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Translation of the Saudi Food and Drug Authority Guidelines (MDS-REQ 10)

Inspection Requirements and Quality Management System for Medical Devices and Supplies

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Introduction

Purpose

The purpose of this document is to define and clarify the requirements for the inspection and the quality management system for medical establishments, devices and supplies that are subject to the provisions of the system and the regulations and in accordance with what was stated in Article (33) of the executive regulations, which stipulates that "the SFDA is stipulated to issue inspection requirements and quality management system for medical devices and supplies; these requirements should include: the duties, powers, obligations, and rights of the inspector."

Scope

These requirements apply to medical establishments, devices and supplies referred to in Article Two of the Medical Devices and Supplies System and Article (1/3) of its Executive Regulations.

For the purpose of verifying compliance with these requirements contained in this document, the SFDA will do the following (when it applies):

- **Initial visit/a visit:** for the purpose of licensing: the objective of the initial evaluation of the establishment requesting the license is to evaluate the condition of the manufacturer. In this stage preliminary information about the manufacturer, manufacturing processes and products are collected.
- **Routine/periodic visit:** for the following purposes:
  - Assessment of the establishment's fulfillment of the requirements of the SDFA.
  - Assessment of the establishment's fulfillment of the requirements of the quality management system according to the latest version of the Saudi Standard (**SFDA.MD/GSO ISO 13485**) or equivalent.
- **Follow-up visit:** for the purpose of evaluating the establishment's implementation of corrective action for non-conformities that were raised during previous visits.
- **Interactive visit:** for the purpose of investigating the establishment as a result of a complaint, report, or a problem.
- **A product verification visit:** in order to ensure that the medical devices and supplies that were manufactured, handled, or dealt with, comply with the requirements of the system and the regulations.

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Basic Information

The SFDA issued this document based on the "Medical Devices and Supplies System" issued by Royal Decree No. (M/54) dated 06/07/1442 H and the following rules:

- **Article 22** which stipulates that "establishments wishing to trade medical devices and supplies in Saudi Arabia are obligated to implement a quality management system."
- **Article 33** which stipulates that "the SFDA undertakes the inspection of establishments, devices and medical supplies to ensure the implementation of the provisions of the system, the regulations and the technical regulations, through several inspectors from the criminal investigation officers, with a decision issued by the council's president."
- **Article 35** which stipulates that: the inspector shall present his work card when performing the tasks of inspection and control, and the establishment shall enable him to perform his work, and not obstruct him."

The Executive Regulations of the Medical Devices and Supplies System issued by Board Resolution No. (3-29-1443) dated 19/02/1443 H through:

Article (33/3) which stipulated that "The SFDA issues the requirements of inspection and the quality management system for medical devices and supplies, which contains the duties, obligations, powers, and rights of the inspector."

Requirements

Establishments wishing to engage in any of the activities subject to the system must comply with the system and its regulations, including the inspection requirements and the quality management system contained in this document.

A. General Requirements

All establishments must abide by the following:

1. Obtaining a valid license from the SFDA.
2. Continuous update of the establishment's information at the SFDA.
3. Comply with the requirements and obligations contained in the requirements for Medical Device Establishment Licensing and the guidelines published on the SFDA's website.
4. Validity of information and provision of documents submitted for obtaining the license. This includes information of academic and professional qualifications of employees.
5. The technical documents and procedures shall be in Arabic or English or translated into one of the two languages.
6. Maintaining the confidentiality of information, procedures and processes that may be viewed before, during or after the inspection visits.
7. All medical devices and supplies manufacturers, importers, and distributors in categories (A) and (B) must obtain a quality management system certificate from one of the conformity assessment bodies of medical devices and supplies and the quality management system recognized by the SFDA in accordance with the Saudi Standard Specification (**SFDA.MD/GSO ISO 13485**) or equivalent.
   Note: recognized conformity assessment bodies by the SFDA are carrying out their activities inside the Kingdom and have a license from the SFDA or located outside the Kingdom and accredited by the International Accreditation Forum (IAF).
8. The authorized representatives, importers, and distributors in categories (C) and (D) must submit evidence of the implementation of the quality management system or inspection report by the SFDA, that confirms its compliance with the requirements of the quality management system in accordance with the Saudi Standard Specification (**SFDA.MD/GSO ISO 13485**) or its equivalent.
9. Provide sufficient and proper staff and other resources respective to the activity of the establishment and commensurate with the tasks assigned to it to meet all requirements of the system and regulations.
10. All medical devices and supplies traded by the establishment must have a Medical Device Marketing Authorization (MDMA) and/or an importation permit issued by the SFDA.

