Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of "Essential Principles of Safety and Performance".

7.4. Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field

7.5. Methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period

7.6. Methods and protocols to communicate effectively with SFDA, notified bodies, economic operators and users

7.7. Reference to procedures to fulfil the manufacturers obligations

7.8. Systematic procedures to identify and initiate appropriate measures including corrective actions

7.9. Effective tools to trace and identify devices for which corrective actions might be necessary

7.10. A Post-market clinical follow-up (PMCF) plan or a justification as to why a PMCF is not applicable

8. Periodic Safety Update Report (PSUR) and Post-Market Surveillance Report

A PSUR is not required for class "A" medical devices. However, manufacturers of class "A" devices shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the SFDA upon request.

Annex (5): Risk Classification Rules for Medical Devices

1. Definitions specific to the classification rules

1.1. Duration of use

- Transient: means normally intended for continuous use for less than 60 minutes.
- Short term: means normally intended for continuous use for between 60 minutes and 30 days.
- Long term: means normally intended for continuous use for more than 30 days.

1.2. Invasive and active devices

- Body orifice: means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
- Invasive device: means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- Surgically invasive device: means:
  - an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and
  - a device which produces penetration other than through a body orifice.
- Implantable device: means any device, including those that are partially or wholly absorbed, which is intended:
  - to be totally introduced into the human body, or
  - to replace an epithelial surface or the surface of the eye,

  by clinical intervention and which is intended to remain in place after the procedure.
  Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.
- Reusable surgical instrument: means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.
- Active device: means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
- Active therapeutic device: means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

- Active device intended for diagnosis and monitoring: means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Central circulatory system: means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.
- Central nervous system: means the brain, meninges and spinal cord.
- Injured skin or mucous membrane: means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

1.3. Others

- Non-viable: means having no potential for metabolism or multiplication.
- Derivative: means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.
- Nanomaterial: means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials.
- Particle:, for the purposes of the definition of nanomaterial, means a minute piece of matter with defined physical boundaries.
- Agglomerate:, for the purposes of the definition of nanomaterial, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.
- Aggregate:, for the purposes of the definition of nanomaterial, means a particle comprising of strongly bound or fused particles.
- Serious deterioration in state of health: means any of the following:
  - life-threatening illness or injury,
  - permanent impairment of a body structure or a body function,
  - hospitalisation or prolongation of patient hospitalisation,
  - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
  - chronic disease

2. Medical device levels
    - Class A: Low risk
    - Class B: Low-moderate risk
    - Class C: Moderate-high Risk
    - Class D: High risk

3. Implementing rules
    - Application of the classification rules shall be governed by the intended purpose of the devices.
    - If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.
    - Accessories for a medical device shall be classified in their own right separately from the device with which they are used.
    - Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.
    - If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.
    - If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.
    - In calculating the duration referred to in Section 1.1 of this Annex, continuous use shall mean:
        a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and
        b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.
    - A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

4. The classification rules

2.1. Non-invasive devices

2.1.1.Rule 1

All non-invasive devices are classified as class A, unless one of the rules set out hereinafter applies.

Examples:

- Body liquid collection devices intended to be used in such a way that a return
- flow is unlikely (e.g. to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage
- devices). They may be connected to the patient by means of catheters and tubing
- Devices used to immobilize body parts and/or to apply force or compression on them (e.g. non-sterile dressings used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosier Compression dressing, garment)
- Sling bandage
- Manually-operated devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs, , examination/treatment chairs and tables,)
- Corrective glasses and frames
- Stethoscopes for diagnosis.
- Eye occlusion plasters
- Incision drapes
- Conductive gels
- Non-invasive electrodes (electrodes for EEG or ECG) (skin)
- Image intensifying screens
- Permanent magnets for removal of ocular debris.
- Chart, eye; amsler grid, colour discrimination, visual acuity.
- Corrective back brace.
- Defibrillation pads.
- Face barrier, resuscitation shield
- Hot/Cold pack
- Orthotic footwear.
- Orthosis.
- Patient restraint.
- Pressure relieving mattress/ pads.
- Radiation shield; apron, bib, blanket, eye, thyroid.
- breast self exam pad.
- Sitz bath
- Nonpneumatic tourniquet

2.1.2.Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class B:

a) if they may be connected to a class B, class C or class D active device; or
b) if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class C.

