الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref.

Medical Devices Registration Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

National medical devices registration is one of the premarketing medical devices regulation processes that is recommended by the WHO (World health organization). It was implemented in 2015 and updated in 2018.

Where it facilitates the importation of the devices by minimizing the number of required documents and enhancing the level of traceability of devices in the kingdom. It also enables the end-user to easily contact the local authorized representatives.

With reference to **Decision (48) 2020, Article (5) "**The Authority establishes an electronic system of the registration of medical devices and products and their facilities, in which all data relating to the device and the establishment, in particular the name of the device, serial number, country of origin and its shelf life, shall be recorded as follows:

- Inventory and management of the information required to register medical devices and products and their facilities.
- A visualization of the market size for medical devices and products in the Kingdom.
- Provide information on facilities engaged in the manufacture, distributors or importers medical devices and products in the Kingdom.
- Provide information on medical devices and products that will be marketed or already used in the Kingdom.**"**

Registration of medical devices is done after ensuring the compliance of medical devices with international standards of quality and safety, this process was adapted from worldwide recognized regulatory authorities' guidelines such as (SFDA, FDA, MHRA, TGA) in order to be harmonized with the global regulations of medical devices. These guidelines were then customized to fit with the size of the kingdom of Bahrain market.

2. General Rules

1. Only registered authorized representative can apply for medical device registration.
2. All medical devices must be registered regardless of its risk classification (class I, IIa, IIb, and III) / IVD (A, B, C, D).
3. All registered medical devices will be published along with their authorized representative on NHRA website.
4. All healthcare facilities will be instructed to purchase only registered medical devices to ensure the patient safety.
5. Registration is not linked to HS codes being regulated by NHRA or not.
6. Registrations fees are now implemented. ***Please refer to "Medical Devices Fees Guideline"***
7. Classification criteria must be fulfilled before submitting for registration **(see classification guideline).**
8. All required official documents should be signed and stamped by the issuer (electronic signature and electronic stamp is accepted).
9. Form submitted must be electronically filled (not filled by hand), searchable, not printed or scanned. In case the electronic signature/electronic stamp is not feasible (Not available), please provide an official letter signed and stamped clearly stating the date of application and that the information provided is genuine and not falsified.
10. Medical devices purchasing and marketing prices required in the registration form will be confidential and will only be used for study purposes only.
11. Accessories/spare parts cannot be registered. In importation, it is mandatory to provide evidence from the legal manufacturer that the product is an accessory, or a spare part related to the main registered device. For example, official letter from the legal manufacturer or a catalogue.
12. Timeline of registration file review 40-80 working day (8-16 weeks).
13. Date of market entry means the date that the device entered the kingdom of Bahrain.
14. NHRA may ask for additional documents as part of the review.

3. Process of Submission

In order to apply for medical device registration, applicant should book an appointment using **"Microsoft Bookings"** system for submitting the registration form along with the required documents.

The documents will be submitted as a softcopy by email to medical_devices@nhra.bh and will be reviewed by NHRA team. Review process timeframe is **40-80 working day (8-16 weeks).** If all requirements are fulfilled, a registration certificate will be issued with a validity of **one year**. However, in case not all requirements are fulfilled, the application will be reverted back to the applicant and an email will be sent with the recommended action to be taken. The applicant will have two more attempts to submit the application (needs to book a new appointment) in order to fulfill the remaining requirements without repaying the application fees. If the application still does not fulfill all the requirements in the third submission, it will be rejected and the applicant needs to pay in order to resubmit the application.

4. Listing

All registered medical devices authorized representatives (AR) must list all medical devices that have been imported or are intended to be imported in the future. Only listed medical devices can be applied for medical device registration. To list the medical devices, the applicant needs to fill the following sheet and submit it to medical_devices@nhra.bh.

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Lists/MDR_Form_Medical%20devices%20listing.xlsx

Note: Listing should be submitted (including all medical devices) prior to submitting medical device registration applications and it should not be submitted as part of the medical device registration application.

5. Requirements of Medical Devices Registration

1) **Medical Device Registration form (Annex 1)**, should be filled, signed, and stamped by the authorized representative.

2) **Technical Details** such as Catalogue, and Service Manual.

3) **Artwork** i.e., Label of the Medical Device. Should include the Name and a device Identification number (catalogue No, reference No, Model No) and legal manufacturer name with address.
(For single bundling applications with more than 3 medical devices, minimum of 3 artworks should be submitted. For family and IVD bundling cases where providing all medical device artworks is not feasible, applicants can contact NHRA through email for recommendation).