11. Provide and implement effective and appropriate standard operating procedures for documenting information on the importation, distribution and use of medical devices and supplies, that assists in tracing the medical device and supplies according to the requirements of the unique device identification (UDI) for medical devices.
12. Provide and implement documented and effective procedures for transportation and storage operations according to manufacturer requirements and transportation and storage requirements for medical devices and supplies published on the SFDA's website.
13. Follow up on the expiry date of medical devices and supplies.
14. Conditions and requirements for the destruction, reprocessing, renewal, resale, loan, or donating of medical devices and supplies in accordance with the requirements of post-marketing surveillance of medical devices and supplies published on the SFDA's website.
15. Maintain records of disposal of medical devices and supplies in accordance with the requirements of post-marketing surveillance of medical supplies published on the SFDA's website.
16. In the event that an infringing product was seized, the device or the supply should continue to be seized until the corrective action is completed in the event of the product's ability to be corrected.
17. Correct all observations raised in previous inspection reports.
18. All advertising and marketing materials prepared for publication must have the approval of the SFDA in accordance with the requirements for approval of advertising & marketing, awareness, or charity campaigns for medical devices and supplies.
19. Provide an archiving database of all relevant data and documents so that they can be easily accessed and retrieved for a period not less than (5) years.
20. Disclosing any other unlicensed establishment's branches or warehouses.
21. Adhere to the post-marketing surveillance requirements for medical devices and supplies published on the SFDA's website.
22. Not to trade medical devices and supplies in violation of the provisions of the System and Regulations.
23. Commitment to the following after the inspection process:
    a. Confirmation of receipt or signature of inspection report.
    b. A comprehensive investigation should be carried out if requested by the SFDA in the cases of non-conformities raised in the inspection report.
    c. Provide a corrective action plan if requested by the SFDA to address the non-conformities -if any- during the period specified in the application.
    d. Implementation of the corrective action plan after its acceptance by the SFDA within the specified period.
    e. Notify the SFDA of the completion of the implementation of the corrective action plan.

B. Special Requirements

In addition to what is stated in the "General Requirements" section, each establishment must comply with the specific requirements listed below, depending on the type of the establishment.

First: Manufacturers of Medical Devices and Supplies

1. The following requirements must be adhered to:

1.1. The design of the manufacturer should be compatible with the nature of the device required to be manufactured.

1.2. The availability of a full-time technical manager and quality manager who are medical devices engineers or technicians or qualified in one of the related fields.

1.3. A pledge that the manufacturer bears full responsibility for the quality of all manufactured batches.

1.4. Requirements of the unique device identification (UDI) for medical devices.

1.5. Keep the following documents and make them available upon request:

1.5.1. The identification information in English, and in Arabic if the user is a lay person.

1.5.2. Instructions related to the handling, transportation, storage, installation, maintenance, and disposal of medical devices and supplies in English, and in Arabic if the user is a lay person.

1.5.3. Advertising and marketing information in English, and in Arabic if the user is a lay person.

1.5.4. Description of the medical device and its specifications, including variations and accessories.

1.5.5. Design and Manufacturing Information.

1.5.6. Risk management file.

1.5.7. Verification and validation of the product including clinical studies.

1.5.8. Post-marketing surveillance (PMS) plan.

1.5.9. Post-marketing surveillance (PMS) report and periodic safety update report (PSUR).

1.5.10. Written procedures to carry out the necessary corrective actions mentioned in the Field Safety Notice (FSN).

1.6. Report to the National Center for Medical Devices Reporting (NCMDR) on incidents of medical devices and supplies.

1.7. Provide after-sales services in accordance with Articles (19/1) and (19/2) of the Executive Regulations.

1.8. The implant card for medical device must contain the following information:

1.8.1. Information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address, and the website of the manufacturer.

1.8.2. Any warnings, precautions, or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations, or environmental conditions.