In all other cases, such devices are classified as class A.

Examples:

- Devices that provide a simple channelling function, with gravity providing the force to transport the liquid, e.g. administration sets for infusion
- Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines
- Syringes without needles.
- Irrigation kit, eye (without solution)
- Irrigator, nasal (without solution)

2.1.3.Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class C, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class B.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class D.

2.1.4.Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

a) class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
   Examples:
   - Wound dressings, such as: absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages (sticking plasters, band-aid), adhesive tape and gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound.
   - Cotton ball
b) class C if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;
c) class B if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and

d) class B in all other cases.
e) This rule applies also to the invasive devices that come into contact with injured mucous membrane.

2.2. Invasive devices

2.2.1.Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class A active device are classified as:

a) class A if they are intended for transient use;
Examples:
- Handheld mirrors used in dentistry to aid in dental diagnosis and surgery
- Dental impression materials
- Tubes used for pumping the stomach
- Impression trays
- Enema devices
- Examination gloves
- Urinary catheters intended for transient use
- Prostatic balloon dilation catheters.
- Articulating paper.
- Dental dam.
- Dental impression tray.
- Dental forceps.
- Dental ring.
- Dental sectional matrix band.
- Dental teeth protector.
- tongue Depressor.
- Gingiva retraction cord.
- Mouth guard, preformed
- Nasal aspirator, manual.
- Vaginal speculum

b) class B if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class A;
Examples:
- Dressings for nose bleeds
- Materials for manufacturing dentures

and

c) class C if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class B.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class B, class C or class D active device, are classified as class B.

2.2.2.Rule 6

All surgically invasive devices intended for transient use are classified as class B unless they:

a) are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class D;
b) are reusable surgical instruments, in which case they are classified as class A;
Examples:
   - Scalpels and scalpel handles
   - Reamers
   - Drill bits
   - Saws, that are not intended for connection to an active device
   - Retractors forceps, excavators and chisels
   - Sternum retractors for transient use
c) are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class D;
d) are intended to supply energy in the form of ionising radiation in which case they are classified as class C;
e) have a biological effect or are wholly or mainly absorbed in which case they are classified as class C; or
f) are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class C.

2.3. Active devices

2.3.1.Rule 10

Active devices intended for diagnosis and monitoring are classified as class B:

a) if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class A;
Example of class A:
   - Mount, light, surgical/examination.
   - Hand-held, oral illumination and examination light.
b) if they are intended to image in vivo distribution of radiopharmaceuticals; or
c) if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for

instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class C.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class C.

2.3.2.Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class B, except if such decisions have an impact that may cause:

a) death or an irreversible deterioration of a person's state of health, in which case it is in class D; or
b) a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class C.

Software intended to monitor physiological processes is classified as class B, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class C.

All other software is classified as class A.

2.3.3.Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class B, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class C.

2.3.4.Rule 13

All other active devices are classified as class A.

Examples:

- Active diagnostic devices intended to illuminate the patient's body in the
- visible spectrum such as examination lights or to optically view the body such as surgical microscopes
- Devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs)
- Active diagnostic devices intended for thermography
- Dental curing lights

Annex (6): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDEL	Medical Devices Establishment License
MDMA	Medical Devices Marketing Authorization
Establishment	any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.
Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: ○ Diagnosis, prevention, monitoring, treatment or alleviation of disease, ○ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, ○ 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 for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Measuring Medical Device	means a medical device that is intended to quantitatively and/or qualitatively measure a physiological, anatomical parameter, energy and substances delivered to or removed from the human body.
Sterile Medical Device	is a finished medical device that is supplied to the end user in a sterile condition by an established sterilization method.
Accessory	means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.
Medical Devices National Registry (MDNR)	is the database of registered establishments and the medical devices they manufacture or import or distribute.
National Center for Medical Device Reporting (NCMDR)	an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
Medical Device National Listing Number	means the code assigned by the SFDA to a single medical device to indicate the device is authorized to be placed on the KSA market and facilitate traceability.
Labeling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.