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

Medical devices registration is one of the services in the pre-market phase of the medical devices regulation that is recommended by the WHO (World health organization).

Medical devices registration facilitates the importation of devices by minimizing the number of required documents and enhancing the level of traceability of devices in the kingdom. It also enables end-users 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' such as SFDA, FDA, MHRA, and TGA in order to be harmonized with the global regulations of medical devices. These regulations 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 medium and high-risk devices must be registered (Class IIa, IIb, and III) / IVD (Class B, C, D). Low risk devices are optional.
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 applied. ***Please refer to "Medical Devices Fees Guideline"***.
7. Classification criteria must be fulfilled (If applicable) before submitting for registration **(see classification guideline).**
8. All required official letters/documents should be signed and stamped by the issuer (electronic signature and electronic stamp are accepted).
9. Medical devices purchasing and marketing prices required in the registration form will be confidential and will be used for study purposes only.
10. 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.
11. The timeframe of registration application review is 20 working days. Fast track (Through third party services) is also available with a time frame of 10 working days.
12. NHRA may ask for additional documents as part of the review.

3. Process of Submission

In order to submit a medical device registration application, applicants should book an appointment through **"Ajheza"** system and submit all required documents at the booked date and time on the system.

The review process timeframe is **20 working days.** 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 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 will need to pay the application fees again 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

Unconditional Requirements:

1) **Technical Details** such as IFU, leaflet or user manual.

2) **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 Similar medical devices bundling group applications with more than 3 medical devices, minimum of 3 artworks should be submitted. For family and IVD bundling group cases where providing all medical device artworks is not feasible, applicants can contact NHRA through email for recommendation).

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

4) **Relationship Letter** issued by the legal manufacturer stating its relationship with the physical manufacturers and invoice issuer regarding the medical device(s). Full addresses must be mentioned.

5) **Quality Management System Certificate (QMS) - ISO 13485** for the **Physical manufacturer** with the address matching requirement 4 along with verification evidence (***See Quality Assurance Certificates and Verification Process Guideline for further clarification.)***.

6) **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 along with verification evidence (***See Quality Assurance Certificates and Verification Process Guideline for further clarification.)***. Not applicable for class I non-sterile and Class A/others IVD.

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

Conditional Requirements:

1) 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 along with verification evidence (***See Quality Assurance Certificates and Verification Process Guideline for further clarification.)***. This document needs to be submitted for class IIB medical devices if available.

2) 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).

3) In some cases, mainly for borderline products, 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)*.**

Additional requirements may be requested depending on the device/case.

6. Software Registration

"Software as a Medical Device" is defined as a 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 the same requirements of medical devices registration given in **Section (5).**

7. Research use only

Research Use Only (RUO) products are 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 medical devices 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 are already stated in the requirements), applicants have 10 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.

Examples:

- 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 in medical device name or product identifier (Model/reference).
- Adding devices to a registration license in case of color, package quantity, or volume variant. Not applicable for IVDs.

- **Major Variation:**

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

Examples:

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

Minor Variation Required documents:

1) Letter of variation from the legal manufacturer regarding the variation with a statement that the changes do 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.
- **Timeframe of NHRA review is 20 working days.**

Variation application outcome:

Minor Variation:

If a variation application is accepted, an approval letter will be issued from NHRA. In case not all requirements are fulfilled, the application will be reverted back to the applicant with the reasons.

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

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

10. Medical Devices Registration License Renewal

Applicants should submit for medical device registration renewal at max 1 month before its expiry date.

Unconditional Requirements:

1) **Changes letter** issued from the legal manufacturer stating whether there are changes/updates done or not from the time of last registration affecting the medical device/s or any of the documents previously submitted. If there are changes, details need to be provided with a statement that these changes do not affect the safety and quality of the medical device.
2) **List of countries** the medical device has been marketed in, issued by the Legal manufacturer.
3) **List of End-users** issued by the **Authorized Representative** in case the medical device exists in Bahrain market.
4) **Free Sale Certificate (FSC)** or **Certificate to foreign government** issued by the regulatory authority of the country of origin or a reference country.
5) If the device has been marketed in Bahrain for a minimum of 3 years, an official letter from the legal manufacturer mentioning **Bahrain market field safety notice records** for the past 3 years is required.
   If the device has not been marketed in Bahrain for a minimum of 3 years, an official letter from the legal manufacturer mentioning **worldwide and Bahrain market field safety notice records** for the past 3 years is required.
   Remark: If there are no field safety notice records, the above points still apply and an **official letter** from the legal manufacturer needs to be provided stating that there are no field safety notice records related to the devices.
6) **Updated verification** of quality documents.

Conditional Requirements:

1) **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.

2) If any of the previously submitted documents expired or amended, updated documents need to be provided.

For Certificates issued before October 2020:

All documents required in "Section 5 and 10" of this guideline should be submitted.