4) **Agreement or Authorization letter** issued by the legal manufacturer to the Authorized Representative for the distribution of the applied Medical Device(s) in the Kingdom of Bahrain.

5) **Official Letter** issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors (invoice issuer) regarding the medical device(s). Full addresses must be stated.

6) **Instruction for use (IFU)** issued by the Legal Manufacturer with the address matching the artwork. Such as operations/user manual, and leaflet.

7) **List of countries** the medical device has been marketed in, issued by the Legal manufacturer.

8) If the device has been marketed in Bahrain for a minimum of 3 years, only **Bahrain market field safety notice records** for the past 3 years are required.
If the device has not been marketed in Bahrain for a minimum of 3 years, **worldwide and Bahrain market field safety notice records** for the past 3 years are required.
If there are no field safety notice records, an **official letter** from the legal manufacturer needs to be provided stating that there are no field safety notice records related to the devices.

9) **If there are field safety notice records affecting Bahrain market**, an **official letter** from NHRA medical devices post market department that each record is closed is required.
If there are worldwide field safety notice records, an **official letter** from the legal manufacturer stating the actions taken regarding each record and whether it was closed is required.

10) **List of End-users** in case the medical device exists in the Bahrain market.

11) **Quality Management System Certificate (QMS) - ISO 13485** for the **Physical manufacturer** with the address matching requirement 5.

12) **Quality Assurance Certificate (QAC)** - CE directives 93/42/EEC, 2017/745, 98/79/EC, 2017/746 or FDA Certificate to Foreign Government (CFG) for the Legal manufacturer with the address matching the artwork. For low-risk medical devices, a **Declaration of Conformity (DOC)** can be submitted instead.

13) For class III medical devices as well as class D IVD's, an **EC Design examination certificate** or an **FDA Certificate to Foreign Government (CFG)** for the legal manufacturer is required. This document needs to be submitted for class IIB medical devices if available.

14) **Verification evidence** for QAC /QMS/ EC Design Examination. (***See Quality Assurance Certificates and Verification Process Guideline for further clarification.)***

15) **Free Sale Certificate (FSC)** or **Certificate to foreign government** issued by the regulatory authority of the country of origin or a reference country.

16) **Declaration of Conformity (DOC) as per EU regulations issued by the legal manufacturer. Risk classification and GMDN code can be included in the DOC or a separate official letter.**

17) If the medical device contains animal tissues/derivatives, a **letter** issued by the legal manufacturer stating that the product is **free from porcine derivatives** is required (Not applicable for in Vitro Diagnostic (IVD) Medical devices).

18) In some cases, it might be requested to fulfill the classification criteria where **NHRA classification letter** issued from MDR department should be provided **(*See Medical Device Classification Process Guideline for further clarification)*.**

19) Provide a screen capture of the medical devices registration listing **email** sent to NHRA.

All required official documents should be signed and stamped by the issuer (electronic signature is accepted).

6. Software Registration

"Software as a Medical Device" is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

If the software is classified as a medical device, then it can be registered in NHRA with same requirements of medical devices registration which is clarified in **Section (5).**

7. Research use only

Research Use Only (RUO) products: Instruments, apparatus, appliances, materials, or other articles, including software, which are intended to be used for research purposes, without any medical objective. **(Not for Clinical use, Not for Diagnosis, or treatment).**

These products are not classified as a medical device and therefore, **not required to be registered in NHRA.**

8. Appeal

If the rejection/reverted back reason can be justified without submitting new documents (that already stated in the requirements), applicants will have 5 working days to submit for appeal and provide justification.

9. License Variation

The medical device license can be amended during the validity period according to the type of variations done in device details which can be:

- **Minor Variation:**

Any modification that does not affect safety or performance of a medical device.

- **Major Variation:**

Any modification that does affect safety or performance of a medical device.

Example of Minor variations:

- Renewal of any certificate or official letter.
- Changes made in the artwork / label of the medical device.
- Changes in the instruction for use.
- Changes made to the authorized representative details.
- Change of notified body due to Brexit (Same NB different number).
- Change in medical device name or product identifier (Model/reference).
- Adding devices to a registration license if difference is color, quantity, or package. Not applicable for IVDs.

