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Medical Devices Regulations in Kingdom of Bahrain

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Registration
- Authorized Representative.
- Medical Devices.

- Importation.
- Classification

- Permit to Use.
- Field Safety Notices
- Medical Devices reporting

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Authorized Representative Registration

- Updates in the guideline and requirements to be more specific to ensure high qualifications of medical devices companies……
- Registered companies are classified into classes (A, B, C, D) based on a scoring criteria extracted from the AR registration essential principles.
- The Authorized Representative Registration Certificate will be valid for minimum **1 years** and must be renewed, 6 months before its expiry date.

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Medical Devices Registration

Updates in the requirements of medical devices registration to include:

- **Quality Management System Certificate (QMS) - ISO 13485** for the Physical manufacturer with the address.
- **Quality Assurance Certificate (QAC) - CE directive 93/42/EEC or FDA** Registration Certificate for the Legal manufacturer with the address matching the artwork and minimum 1 year validity.
- For class 1 non-sterile or General/other IVD medical devices, a **Declaration Of Conformity (DOC)** can be submitted instead.
- If the medical device/IVD risk classification is class III/class D(IVD), an **EC Design examination certificate or an FDA** registration certificate is required with a minimum 1 year validity.
- If the medical device risk classification is class II B or an active implantable medical device, manufacturing site (Physical Manufacturer) **recent audit report is required**.

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Medical Devices Registration

- NHRA cooperation with the **(Medespero)** company; in order to facilitate the process of medical devices registration to applicants who are facing difficulties in preparing the required documents in order to speed up the registration process.

- Registering of medical devices local manufacturer and issue a guideline explaining the requirements and process of registration.

Medical Devices Advertisements

- Issue a guideline intended to clarify process and requirements of medical devices advertising for the manufacturers, importers, distributors, AR and HCF in order to comply with NHRA regulations and avoid legal issues.

Importation

- In case of legal manufacturer and Physical manufacturer are different:

➢ Quality Assurance Certificate **(CE)** should be provided for the physical manufacturer.
➢ Quality Management System **(ISO 13485)** should be provided for the legal manufacturer.

- For medical devices class I, provide ISO 13485 for legal manufacturer and DOC for physical manufacturer.

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Classification

- The term **“Combined Medical Devices”** and its process is no longer valid and the importation process is moved to OFOQ system and there is a new subcategory HS codes list published on the website.

- In case of importing products single use medical devices, request will be transferred to classification and if the product falls under the medical device regulation then a classification letter will be issued stating that the product is classified as a medical device.

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Permit to Use

No updates, Same process and requirements

Phase 1 Listing the medical devices

*Collecting the data starting from hospitals , health centers , clinics .

* Ensure that the listed devices match with the HCF specialty.

Phase 2 Providing the required QAC

*Ensure that the QAC and QMS are valid .

*Ensure that the QAC and QMS scope matches with HCF devices

Phase 3 Approved medical devices will be labeld and published on NHRA wesite

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Field Safety Notice

- FSN form updated

- Defining the roles of Authorized representative, end user and regulatory authority in the guideline.

- FSN classification with reporting time frame based on severity :
  - Very high risk (2 working days)
  - High risk (5 working days)
  - Moderate (10 working days)

- Reporting time frame, 1 month starting from the date of informing AR to provide required documents and close the FSN case.

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Medical Devices Reporting

According to the severity of the adverse event, NHRA should be informed during the time frame set below:

Reporter	Type of problem	Report to whom	Time frame
Manufacturer	Death / Serious injury	NHRA	10 working days.
	Other Problems not associated with high risk or injury.	NHRA	30 working days.
AR / Supplier	Death / Serious injury	Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury.	Manufacturer / NHRA	30 working days.
Healthcare Facilities	Death / Serious injury	Supplier / Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury.	Supplier / Manufacturer / NHRA	30 working days.

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COVID-19 Updates

- Issue COVID-19 Guideline including all topics related to COVID (importation of face masks, hand sanitizers, disinfections, Rapid tests).