1.8.3. Any information about the expected lifetime of the device and any necessary follow up.

1.8.4. Any other information to ensure safe use of the device by the patient.

2. Manufacturer must do the following before the visit:

2.1. Pay the fees for the visit within the specified period, according to what is published on the SFDA's website.

2.2. Reply to confirm the date of the visit sent to the local manufacturer/the authorized representative for overseas manufacturer within the specified period.

2.3. Sending the following data and documents within the specified period:

2.3.1. Manufacturer address (coordinates of the manufacturer location and any other locations related to production and storage operations).

2.3.2. The scope of manufacturing and related activities.

2.3.3. Quality manual and work procedures according to the latest version of the Saudi Standard (**SFDA.MD/GSO ISO 13485**) or equivalent.

2.3.4. Previous audit reports.

2.3.5. A list of manufactured medical devices with their risk classification and its QMS certificates.

2.3.6. Any instructions specific to the manufacturing site, such as instructions for entry, exit, security, health, and safety.

2.3.7. Notice of approval for the attendance of observers and trainees (if any).

2.3.8. Any other documents required by the SFDA.

3. The SFDA will create the visit plan where it will indicate, the type of visit, its number of days, and the members of inspecting team are determined based on several factors which include: (the scope of the quality management system, the number of production lines, the type of products and risk class, and of the manufacturer's compliance records). The manufacturer must do so by:

3.1. Review the visit plan and prepare the documents and sites that will be audited according to the plan.

3.2. Provide a copy of the latest version of the Quality Manual, SOPs, and records to have them ready in location during the visit.

4. The manufacturer should do the following during the visit:
   - 4.1. Commit to the audit period according to the plan.
   - 4.2. Provide an office or a meeting room and a printer.
   - 4.3. Provide an interpreter if the inspection is approved in a language other than English.
   - 4.4. Commit to the following during the opening meeting:
     - 4.4.1. The attendance of representatives from senior management in addition to the relevant employees.
     - 4.4.2. Signing the attendance sheet.
     - 4.4.3. Confirm the inspection plan and other relevant arrangements, such as the date and time of the closing meeting and any meetings between the inspection team and the manufacturer.
     - 4.4.4. Confirm the language to be used during the inspection.
     - 4.4.5. Confirmation of matters related to confidentiality and information security.
     - 4.4.6. Confirmation of health, safety, emergency, and security procedures.
     - 4.4.7. Emphasis on providing the resources and facilities required to perform all inspection activities.
     - 4.4.8. Emphasis on enabling inspectors to review documents during inspection and providing them immediately upon request.
     - 4.4.9. Emphasis on enabling inspectors to collect and verify information, including opening the sites they request and interviewing people when necessary.
     - 4.4.10. Provide a brief explanation about the manufacturer, its activity, and its products.
     - 4.4.11. Discussing previous inspection results -if any-.
   - 4.5. Adhere to the following during the visit:
     - 4.5.1. Enable the inspectors to view all the facilities of the manufacturer which includes - but not limited to:
       - 4.5.1.1. Areas for receiving and storing primary products (raw materials).
       - 4.5.1.2. Production areas (including clean rooms and sterilization areas).
       - 4.5.1.3. Quality laboratories.
       - 4.5.1.4. Final product storage areas.
       - 4.5.1.5. Desalination and water treatment plants.
       - 4.5.1.6. Maintenance areas.
       - 4.5.1.7. Transportation methods.
       - 4.5.1.8. Any other facilities associated with the manufacturing activity.
     - 4.5.2. Provide protective clothing in case it is necessary to wear certain clothes to enter some facilities for the purpose of safety of the product and people.
     - 4.5.3. Provide records/documents in Arabic or English.

4.5.4. Notify the inspection team upon entering any facility of potential health, safety, emergency, and security risks.

4.6. Commit to the following during the closing meeting:

4.6.1. The attendance of senior management in addition to the relevant employees.

4.6.2. Signing the attendance sheet.

5. The SFDA issues the inspection report within (15) days from the end of the visit and deliver it to the local manufacturer or the authorized representative of the overseas manufacturer through e-mail, administrative communications in the SFDA headquarter, or any other means.

