Medical Devices Registration Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

Jul 2019

Version 3.0

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1. Main Definitions

- **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;
  8. 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.

- **Combined medical device:** Term used in the kingdom of Bahrain to differentiate between Medical devices with Pharma HS code that requires manual approval and Active Medical devices HS code. Most of these device are mixed with pharmaceutical or chemical materials and does not achieve their action by pharmacological, immunological or metabolic means, used for prevention of illness. It also covers IVD with pharmaceutical or biological materials.

- **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.

2. Introduction

Medical device registration was implemented in 2015 to accelerate the process of importation, in 2018 a new process of registration was implemented and it will be highlighted in details in this guideline.

National medical devices registration is one of the medical devices regulation process that is recommended by the WHO (World health organization) which is implemented in the premarketing regulation.

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

3. General Rules

1. Registration of medical devices is done after the registration of the authorized representative in NHRA.
2. All medical devices must be registered class I, II and III.
3. Only authorized representative can apply for medical device register.
4. All registered medical devices will be published along with their authorized representative on NHRA website.
5. All healthcare facilities will be instructed to purchase only registered medical device.
6. Registration is not linked to importation process whether HS code is regulated by NHRA or not.
7. Registrations fees is not implemented yet, once implemented a circular will be published on our website.
8. Classification criteria must be full filled before submitting for registration **(see classification guideline)**

9. Medical device License **Renewal** should be submitted 9 months before expiration date.

10. All medical devices should have a valid and verified quality assurance certificate (ex: SFDA, FDA, CE mark, ISO 13485) and it should be issued from a recognized notifying body.

4. Process of Registration

In order to apply for medical device registration, applicant should send an email to Medical_Device@nhra.bh to fix an appointment for submission the registration form with the required documents as per the checklist.

There are two forms for Medical Device Registration:

1. Registration Form of Medical Devices with Medical Device Marketing authorization "MDMA" which means the device is registered in Saudi Food and Drug Administration.
2. Registration Form of Medical Devices without MDMA.

These documents will be reviewed By NHRA team, then a Registration Certificate will be issued with a validity of 5 years or 3 years

Prices information required in the registration form will be confidential for study purposes only.

5. Requirements of Non-SFDA Medical Devices Registration

The required documents for registration of are:

- Medical Device Registration form should be filled, signed and stamped by the authorized representative.
- Agreement or Authorization letter from the manufacturer to the applicant, stating that they are the authorized importers in the Kingdom of Bahrain.
- The Quality Assurance Certificate & Quality Management System with its verification (EX: SFDA, ISO 13485, CE, FDA).

- CE Design Examination for medical devices Class III.
- Relationship letter between the legal Manufacturer and the Quality Assurance Certificate holder (if required).

- Technical details. (Ex: User Manual or Catalogue or Service Manual).
- Instruction for use (IFU). (Ex: leaflet, MSDS Material Safety Data Sheet)
- List of the countries the medical device has been marketed in, issued, signed and stamped by Manufacturer.
- List of Product's name, model, brand, and clear GMDN/UMDN description.
- Free Sale Certificate from the Regulatory Authority in the country of origin stating the Device Name and Manufacturer.
- Art work i.e. label of the product, it should be clear in English or Arabic.
- Letter from the manufacturer stating the history of product recall in Bahrain market for past 5 years, if not; a declaration from the manufacturer stating no recall history.
- Declaration of conformity form the Manufacturer stating risk class.
- Acknowledgment signed and stamped from the authorized representative should be provided with the required documents stating the request of the registration with date of submission the documents.

6. Requirements of SFDA Medical Devices Registration

The required documents for registration of are:

- SFDA Medical Device Form should be filled, signed and stamped by the company.
- Medical Device Marketing Authorization Certificate (MDMA) and the product listing.
- Letter from the manufacturer stating the history of product recall, if not; a declaration from the manufacturer stating no recall history.
- List of Product's name, model, brand, and clear GMDN/UMDN description.
- Agreement or Authorization letter from the manufacturer to the applicant, stating that they are the authorized importers in the Kingdom of Bahrain.
- Instruction for use (Ex: leaflet, MSDS Material Safety Data Sheet).

- Quality Assurance Certificate & Quality Management System with its verification (EX: SFDA, ISO 13485, CE, FDA).and if more than one country of origin a relationship letter should be provided stating the relation between the legal manufacturer and its sites OR QAC for the other sites should be provided with its verification.

- List of the countries the medical device has been marketed in, issued, signed and stamped by Manufacturer.
- Art work i.e. label of the product, it should be clear in English or Arabic.