Example of Major variations:

- Changing the legal / physical manufacturer or changing the address.
- Changes made in the manufacturing process of the medical devices.
- Changing design or detailed specification of the device.
- Change in risk classification of the medical devices.

Minor Variation Required documents:

1) Letter of justification from the legal manufacturer regarding the variation with a statement that the changes does not affect the safety and quality of the medical device. The letter should also state the reason behind the variation and whether the notified body has been informed regarding the change in addition to if there are any impacts on the quality documents.

2) Updated and varied version of the document. For example, if the variation is in the artwork, the updated artwork needs to be provided.
3) Based on the variation, other requirements may be requested.

General directions:

- No need to submit for variation when it is related to price.
- Validity of the certificate will not change and will remain the same.
- For software registration, Submission of variation for each new version is required. if the software updates don't affect the main function then it will be considered as a minor variation, but if the updates affect the intended use of the software, then it will be considered as a major variation.
- Timeline of reporting for variation: NHRA should be informed instantly by email (without the need to take an appointment) from the time of receiving a change notification from the manufacturer.
- **Timeline of NHRA review is 40 working day (8 weeks).**

Variation request outcome:

Minor Variation:

If variation request is accepted, an approval letter/email will be issued from NHRA. In case not all requirements are fulfilled, the application will be reverted back to the applicant and an email will be sent with the recommended action to be taken.

Major Variation: applicant should submit for new medical device registration application.

Please note that the approval of the submitted variation should be done prior to the importation of the modified medical device.

10. Transferring Local Representative

Transferring agency from an authorized representative to another one will be considered as a **minor variation** and the registration of the medical device will not be affected as long as the registration certificate is valid, the below required documents should be provided:

1. Official letter issued from the new authorized representative stating the full responsibility of the medical device and full handover for the device data have been delivered to the new authorized representative, including:
   Distribution records, Recalls and Adverse events, Maintenance records (if any)

2. Authorization letter issued from the manufacturer to the new authorized representative.

11. Medical Devices Registration License Renewal

Licenses can always be renewed, and applicants should submit for Registration Certificate renewal at max 1 month before its expiry date.

Required documents to renew licenses issued after October 2020 to be submitted along with the form:

1) An official letter issued from the legal manufacturer stating whether there are changes/updates done to the medical device/s or not.

2) Requirements number 8,9,10, and 14 in "Section 5" in the guideline should be submitted (updated and newly issued) and the updated details should be highlighted (if any).

*Please note that licenses that are reissued after variation does not fall under this section and initial license issuance date must be after October 2020.

Required documents to renew licenses issued before October 2020 to be submitted along with the form:

1) An official letter issued from the legal manufacturer stating whether there are changes/updates done to the medical device/s or not.

2) All documents required in "Section 5" in the guideline should be submitted and the updated details should be highlighted (if any).

12. Manufacturer Acquisition

An acquisition is when one manufacturer purchases most or all of another manufacturer's shares to gain control of that company.
In this case, manufacturer acquisition is considered a variation and based on provided documents NHRA will determine whether it is a minor or major variation.

Required documents are:

