مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Medical Device Central Registration Regulation

(Gulf Health Council)

Issue	Prepared by	Date
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Article (1): 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.

Combined Medical Devices and Supplies: Anything combined in one set to meet user requirements and might incorporate non-medical devices or supplies.

Single-Use Medical Device and Supply: A medical device manufactured for use during a single medical procedure for one patient once, then is disposed thereof.

User: Anyone uses a medical device and supply, whether a specialist, a layperson or a patient.

Facility: A systematic entity that practices an activity pertaining to medical devices and supplies.

Manufacturer: Any local or foreign facility, whose purpose is to design or manufacture medical devices or supplies, to offer them for use under its name, whether inside or outside GCC states. Manufacturing includes: Refurbishment, assembly, packaging and placing identification information on it.

Authorized Representative: A legal person, whose registered office is located inside GCC states, which is authorized in writing by a foreign manufacturer to represent it inside member states, in connection with the application of the law and the regulation.

Classification System: A system approved by the Committee for evaluating the risk degree related to the medical device or supply and evaluating its safety.

Quality Management System: A system approved by the Committee for verifying the medical device or supply's quality, effectiveness and safety, according to the latest version of the technical specification (ISO 13485) or its equivalent, as shown in the regulation.

Identifying Information: Any statement, piece of information drawn or illustrated, written or printed on the medical device and supply, including information that identifies it, its technical description, and instruction of use, store and transport it.

Safety Alert Corrective Procedure: A procedure taken by the manufacturer to limit or minimize risks affecting the safety of the medical device or supply.

Medical Device and Supply Incidents: Any deficiency or change in the characteristics or performance of the medical device or supply that might cause or contribute directly or indirectly to the user's death or serious injury.

Home-Use Medical Device or Supply: A medical device or supply dedicated to be used in any environment outside the healthcare facility.

Lay Person: A person who has not received any certified training or education in a relevant field or specialty.

Supply Chain: A set of activities under which the medical device or supply goes through, from the design and manufacturing stages until it reaches the user.

Importer: A facility in the supply chain that imports medical devices or supply to GCC states.

Distributor: A facility in the supply chain that provides the medical device or supply to another distributor or the end-user.

Publicity and Advertisement: Any statement, whether written, audible, visual or otherwise, meant to promote a medical device or supply, the technology of the medical device or supply, or direct or indirect sales.

Inspection: A procedure taken by the Council to assure that the facility or the manufacturer adheres to stipulations and requirements of facilities, medical devices and supplies as stated in the Law and the Regulation.

Corrective Procedure: A procedure taken to address causes of non-conformity in connection with the facility, the manufacturer, or the medical device or supply.

Technical Documents: Technical and scientific documents and information related to the medical device or supply and the manufacturer, including documented and approved procedures that prove the conformity of the device or supply to the safety, efficiency, and quality requirements specified in the law and its regulation.

Intend of Use: The purpose identified by the manufacturer behind the use of the medical device or supply.

Transplanted Medical Device: A medical device that is surgically inserted entirely into the human body, replaces the external/epithelial surface of the body, or put on the eye surface including those partially or fully absorbed by the body, and remains in the body after the surgical procedure, including devices that are surgically inserted partially for use for 30 days or more.

Committee: Medical Device Central Registration Committee at Gulf Health Council

Article (2):

This Regulation is intended to identify requirements and conditions necessary for obtaining the central registration certificate of medical devices and supplies issued by the Gulf Health Council.

Article (3):

This Regulation shall apply to the following persons, medical devices and supplies:

1. The manufacturer, the authorized representative and the importer
2. Medical Devices and Supplies

Article (4):

Medical devices and supplies' accessories shall be treated like medical devices and supplies and shall meet the conditions and requirements stated in this Regulation.

Article (5):

The medical device or supply shall meet technical requirements of the registration of medical devices and supplies in GCC states, ensuring that Saudi Arabia is one of the technical file's evaluators.

Article (6):

The Council has established an electronic system for medical devices and supplies, and facilities, concerned with:

1. Registering medical devices and supplies.
2. Counting facilities and managing information required for listing medical devices and supplies.
3. Create a vision of the market size of medical devices and supplies in GCC states.
4. Providing information about medical devices and supplies that will be in gulf countries market.

Article (7):

The Council shall issue a medical device central registration which is valid for five years from the date of issuance. The certificate shall be renewed upon the company request to be submitted within six months prior to the certificate expiry date.

Article (8):

The Committee shall have the right to terminate the registration in following cases:

1. If the Committee receives reports issued by the National Center for Medical Device Reporting at the Saudi Food and Drug Authority (SFDA).
2. If the use of the device or supply is suspended upon the recommendation of one of the international regulatory bodies or the National Center for Medical Device Reporting at the SFDA and has been accepted or if the Council receives reports from the competent health authorities proving that it has harmful side effects, or for any technical reasons deemed by the Council.
3. The company registration shall be terminated or suspended in the event the manufacturer does not meet the requirements of quality management systems or any provision of the Regulation.