- Acknowledgment signed and stamped from the company should be provided with the required documents stating the request of the registration with date of submission the documents.

7. 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

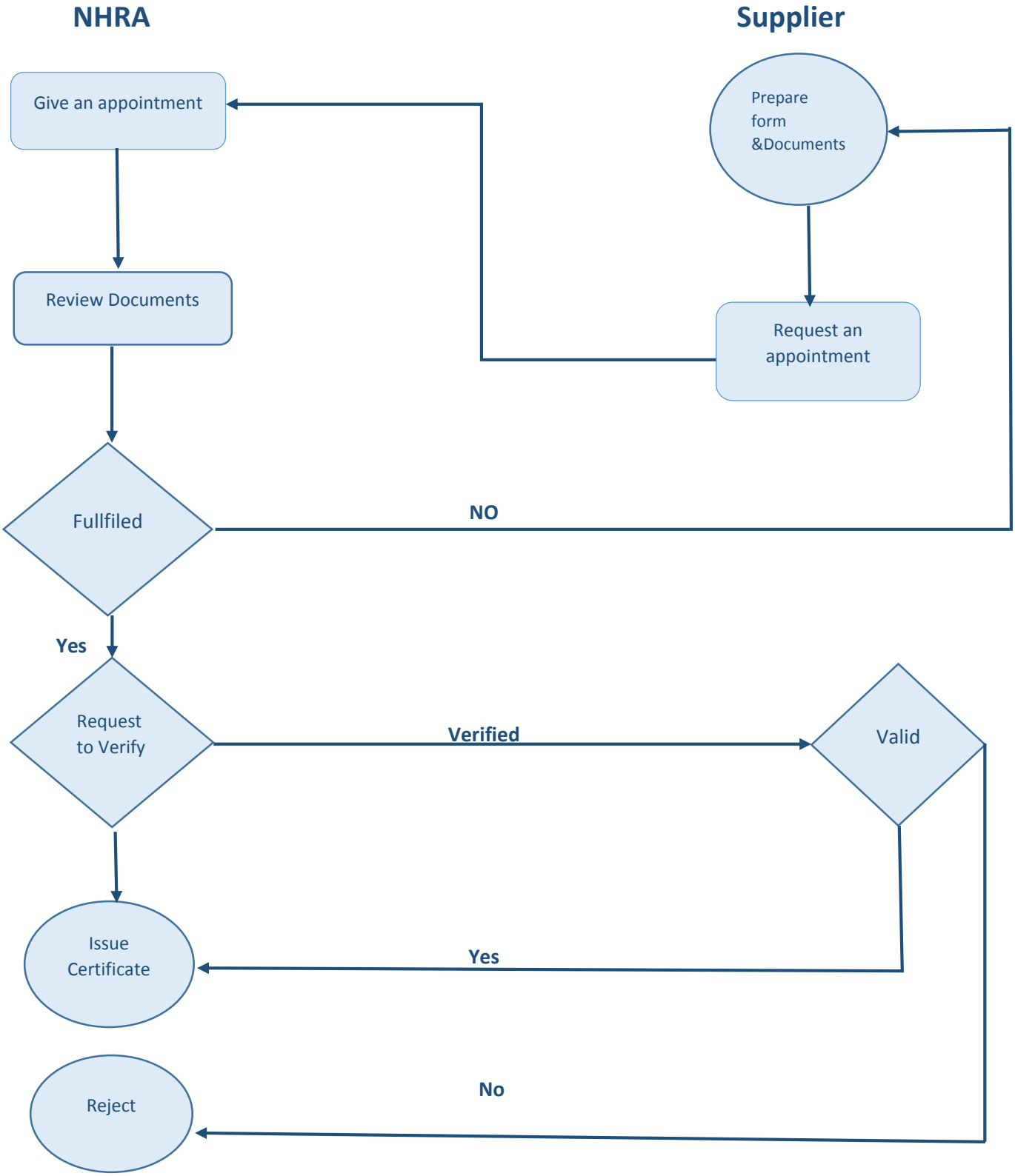
Any modification that does not affect safety or performance of a medical device which obtained a marketing authorization

Major Variation

Any modification that does affect safety or performance of a medical device, such as changing the physical manufacture location, changing detailed specification of the device

Minor changes can be amended via an official letter from the manufacturer, however Major changes means that medical devices registration form must be submitted and the previous license will be cancelled.