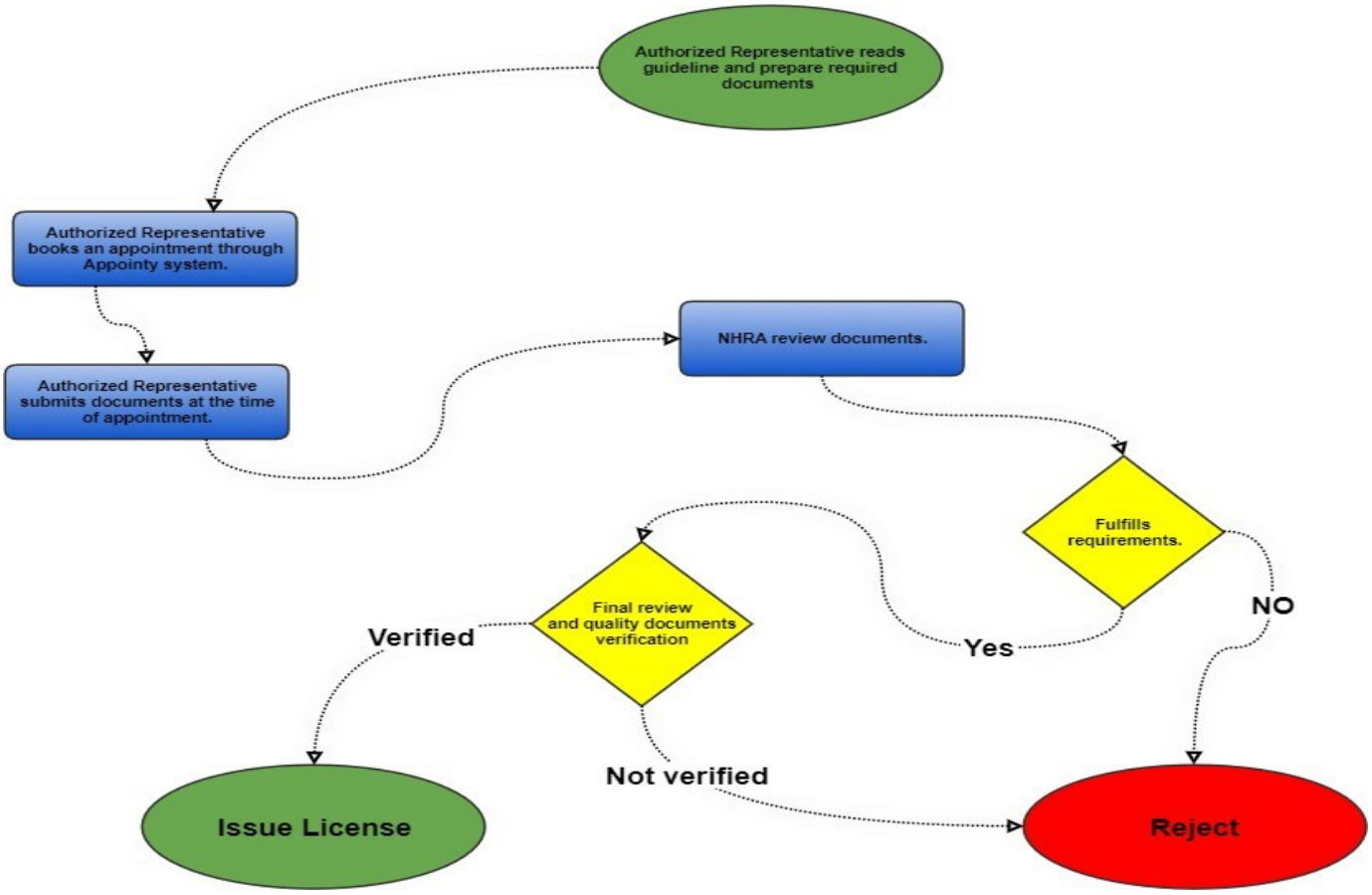
- New / old artwork (highlighting differences)
- Agreement / Letter of acquisition signed and stamped by both manufacturers stating the roles and responsibilities of each entity and explaining the impact of acquisition on the medical device in the market.

- Official declaration issued from new manufacturer stating that all acquisition changes has been clearly declared to NHRA with supportive documents.
- Quality certificates (QAC, QMS) for new manufacturer.
- Free Sale Certificate.
- List of affected medical devices by the acquisition in Bahrain market.
- Technical Details.

13. Registration Cancellation Reasons

1. The Quality Assurance Certificate/Quality Management System is expired (not renewed) or invalid (no longer available on notifying body website) with no valid justification from the Authorized Representative.
2. In case of major variation.
3. The medical device is subjected to a recall or caused a serious adverse event.
4. The authorized representative did not apply for registration renewal.
5. CR expired/deactivated due to violations causing a delay in renewal application.
6. Authorization agreement between the authorized representative and the legal manufacturer is cancelled or no longer valid.
7. Relationship letter gets cancelled for reasons such changing the physical manufacturer and NHRA have not been informed for variation.
8. Any other reasons determined by the national healthcare regulatory authority.

