

The logo of the Saudi Food & Drug Authority (SFDA) is centered on the page. It features a stylized human figure in blue and green, with an orange circle above its head. The letters 'SFDA' are written in a light green font to the right of the figure.

The Saudi Quality Management System
Requirements for Medical Devices

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Content

Article One: Scope	3
Article Two: Definitions	3
Article Three: General Provisions	4
Article Four: Quality Management Systems	4
Article Five: Pre-marketing procedures	7
Article Six: Post-Marketing Procedures	7
Article Seven: Conclusion Measures	8



Article One: Scope

These requirements apply to:

1. Local and overseas manufacturers of medical devices.
2. Authorized representatives, importers and distributors of medical devices.
3. Healthcare providers importing medical devices.

Article Two: Definitions

For the purpose of this document, the following definitions shall apply:

SFDA: Saudi Food and Drug Authority

Establishment: any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.

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.

Inspection: is a documented, systematic process through field visits carried out by SFDA's inspectors to ensure establishment/manufacturer compliance with these requirements.

Quality Management System (QMS): is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Technical Documentation: is documented procedures that demonstrate compliance with the requirements of the followed quality management systems that approve the conformity of the medical device with the essential principles of safety and performance.

Audit: is a documented, systematic assessment of the efficiency of the quality management system in the establishment/manufacturer to determine its compliance with these requirements.

Article Three: General Provisions

1. Establishment/manufacturer involved in the scope shall apply the Saudi quality management system requirements for medical devices.
2. SFDA has the right to audit the parties involved, if needed.
3. SFDA shall determine the audit fees.
4. SFDA shall publish guidance documents for the parties involved in the scope specifying the requirements for each establishment/manufacturer.

Article Four: Quality Management Systems

All establishments/manufacturer of medical devices shall establish, document, maintain and apply a QMS in accordance with the Saudi standard entitled “Medical devices -- Quality management systems -- Requirements for regulatory purposes (SFDA.MD/GSO ISO 13485:2017)” that is based on the standard entitled “Medical devices -- Quality management systems -- Requirements for regulatory purposes (ISO 13485:2016)”. This includes but not limited to the following:

1. Ensuring the role of top management in supporting and endorsing the quality system, approving relevant plans, setting quality policies and objectives, carrying out management reviews periodically and ensuring the availability of resources.
2. All the elements and requirements of quality systems shall be documented in a systematic and orderly manner in the form of policies and procedures, such as quality programmes, quality plans, quality manuals, quality records, and others. The documents may be in a paper or electronic medium.
3. Managing resources and qualifying staff, maintaining appropriate infrastructure, and identifying and managing the work environment necessary to achieve the requirements.
4. Managing storage, distribution and tracking operations.
5. Reviewing and verification of the design and development processes with adjusting design changes and maintaining records.
6. Managing of procurement, sales and distribution operations.
7. Planning and implementation of monitoring, measurement and analysis processes.
8. The quality manual shall include, as a minimum:
 - A. The name and address of the establishment/manufacturer and of the establishment/manufacturer site(s) covered by the QMS.
 - B. Quality policies and objectives.
 - C. Exceptions for not applying certain provisions of the system with justification.

- D. The organization of the business and in particular the organizational structures, the responsibilities of the managerial staff and their organizational authority.
- E. An overview of the types of medical devices covered by the QMS and their classification.
- F. An outline of the structure of the documentation used in the QMS.
- G. The documented procedures established for the QMS, or references to them, including the risk management.
- H. A description of the interaction between the business procedures.
- I. The methods of monitoring the efficient of operations to ensure its ability to achieve the desired quality, including control of devices which fail to conform
- J. Where the design, manufacture, processing, and/or final inspection and testing of the devices, or elements thereof, is outsourced to another party, the methods of monitoring the efficient operation of the QMS and the control of their application to the other party shall be done by the manufacturer. The procedures shall include appropriate risk management activities for these processes and products, by planning and ensuring risk control measures are appropriately applied.
- K. The procedures for developing and designing the product such that it meets the SFDA requirements during its lifetime.
- L. The procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques. Design and development activities shall include risk management procedures and associated activities to control risks to an acceptable level.
- M. The procedure to assess whether risks continue to remain acceptable during the lifetime of the device and whether any new hazards or risks arise. The procedure will take account, among other factors, of any adverse event that occurs, user feedback and inspectors visits undertaken by the SFDA/CAB. If at any time, a risk is determined to be unacceptable, the risk analysis should be repeated and appropriate action taken to meet the risk acceptability criteria.
- N. The inspection and quality assurance techniques applied during the manufacturing stage, and in particular:
 - 1. The processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

