مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Medical Devices Registration

Technical File Requirements

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Purpose

To clarify the technical requirements for Medical Devices registration in order to obtain certification from the GCC Health Council. This guidance covers All medical devices including IVDs.

Definitions:

Medical Device: Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes 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 return it may be assisted in its intended function by such means.

IVD Medical Device: a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

GCC: Gulf Cooperation Council.

GHC: Gulf Health Council

TAAWON Portal: The portal will enable companies to apply for applications and/or submit other requests.

Medical Devices Classification: A system adopted by the GHC that assesses the level of risk related to the medical device and its safety.

Summary of Technical Requirements:

#	Requirements	Class (A)	Class (B)	Class (C)	Class (D)
1	**Device Description and Specification** • Product or trade name of the device • Product and accessories identification • Description of the device and any accessories • Intended purpose of the device • Global Market History: Up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing (Approvals/Certificates) – examples; (including regulatory certificates such as free sales certificates, CE, PMA. ..etc)	√	√	√	√
2	**Information to be Provided by The Manufacturer** • Labels • Manufacturer's instructions • Promotional material	√	√	√	√
3	**Design and Manufacturing Information** • Full device description • Design stages • Manufacturing processes	×	√	√	√

4	**Essential Principles of Safety and Performance** • Essential Principles (EPs) checklist • Evidence of conformance	√	√	√	√
5	**Risk Management** • Risk Management File (RMF) in accordance to ISO 14971	√	√	√	√
6	**Product Verification & Validation** • Test Reports • Clinical Validation • Pre-clinical data and clinical data	×	√	√	√
7	**Post-Market Surveillance Plan** • Sources of potential post market surveillance data • Tools to trace and identify devices	√	√	√	√
8	**Periodic Safety Update Report (PSUR)** • The main findings of the Post-market clinical follow-up (PMCF) • The volume of sales of the device and an estimate of the size	×	√	√	√
9	**Quality Management System in reference to international practices (ISO13485 or similar)**	√	√	√	√

Detailed Technical Requirements

1. Device Description

- ✓ **Product or trade name of the device**
- ✓ **Product and accessories identification**
- ✓ **Description of the device and any accessories**
  - Physical description (i.e. what the device looks like)
  - Components/parts/spares/accessories (i.e. what parts it comprises of)
  - Materials and which of these have direct or indirect contact with the human body (i.e. what it is made of)
  - Principles of operation/mode of action (i.e. how it works/operates)
  - Any specific performance characteristics it has and how they different between models
  - Options/configurations/sizes (i.e. detail what options/configurations/sizes are available for the market if applicable)
- ✓ **Picture or drawing of the device which should be detailed enough to aid understanding of the device operation and include sufficient explanation to understand the drawing**
- ✓ **Intended purpose of the device**
  - Key indications
  - Medical conditions

- Patient populations
- Contraindications

✓ **Intended users of the device**

- Patient/Clinician/Career
- Any user restrictions

✓ **Classification of the device and any accessories**

✓ Global Market History: Up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing (Approvals/Certificates)

✓ **An explanation of any novel features**

- new to market technology
- new types of materials used
- new application of existing technology

✓ **Description of any devices required to operate the device that are not included**

- (e.g. IT infrastructure, laptop, mobile 'smart' phone)

- Device history (i.e. provide an overview of the previous generation or generations of the device if applicable)
- Device market position (i.e. are there similar devices in Gulf States or other international markets)
- Declarations (i.e. does the device require any specific declarations to be made such as containing animal tissue/medicines/human blood derivatives)

- **The manufacturer is responsible for determining the classification of a device using classification rules**

2. Information to Be Supplied by the Manufacturer

✓ **The Technical Documentation shall include:**

- A full set of labels for the device and packaging which includes the instructions for use (IFU) and any promotional material as applicable.

✓ **Promotional material must not contain claims that exceed those in the instructions for use, clinical evaluation or technical documentation.**

✓ **Manufacturer's instructions for handling, storage, transportation, installation, maintenance (including service manuals), and disposal of the medical devices.**

3. Design and Manufacturing Information

Full device description:

- Technical drawings
- Bill of materials
- Information to describe the function and assembly of the device

Applied parts

- Explanation of which parts of the device contact the human body either directly or indirectly
- Identification of the contact materials

Technical specifications

- Device features
- Dimensions

- Performance attributes
- Voltages
- Output
- Temperatures
- Flows
- Weight
- Speed
- Other specifications

Requirements documentation

- User requirements
- Product requirements
- Software requirements
- Hardware requirements
- Other requirements

Design traceability

- Traceability matrix to show how user requirements have been validated and product/design requirements have been verified.

Design stages

- Reference to design procedure
- Description of design stages
- Confirmation of the verification and validation conducted on the device

Manufacturing processes

- Manufacturing process flow
- Manufacturing specifications including in process testing
- Final inspection and acceptance criteria
- Manufacturing validation

Manufacturing structure

- Name and address of place where design was carried out (all sites and subcontractors)
- Name and address of place where manufacturing is carried out (all sites and subcontractors)
- Detail of suppliers including identification of critical suppliers

4. Essential Principles of Safety and Performance

Essential Principles (EPs)/ General Safety and Performance Requirements (GSPR) checklist

- The essential principles requirements that apply to the device and an explanation as to why others do not apply
- The method or methods used to demonstrate conformity with each applicable essential principles requirement
- Any standards, or other solutions applied

Evidence of conformance to applicable EPs

- The precise identity of the controlled documents offering evidence of conformity with each standard, or other method applied to demonstrate conformity with the essential principles requirements.

5. Risk Management

Benefit-risk Analysis.

Risk Management File (RMF) in accordance to ISO 14971

- Procedure
- Risk Management Plan
- Risk Analysis
- Risk Management Report

6. Product Verification & Validation

Pre-clinical data and clinical data

- Engineering, laboratory, simulated use and animal tests

Test Reports

- Biocompatibility
- Physical, chemical and microbiological characterisation
- Electrical Safety & EMC
- Software Verification & Validation
- Packaging, Transportation, and Stability Testing (Shelf-life)
- Performance and Safety
- Sterilization Validation
- Usability studies

Clinical Validation

- Clinical Investigation, Clinical Evaluation Report, Post-Market Clinical Follow-up (PMCF)

7. Post-Market Surveillance Plan

- Sources of potential post market surveillance data
- A proactive and systematic process to collect information.
- Methods and processes to assess the collected data.
- Continuous reassessment of the benefit-risk analysis and of the risk management
- Methods and tools to investigate complaints and analyze market-related experience collected in the field.
- Tools to trace and identify devices for which corrective actions might be necessary.
- Methods and protocols to communicate effectively with SFDA Reporting Center.

8. Periodic Safety Update Report (PSUR)

PSUR is required for class B, class C and class D devices

PSUR summarize the results and conclusions of the analyses of the post-market surveillance data

PSUR shall set out:

- The conclusions of the benefit-risk determination
- The main findings of the Post-market clinical follow-up (PMCF)

- The volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device

Manufacturers of class C and D devices shall update the PSUR at least annually.

Manufacturers of class B devices shall update the PSUR when necessary and at least every two years.

9. Quality Management System

Local and Overseas Manufacturers of Medical Devices Shall establish a Quality Management system in reference to international practices (ISO13485 or similar)

10. Taawon Portal:

Companies must submit all types of requests through Taawon portal.