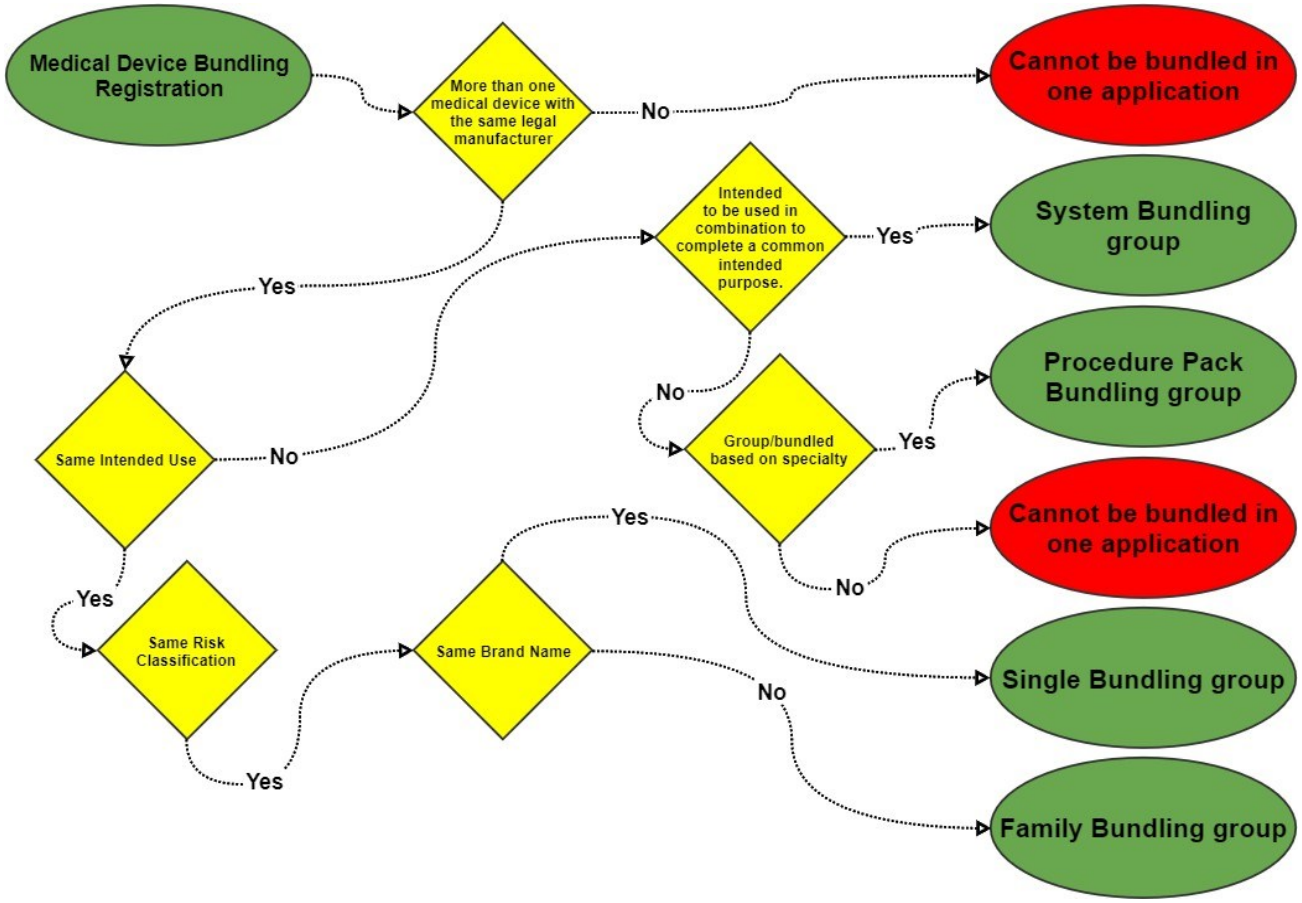
The following flowchart can simplify the process of Medical Device Registration:



14. Bundling Process

This is to clarify the submission process of the documents where some devices can be grouped (Bundled) in one submission, and others must be submitted separately. Bundling process is adapted from SFDA bundling guidelines, it is clarified in the flow chart below, and it is divided into four bundling groups as follows:

1. **Single Medical Devices.**
2. **Medical Devices Family.**
3. **Medical Devices System(s).**
4. **Medical Devices Procedure Pack.**
5. **IVD (In-Vitro Diagnostic).**



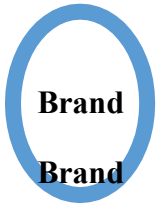
1. Single Medical Devices

A medical device that could have different models including color, quantity, range of size, number of units…. etc. For example, contact lenses. Medical device that have more than one model may be bundled/grouped within one application **only** if they have:


Same Legal manufacturer


Same Intended use

Same risk class



Same Brand Name

2. Medical Devices Family

A group of single medical devices that are made by the same manufacturer, have the same common intended use/purpose and the same risk classification and only differ in features**.** Differences in features may include, material, structural characteristic, design, patient groups, energy source, purpose, brand name, model name or device description, area of application, additional function, and additional secondary intended use/purpose**.** Medical devices that have different features may be bundled/grouped within one application only if they have:


Same Legal manufacturer


Same Intended use

Same risk class

3. Medical Devices System(s)

Means a device comprises of a number of single medical devices, which can be combined or operated in combination to achieve a common intended use/purpose.