6. The manufacturer must, after the visit, abide by the following in addition to what was stated in Paragraph No. (23) of the "General Requirements" section.

6.1. Respond on raised non-conformities and submit the corrective action plan using the form sent with the inspection report, within the specified period, provided that the plan includes the following:

6.1.1. Responding to all non-conformities listed in the inspection report.

6.1.2. Clarifying the root cause of the non-conformities.

6.1.3. Procedures for immediate correction of non-conformities.

6.1.4. Corrective action procedures for non-conformities.

6.1.5. Preventive actions for non-conformities.

6.1.6. Date of implementation of the corrective action plan.

6.2. The date of implementing of the corrective action plan should be proportional to the nature of the non-conformities.

6.3. The SFDA evaluates the corrective action plan submitted by the manufacturer, and responds to the manufacturer with the evaluation result, either with acceptance or non-acceptance, with the form returned to the manufacturer to amend the corrective action plan.

6.4. Sending the amended corrective action plan within the period specified in the application.

7. SFDA grants the manufacturer a maximum of three review cycles to amend the corrective action plan.

8. SFDA shall schedule a follow-up visit to ensure that corrective and preventive actions are implemented -when needed-.

9. SFDA sends the inspection report to the manufacturer.

10. In the event that the manufacturer fails to submit an acceptable corrective action plan within the specified period or when exceeding the three review cycles, it will escalate the situation to take the appropriate action.

Second: Distributors, Importers and Authorized Representatives

1. Distributors and importers must comply with the following requirements:
   - **1.1.** The availability of an authorized representative licensed by the SFDA for each overseas manufacturer the establishment deals with.
   - **1.2.** Appointing a person authorized by the establishment to deal with the SFDA, provided that he holds an appropriate qualification in one of the related fields.
   - **1.3.** Having a warehouse license or a space warehouse license issued by the SFDA in accordance with the requirements for licensing medical devices establishments. As for the sales outlets, a storage area inside the establishment that complies with the requirements for transportation and storage of medical devices and supplies will suffice.
   - **1.4.** If the establishment wishes to provide maintenance services for its medical devices and supplies, follow the manufacturer's instructions and the requirements for maintaining medical devices and supplies listed in the post-market surveillance requirements published on the SFDA's website. In the event that the establishment wishes to provide maintenance services for medical devices and supplies that are not affiliated with it, a license must be obtained for a medical maintenance service provider in accordance with the medical device establishment license requirements.
   - **1.5.** The persons involved in marketing and selling medical devices and supplies have sufficient information about the devices in order to ensure that the correct information for its marketing and sales is delivered.
   - **1.6.** No high-risk medical device must be dispensed for use outside healthcare facilities except with a prescription. This is according to the list of high-risk medical devices and supplies published on the website of SFDA while keeping its records for a period of no less than (5) years.

2. An authorized representative must comply with the following requirements:
   - **2.1.** Availability of an official to handle tasks related to regulatory affairs and post-marketing surveillance of medical devices and supplies in accordance with the requirements of post-marketing surveillance of medical devices and supplies published on the SFDA's website.
   - **2.2.** The availability of an approved authorized representative license issued by the SFDA for each manufacturer represented.
   - **2.3.** Report to the National Center for Medical Devices Reporting (NCMDR) on incidents of its medical devices and supplies.
   - **2.4.** Availability and implementation of effective work procedures to follow up on reports and acknowledged corrective actions plans for medical devices and supplies by the SFDA and the manufacturers mentioned in Field Safety Notices (FSNs).