11. 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 confirming taking full responsibility of the medical device and that full handover for the device data have been transferred including.:
   Distribution records, Adverse events, FSN records, and Maintenance records (if any).

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

12. Manufacturer Acquisition

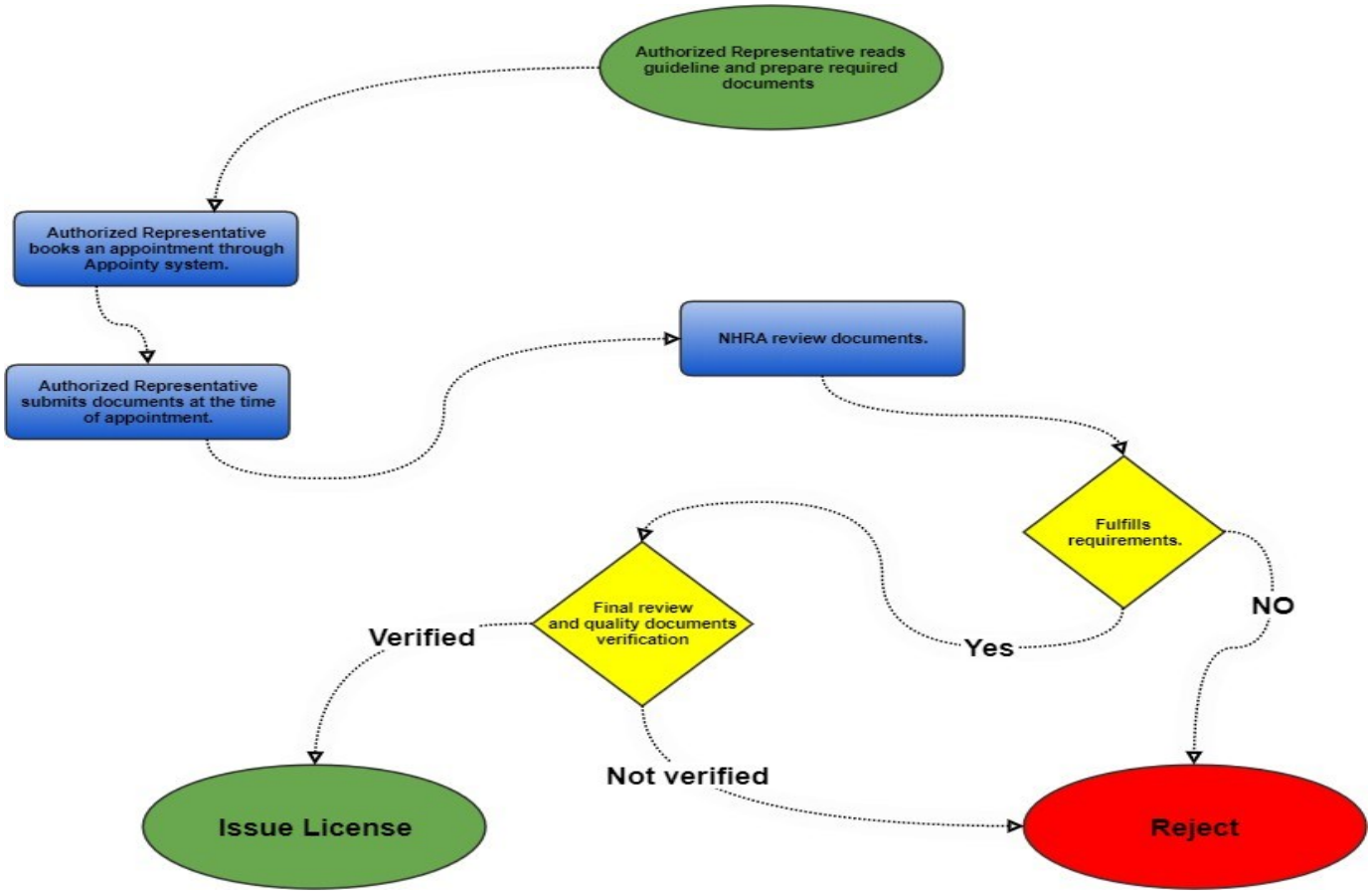
An acquisition is when one manufacturer purchases most or all of another manufacturer's shares to gain control of that company.
In this case, manufacturer acquisition is considered a variation and based on provided documents NHRA will determine whether it is a minor or major variation.
Required documents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