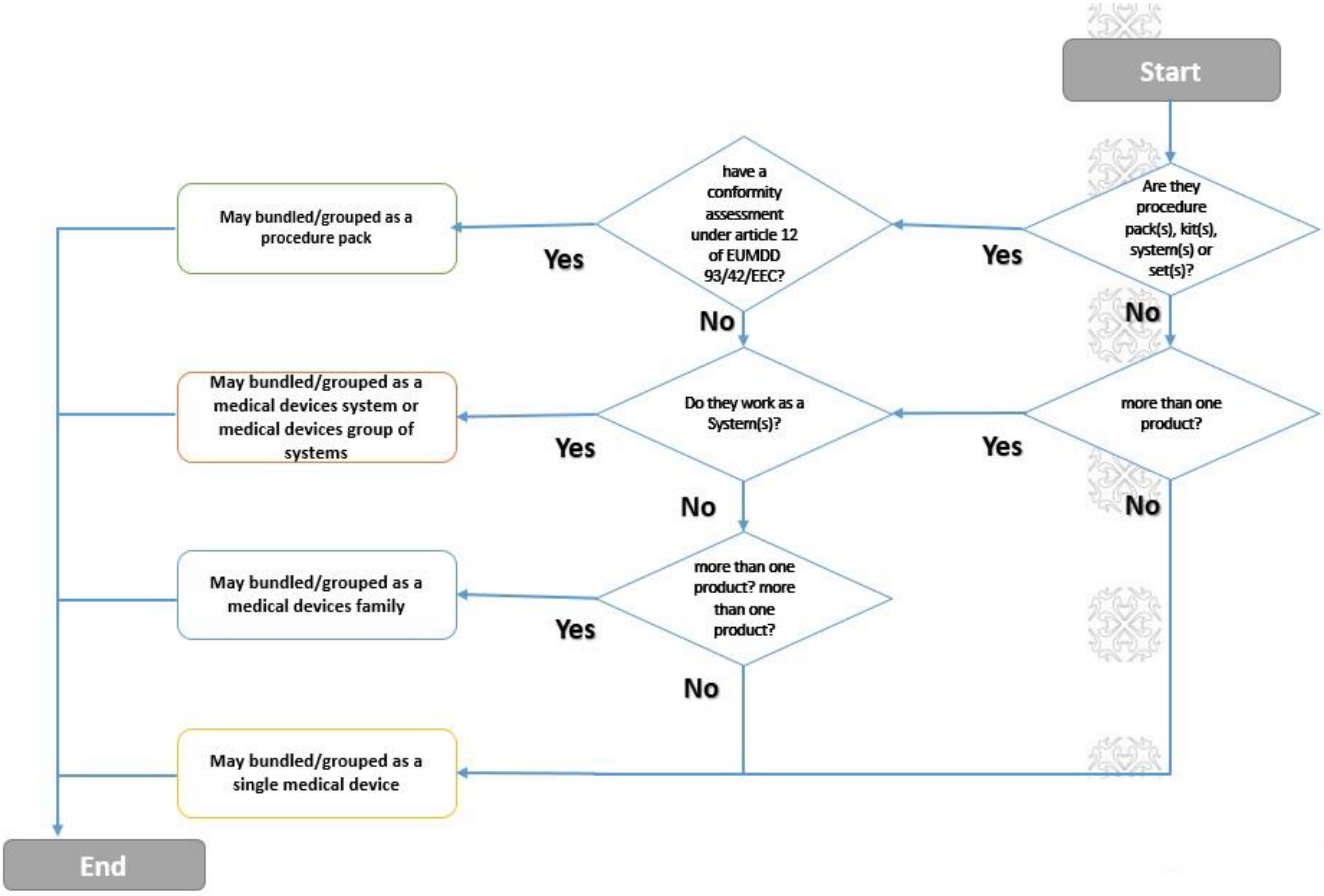
The following flowchart can simplify the process of Medical Device Registration:



8. 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; which is clarified in the flow chart below, which is divided into four bundling groups as follows:

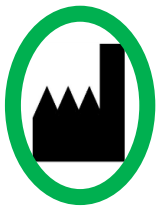
1. **Single Medical Devices.**
2. **Medical Devices Family.**
3. **Medical Devices System(s).**
4. **Medical Devices Procedure Pack.**
5. **IVD (In-Vitro Diagnostic).**



1. Single Medical Devices

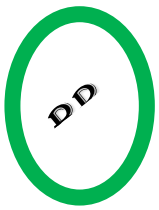
A medical device that could have different models including: color, quantity, range of size, number of units….etc.