For example an endoscopy tower which consists of:

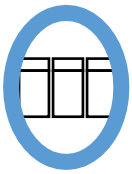
- Endoscopy camera
- Monitor
- Scopes
- Surgical tools

medical devices **with different intended use/purpose** may be bundled/grouped


Same Legal


are compatible when used as medical devices


Intended to be used in combination to complete a common


Sold under a medical devices system name; or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component

4. Medical Devices Procedure Pack

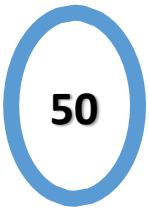
A collection of two or more medical devices, assembled together to perform a certain procedure as one package by a manufacturer.

Packs, sets or kits may be bundled/grouped within one application **only** if they have conformity assessment under **article 12** of EU MDD 93/42/EEC.

Same Legal manufacturer for the Packs

Common intended use

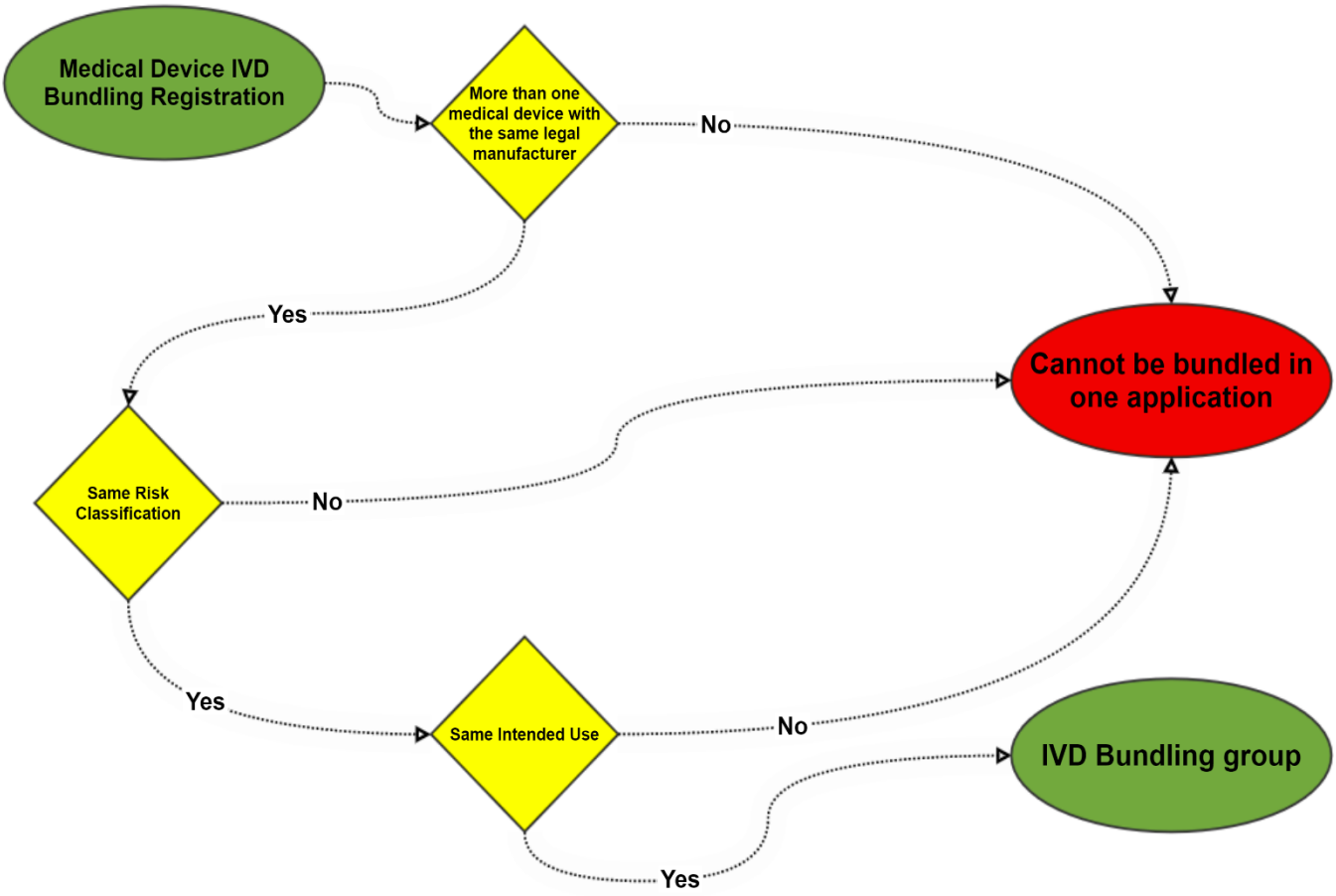
Grouped/ bundled based on specialty.