Article (9):

- The Committee shall have the right to postpone, reject or terminate the registration of any medical device or supply, upon expressing justifications and reasons.
- The registration applicant has the right to object to the committee's decision and provide reasons of objection to the Council within two months of being informed of the Council's decision. The Council's decision shall be deemed final after studying the objection.

Article (10):

1. Facilities using medical devices and supplies shall obtain a facility license from GCC countries.
2. A facility is allowed to work as an authorized representative, after obtaining necessary licenses where they operate.

Article (11):

Importer's commitments are:

1. Notify the medical device or supply's manufacturer or authorized representative when wishes to enter the GCC medical devices market.
2. Document the procedure for tracking the medical device during the importing or distribution phase. as well as taking the full responsibility to track the medical device during the usage.

Article (12):

1. The manufacturer shall appoint an authorized representative to act on its behalf in member states, and its responsibilities shall be identified pursuant to an identified-term agreement incorporating all necessary certifications, provided that the manufacturer shall notify the Committee of any amendment made to the Agreement within ten business days as of its date.
2. In case of changing the authorized representative, the manufacturer is responsible for concluding an agreement with a new authorized representative, without affecting the availability and the use of the product in member states.

Article (13):

The Council shall issue the facility registration number and a number to each medical device or supply.

Article (14):

The Committee shall study and evaluate the submitted documents to ensure that the medical device or supply complies with the provisions of this Regulation.

Article (15):

When the committee disapproves the registration application, the applicant shall be notified along with the reasons behind the rejection, and the applicant may object to the disapproval decision according to the applicable procedures.

Article (16):

The manufacturer or the authorized representative has the right to object to the medical device committee's decision, and express causes of objection within two months after the notification date, and the decision shall be deemed final after studying the objection.

Article (17):

The manufacturer or the authorized representative is permitted to apply for re-registration upon the Council's recommendation after the reasons that led to the cancellation of the registration have been removed.

Article (18):

The manufacturer or the authorized representative shall respond to the Council's remarks during the period specified by the Committee as of the date of notification, otherwise the registration application will be rejected.

Article (19):

If the medical device or supply does not comply with the provisions of this Regulation, the Council shall suspend or terminate the registration or as the case may require and shall notify the manufacturer or the authorized representative of the causes of the suspension or cancellation, and the mechanism for addressing the decision.

Article (20):

Manufacturers wishing to obtain medical device central registration shall adhere to the implementation of the approved quality management system.

Article (21):

The Council shall appoint a GCC team from the member states to visit manufacturers to ensure that the provisions of this Regulation and the evidence approved by the Council are applied after paying the inspection's fees, in accordance with the ministerial decisions issued in this regard.

Article (22):

The manufacturer or the authorized representative shall notify the Council in writing of any sale, purchase, acquisition or any legal or commercial procedure pertaining to the manufacturer or any of its manufacturing

facilities within (30) days as of the procedure completion, provided that the manufacturer shall update its data as deemed appropriate by the Council.

Article (23):

GCC manufacturers of medical devices or their authorized representatives shall apply for registration renewal, fulfill the documents and registration approved by the Council and published on its website (Taawon Portal).

Article (24):

Medical devices and supplies may be merged in one application, according to the application guidelines published by the Committee.

Article (25):

The manufacturer shall submit a change request, in case of amending or changing the registration data, in pursuance of changes to guidelines issued by the Committee.

Article (26):

The medical device or supply's risk of classification shall be classified according to the classification guidelines issued by the Committee.

Article (27):

Applicants shall provide the following information:

1. Undertaking the validity and accuracy of the information provided.
2. Updating the registration data of the facility or medical devices and supplies within thirty days as of any significant change.

Article (28):

For the purposes of information security and confidentiality, the following shall be observed:

1. All parties covered by this Regulation shall maintain the confidentiality of relevant information obtained for the purpose of completing their tasks.
2. This does not affect the Council and member states' commitment to the information exchange and notifications helping to promote the public health.

Article (29):

Compliance with the provisions, conditions and requirements outlined in this Regulation shall not replace any additional requirements in member state.

Article (30):

If the authorized representative breaches the Regulation, the regulatory authorities shall take the necessary procedures.

Article (31):

The Council shall publish the financial consideration for services related to medical devices and supplies.

Article (32):

The Council shall develop and publish procedural rules complementary to this Regulation, which define its specific requirements and effective dates of procedural rules and the relevant articles in this Regulation.

Article (33):

This Regulation shall be published after being approved by the ministries of health in GCC, and shall enter into force after ninety days from its publication date.