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

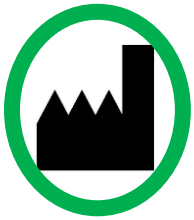

Same Generic Name

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 differ in only 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

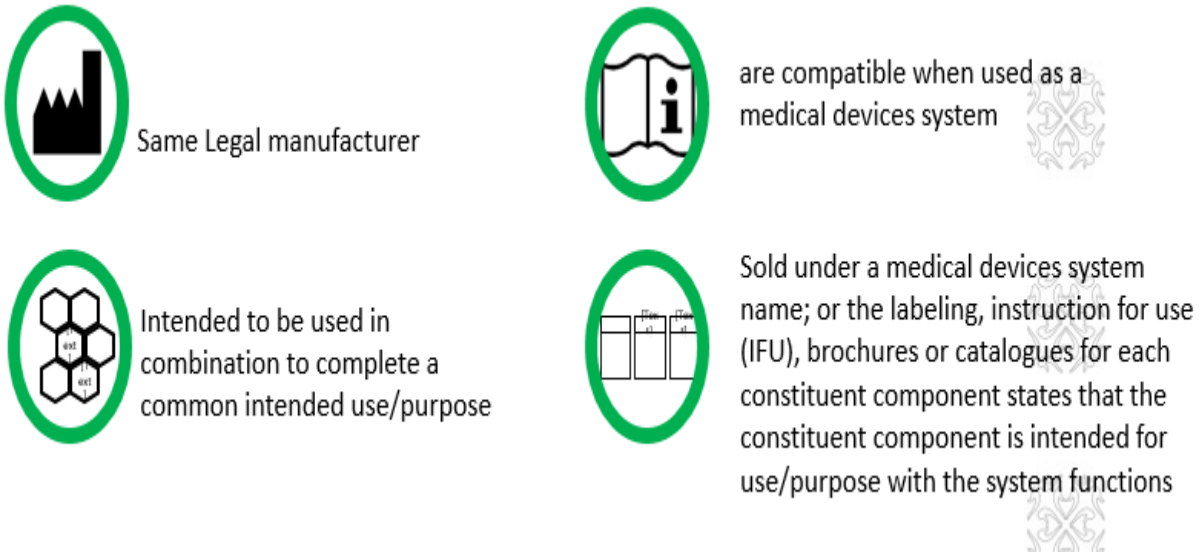
3. Medical Devices System(s)

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

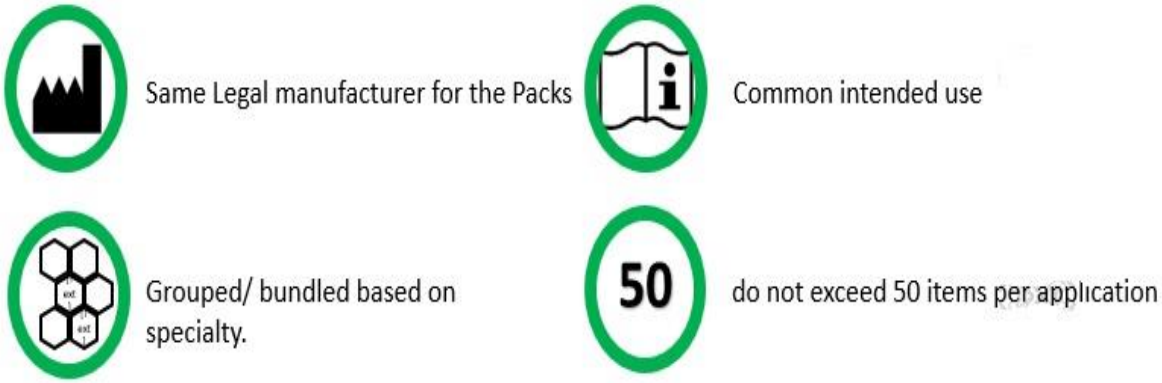
Medical devices **with different intended use/purpose** may be bundled/grouped within one application **only** if they:



4. Medical Devices Procedure Pack

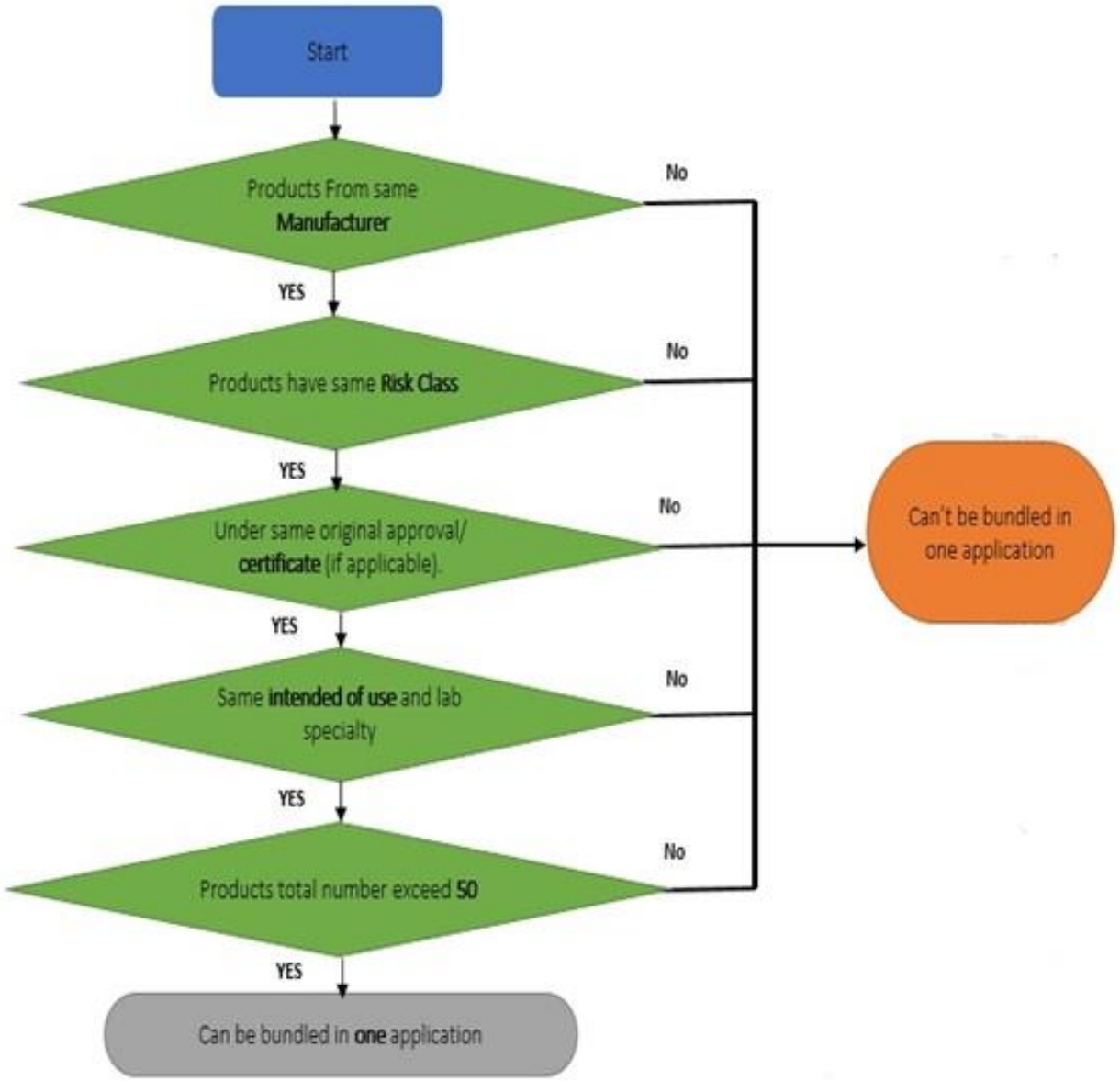
A collection of two or more medical devices, assembled together to perform a certain procedure as one package by a manufacturer.

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.



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 of use and under the same original approval (QAC).



9. Glossary

No.	Terminology	Definition
1	**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.
2	**Importer**	Means any natural or legal person in the supply chain who is the first to make medical device, manufactured in another jurisdiction, available in Bahrain.
3	**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.
4	**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, blo od transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed[4] and veterinary products.

No.	Terminology	Definition
5	**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.
6	**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. .
7	**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.
8	**Quality Assurance Certificate Verification**	Means to check the validity of the quality assurance certificate by contacting the notifying body either by sending an email or online through the website of the notifying body. (refer to Verification guideline on NHRA website)

No.	Terminology	Definition
9	**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.
10	**Authorized Representative**	The authorized agent from the manufacturer through an authorization letter stating that it is the exclusive distributer in the Kingdom of Bahrain for marketing the imported medical devices.

10.Annex

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

1. **Medical Device Registration Form.**
2. **Medical Device Registration Checklist.**
3. **SFDA Medical Device Registration Checklist**
4. **SFDA Medical Device Registration Form.**
5. **Medical Device Variation form.**