do not exceed 50 items per application

5. IVD (In-Vitro Diagnostic)

Registration of IVDs can be bundled in one application if they are from same manufacturer, with same risk classification, have same intended use and under the same original approval (QAC).



15. Glossary

No.	Terminology	Definition
1	**Medical Device**	means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: 1. Diagnosis, prevention, monitoring, treatment or alleviation of disease. 2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury. 3. Investigation, replacement, modification, or support of the anatomy or of a physiological process. 4. Supporting or sustaining life. 5. Control of conception. 6. Disinfection of medical devices. 7. Providing information by means of in vitro examination of specimens derived from the human body. And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
2	**IVD (In-Vitro Diagnostic)**:	any Medical Device which is a reagent, reagent product, calibrator, control material, kit, instrument apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • Concerning a physiological or pathological state, or • Concerning a congenital abnormality, or • To determine the safety and compatibility with potential recipients, or • To monitor therapeutic measures.
3	**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.

No.	Terminology	Definition
4	**SFDA**	**Saudi Food and Drug Authority**, which regulates, oversee, and control food, drug, medical devices, as well as to set mandatory standard specifications thereof, whether they are imported or locally manufactured.
5	**ISO 13485**	**International Organization for Standardization** Quality management systems required for regulatory purposes is an (ISO) standard published for the first time in 1996; it represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
6	**CE mark**	**Conformity European** which literately means "European Conformity". The term initially used was "EC Mark" and it was officially replaced by "CE Marking" in the Directive 93/68/EEC in 1993, declaring that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations.
7	**Quality Assurance Certificate Verification**	Means to check the validity of the quality assurance certificate by contacting the notifying body either by sending an email (6 months validity) or online through the website of the notifying body. (Refer to Verification guideline on NHRA website)
8	**Audit Report**	Report issued from the notifying body to ensure the manufacturer process and documentation in addition to the corrective action taken in case of non-compliance is as per international standards.
9	**Authorized distributor**	Regional authorized distributor who is responsible of issuing invoices to Bahrain authorized representative.
10	**Certifying Body**	The role of the certified Body is to conduct a conformity assessment under the relevant EU Directives. The conformity assessment usually involves an audit of the manufacturer's quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. Once the certified Body has determined a manufacturer has conformed to the relevant assessment criteria, it issues a certificate to show that the products assessed meet the requirements.

No.	Terminology	Definition
11	**Authorized Representative**	A firm registered by NHRA, authorized by the manufacturer through an official document; declaring them as their representing entity in the kingdom of Bahrain.
12	**HS code**	The Harmonized Commodity Description and Coding System generally referred to as "**Harmonized System**" or simply "HS" is a multipurpose international product nomenclature developed by the **World Customs Organization (WCO).** The Harmonized Commodity Description and Coding System (HS) is broad and is not structured for medical devices field.
13	**FDA**	**Food and Drug Administration,** it is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed[4] and veterinary products.
14	**Reference countries**	Saudi Arabia, USA, UK, Australia, Canada, Japan, Switzerland, Ireland, Denmark, New Zealand, France, Holland, Belgium.
15	**Low risk medical devices**	MDD: Class I-Non-sterile. MDR: Class Im, Class Ir. IVDD: Other/general IVD. IVDR: Class A.
16	**Medium risk medical devices**	MDD and MDR: Class IIa and Class IIb. IVDD: Annex III list B. IVDR: Class B and Class C.
17	**High risk medical devices**	MDD and MDR: Class III. IVDD: Annex III list A. IVDR: Class D.

16. Annex

Please visit NHRA website www.nhra.bh for more information about the following forms and checklists:

1. **Medical Device Registration Application Form:**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/MDR_Form_Medical%20Device%20Registration_10%20November%202021.pdf