3. The establishment shall, before the inspection team visit, verify the implementation of the quality management system:
   - 3.1. Send the following data and documents before the date of the visit:
     - 3.1.1. The address and coordinates of the establishment.
     - 3.1.2. Identifying the activities and operations practiced by the establishment: storage, distribution, installation, maintenance, etc.
     - 3.1.3. Quality manual and Standard Operating Procedures (SOPs) according to the latest version of the Saudi Standard Specification (**SFDA.MD/GSO ISO 13485**) or its equivalent.
     - 3.1.4. Previous audit reports issued by conformity assessment bodies -if any-.
     - 3.1.5. List of medical devices and supplies.
     - 3.1.6. Any instructions related to the manufacturing site, such as entry and exit instructions, security, health, safety, etc.
     - 3.1.7. Any other documents required by the SFDA.
   - 3.2. During the visit, the establishment must:
     - 3.2.1. Commit to the agreed inspection period.
     - 3.2.2. Provide an office or a meeting room and a printer.
     - 3.2.3. Provide an interpreter in case the inspection was approved to be in a language other than English.
     - 3.2.4. The attendance of senior management representatives for the opening meeting.
     - 3.2.5. Enabling the inspectors to review the relevant documents during the inspection and provide them immediately upon request.
     - 3.2.6. Enabling the inspectors to collect and verify information, including opening the sites they request and conducting interviews with people when necessary.
     - 3.2.7. Providing copies of relevant documents.
     - 3.2.8. Attending the closing meeting.
     - 3.2.9. Signing the attendance sheet.
   - 3.3. The SFDA issues the inspection report within (10) days from the end of the visit and deliver it to the establishment through e-mail or administrative communications in the SFDA headquarter or any other means.
   - 3.4. After the visit, the establishment must abide by what was stated in Paragraph No. 23 of the “General Requirements” section.

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The Powers, Duties, Obligations and Rights of the Inspector

1. **The inspector shall have the following powers and rights:**
   - **1.1.** Interview and question any employee within the establishment's facilities.
   - **1.2.** View all records and documents related to the establishment's activity.
   - **1.3.** Photocopy/requesting a copy of any document, paper, or electronic record.
   - **1.4.** View all equipment and devices in the manufacturer’s facilities and record their data.
   - **1.5.** Access to electronic systems and programs related to the establishment's activity.
   - **1.6.** Access to documents and records of all studies conducted on the product (example: clinical studies).
   - **1.7.** View all records and documents of the establishment's clients.
   - **1.8.** Accompany any other member not mentioned in the visit plan to join the inspection team, as needed.
   - **1.9.** Bring any equipment or tools to use for inspection purposes.
   - **1.10.** Photographing or documenting the manufacturer’s facilities related to manufacturing activities in case of suspected violations.
   - **1.11.** Withdraw samples from any product for the purpose of ensuring that it complies to the specifications in accordance with the guideline for samples of medical devices and supplies for laboratory testing published on the SFDA’s website.
   - **1.12.** Take notes during the visit or review records and documents.
   - **1.13.** Re-review any facility when needed.
   - **1.14.** Seize of any violating or suspected product.
   - **1.15.** Call the security authorities or the relevant authorities when needed.
   - **1.16.** Terminate the visit when health, safety, emergency, and security risks may arise.
   - **1.17.** It is not allowed to take the official work card as a condition for entering the establishment.
   - **1.18.** Coordination with the manufacturer to suggest the appropriate hotel, provided that the housing costs are paid by the members of the inspection team.

1.19. Obtaining some logistic information from the manufacturer/authorized representative in a way that does not conflict with the inspection tasks.

1.20. Coordination with the manufacturer/authorized representative to issue visas to the team by the concerned authorities, provided that the costs of the visa are paid by the members of the inspection team.

1.21. The overseas manufacturer shall be responsible for the transportation of the inspection team members from the airport to the residence, as well as from the residence to the manufacturer during the inspection period.

1.22. Not to photocopy or copy the inspector's official work card after reviewing it.

1.23. Not to ask the inspector to sign any pledge or obligation while performing the inspection work.

1.24. Not to record or photograph the inspectors during their inspection activities.

2. **The inspector shall abide by the following duties and obligations:**

2.1. Present the official work card during the inspection.

2.2. Commitment to wearing the special attire for local visits, except for some special cases as needed.

2.3. Adhere to the procedures covered in the guideline for samples of medical devices and supplies for laboratory testing published on the SFDA's website.

2.4. Adhere to public safety, radiological and chemical safety requirements during inspections and any other procedures related to health, safety, emergency, and security.

2.5. Not accepting any invitation from the establishments for meals, banquets and parties, and the establishment may provide a light lunch.