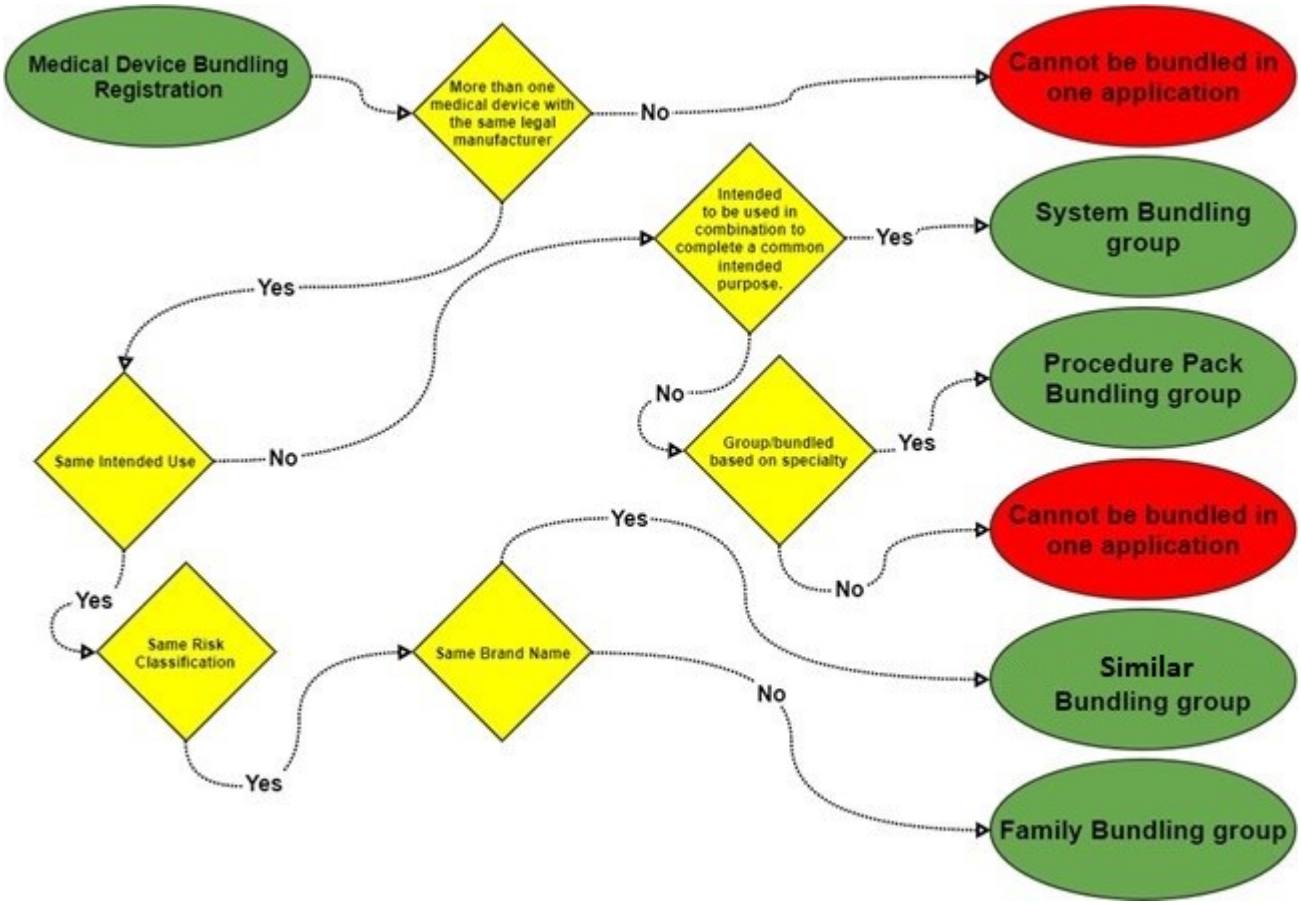
The following flowchart can simplify the process of Medical Device Registration:



14. Bundling Process

Bundling is submitting multiple devices in one application. The Bundling process is clarified in the flow chart below, and it is divided into five bundling groups as follows:

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



1. Similar 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 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 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:

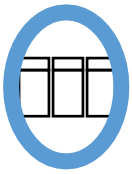
- Endoscopy camera
- Monitor
- Scopes
- Surgical tools

medical devices **with different intended use/purpose** may be bundled/grouped if they fulfill the below criteria:

Same Legal manufacturer

Compatible when used as medical devices.

Intended to be used in combination to complete a common intended use/purpose.



Sold under a medical devices system name; or the labeling, instruction for use (IFU), brochures or catalogues for each constituent component is intended for use/purpose with the system.

4. Medical Devices Procedure Pack

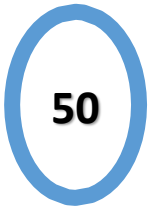
A collection of two or more medical devices, assembled together to perform a certain procedure as one package by a manufacturer.