2. The product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.
 - O. The tests and trials which will be carried out before, during and after manufacture, identification of the test equipment used, and the calibration procedures.
 - P. The tracking and documentation on the post-marketing surveillance plan, including a plan for the post-marketing clinical follow-up, and the procedures put in place to ensure compliance with the QMS.
 - Q. A description of the procedures in place to keep up to date the post-marketing surveillance plan, including a plan for the post-marketing clinical follow-up, and the procedures put in place to ensure compliance with the QMS.
 - R. A description of the internal auditing procedure undertaken by the manufacturer's control and the manner in which its findings will be used to maintain the integrity and effectiveness of the QMS.
9. Medical devices manufacturers/establishments shall undertake to:
- A. Incorporate changes within the QMS, both substantial and routine, that result from any SFDA audit report,
 - B. Inform the SFDA of any substantial change it wishes to make to the QMS,
 - C. Proceed with the proposed change only after the SFDA has agreed to it,
 - D. Report to the SFDA of any relevant adverse event of which it becomes aware, that involves the medical device, and
 - E. Take necessary corrective actions to ensure safety, effectiveness, and quality of medical devices.

Article Five: Pre-marketing procedures

If the QMS conforms to these requirements, the SFDA/CAB shall issue the manufacturer with an audit report, including:

- Name and address of the establishment/manufacturer.
- Areas of correction or development.
- Its issuance and expiration date.
- Identification the device or categories of the device covered by the QMS.

Article Six: Post-Marketing Procedures

1. The aim of surveillance is to ensure that the manufacturer duly fulfills the obligations imposed by the approved QMS.
2. The establishment/manufacturer shall authorize the SFDA to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:
 - The documentation of the QMS,
 - The documentation on the post-market surveillance plan, including a post-market clinical follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan,
 - The data stipulated in the part of the QMS relating to design, such as the results of analyses, calculations, tests, the solutions adopted regarding the risk-management, preclinical and clinical evaluation, and
 - The data stipulated in the part of the QMS relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
3. The SFDA shall periodically carry out appropriate audits and assessments to make sure that the manufacturer applies the approved QMS and the post-marketing surveillance plan.
4. The SFDA shall, where necessary, carry out or ask for tests in order to check that the QMS is working properly. It shall provide the manufacturer with a report.
5. The SFDA shall:
 - Randomly perform unannounced inspections to establishment/manufacturer if needed; which may be combined with the periodic surveillance assessment,
 - Establish a plan for the unannounced inspections which must not be disclosed to the manufacturer,

- Check an adequate sample from the production or the manufacturing process to verify that the devices are in conformity with the technical documentation and/or design dossier,
 - Specify the relevant sampling criteria and testing procedure prior to the unannounced inspection,
 - Take samples of devices from the market to verify that the device is in conformity with the technical documentation,
 - Specify the relevant sampling criteria and testing procedure, and
 - Provide the manufacturer with an inspection report which shall include the result of the sample check.
6. In the case of devices classified as moderate-high risk or high risk, the audit report shall include the assessment of the design documentation within the technical documentation of the device(s) concerned.
 7. If the SFDA establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

Article Seven: Conclusion Measures

1. The SFDA reserves the right to take the appropriate actions when any provisions of these requirements are violated, as stated in the Medical Devices Interim Regulation.
2. The SFDA reserves the right to withdraw samples and perform the necessary tests to ensure its safety and quality at the expense of the establishment/manufacturer.
3. The SFDA reserves the right to suspend the importation license for the local manufacturer in case of selling non-finished products as final products.