2.6. Not accepting any invitations for trips or visits outside the scope of the inspection.

2.7. Not accepting gifts or tips.

2.8. Maintain confidentiality of information.

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Final Provisions

1. Anyone who commits any violation of the provisions of these requirements shall be punished in accordance with the table of classification of violations and the penalties set accordance with the medical devices and supplies system and its executive regulations published on the SFDA's website.
2. Establishments may object to the observations or non-conformities raised in the inspection report and to provide justifications for that. The objection shall be in accordance with the legal procedures followed.
3. The SFDA explains in a specific annex within the Saudi Standard (**SFDA.MD/GSO ISO 13485**) the extent of implementation of the standard's clauses for each establishment type.

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Annex (1): Definitions & Abbreviations

Kingdom	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
System	Medical Devices and Supplies System
Implementing Regulations	Medical Devices and Supplies Regulation
NCMDR	National Center for Medical Devices Reporting
Visit	Inspection visit
Medical Device	Means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: **A)** Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: • Diagnosis, prevention, monitoring, treatment, or alleviation of disease, • Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, • Investigation, replacement, modification, or support of the anatomy or of a physiological process, • Supporting or sustaining life, • Control of conception, • Disinfection of medical devices, • Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and **B)** Which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.
Medical Supplies	Medical materials and products, used in diagnosis, treatment, replacement, orthodontics, disabilities, or other medical uses for human being, including medicinal gases.
User	Who uses the medical device and supplies, whether a professional, a layperson or a patient.
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.

Authorized Representative (AR)	Any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer inside the kingdom.
Importer	Establishment in the supply chain that supplies medical devices to Saudi Arabia.
Distributor	Establishment in the supply chain that provide medical device to another distributor or to end user.
Healthcare provider	Any governmental or private establishment that provides healthcare services.
License	A document issued by SFDA to carry out any of the activities subject to the System.
Medical Device Marketing Authorization (MDMA)	A document issued by the SFDA for any medical device or supplies that Allows it to be traded in Saudi Arabia.
Field Safety Notice (FSN)	A notice issued by the NCMDR stating the risks associated with a medical device or supply and the corrective action to be taken to alleviate the risks
Field Safety Corrective Action	A corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.
Incident	Means any malfunction or deterioration in the characteristics or performance of a device made available on the market, that could lead in a direct or indirect way to the death or serious injury to the user.
Marketing and Advertising	Any statement, whether written, audio, visual, or otherwise, that is intended to promote medical device or supplies, or the direct or indirect sales.
Corrective Action	Action taken to eliminate the cause of a potential or actual nonconformity or other undesirable situation raised on the establishment, manufacturer, medical device, or medical supply.
Implantable Medical Device	Any device, including those that are partially or wholly absorbed, which is intended: • to be totally introduced into the human body, or • to replace an epithelial surface, or • to replace the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure for at least 30 days.

Unique Device Identifier (UDI)	Means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.
Inspection	A procedure carried out by SFDA to ensure that the establishment or the manufacturer complies with the Medical Device Establishment Requirements stipulated in the System and Regulations.
Auditing	A systematic, independent, and documented evaluation for the efficiency of the quality management system to indicate its compliance level to requirements.
Quality Manual	A specific quality management system document that provides an overview of the establishment quality management system and includes: • Description of the scope of the QMS, including any exclusions. • List or reference QMS standard operating procedures (SOPs). • Describe interactions between QMS processes. • Provide an outline of QMS documentation structure.
Immediate Corrective Action	Action to remove the cause of the non-conformity and prevent its recurrence

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Annex (2): List of Changes on the Previous Version

Number and Date of the Previous Version	Description
MDS-G35 1.0, 11/4/2019 MDS-G45 1.0, 2/1/2020 1.0, 1/1/2018	• **Updating and merging the following documents:** ○ Guidance to Implement a Medical Devices Standard "Quality Management System" Regulatory Requirement (ISO 13485:2016) (MDS-G35). ○ Guidance on Requirements of Medical Devices Quality Management System for Distributors, Importers and Authorized Representatives (MDS-G45). ○ Requirements of the Saudi Quality Management System for Medical Devices and Products.

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Bio-Standards® has the right skillset and technical knowledge to support you with your regulatory and registration needs with the Saudi Food & Drug Authority (SFDA).

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