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

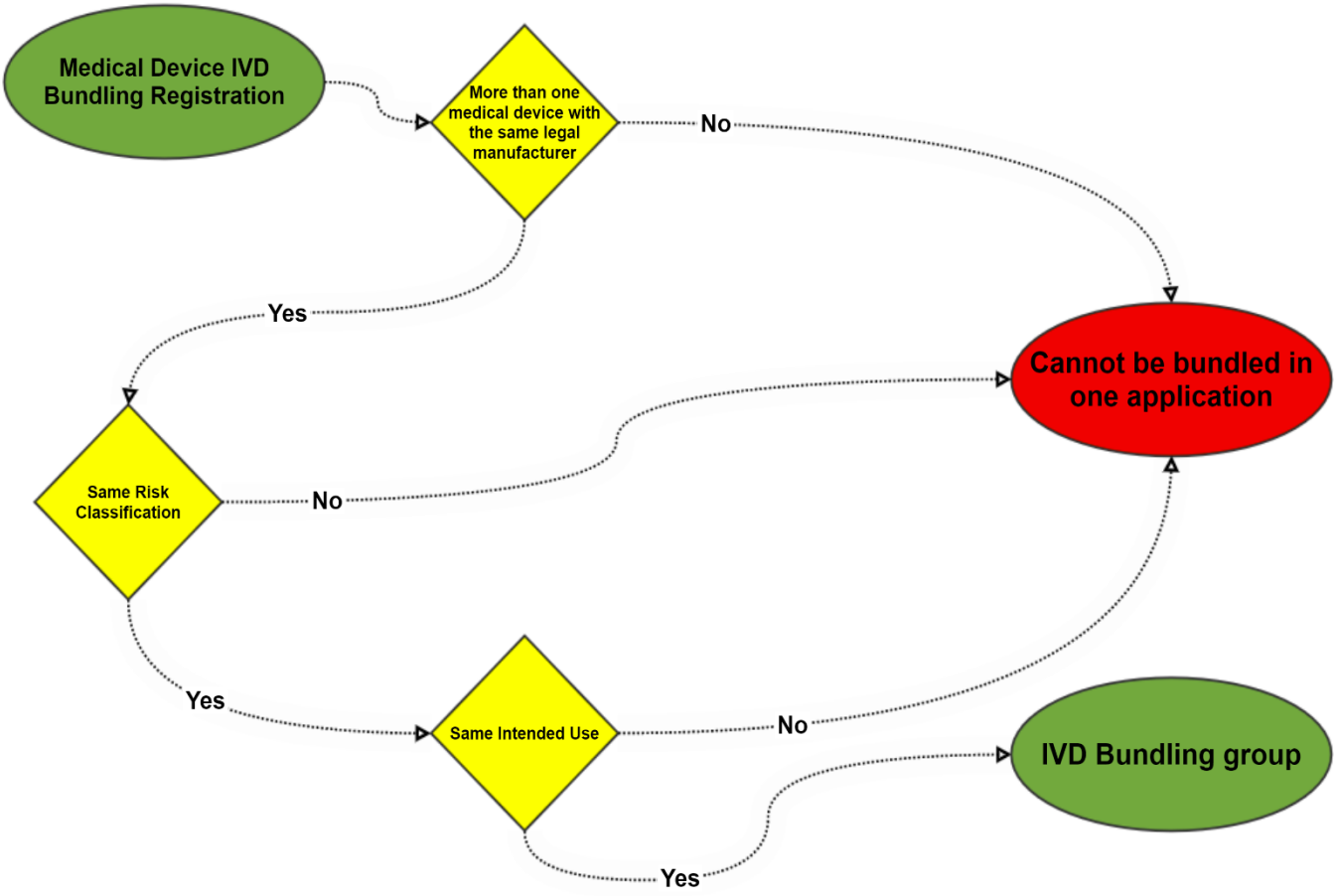
Grouped/ bundled based on specialty.



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 the same manufacturer, with same risk classification, have same intended use and under the same original approval (QAC). The maximum number of devices per application is 50.



15. Glossary

No.	Terminology	Definition
1	**Medical Device**	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**	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
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.
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.

No.	Terminology	Definition
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 I, Im (with a measuring function), Ir (Reusable surgical instruments), Is (Sterile). IVDD: Other/general IVD. IVDR: Class A.
16	**Medium risk medical devices**	MDD and MDR: Class IIa and Class IIb. IVDD: Annex II list B. IVDR: Class B and Class C.
17	**High risk medical devices**	MDD and MDR: Class III. IVDD: Annex II list A. IVDR: Class D.
18	**MDD**	Medical Device Directive 93/42/EEC.
19	**MDR**	Medical Device Regulation 2017/746.
20	**IVDD**	In Vitro Diagnostic Directive 98/79/EC.
21	**IVDR**	In Vitro Diagnostic Devices Regulation 2017/746
22	**Date of market entry**	The date that the device entered the kingdom of Bahrain.

16. Annex

Please visit NHRA website www.nhra.bh for more information about Ajheza system and Fast Track submission route.