# MDS – G009

Guidance for Points of Care (POC) Medical Devices Manufacturing

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# Introduction

## Purpose

The purpose of this document is to define and clarify the requirements for manufacturing medical devices at Points of Care (POC).

## Scope

- This document applies to healthcare providers wishing to manufacture medical devices within their facilities for their own use and for non-industrial scale (with regard to the magnitude and methods of production).
- This document applies to the following activities:
  1. Manufacturing of medical devices using 3D printer inside a healthcare facility.
  2. Manufacturing according to the Medical Device Production System (MDPS).
  3. In-House IVD.
  4. All Medical Devices modified or developed within Healthcare facility.

## Background

SFDA has issued this guidance document in accordance to

The “Medical Devices Law” issued by the Royal Decree No. (M/54) dated 6/7/1442 H through the following:

- Article 8 stipulating, “Medical devices cannot be marketed/used unless obtaining a registration and Marketing Authorization, and The SFDA may exempt some medical devices from the requirement to obtain a Marketing Authorization, after ensuring their safety, and not using them for commercial purposes”.
- Article 26 stipulating, “The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices and supplies in diagnosis and treatment”.
- Article 28 stipulating, “The manufacturer, authorized representative, and healthcare provider shall report to the NCMDR any adverse event relating to their medical devices and supplies”.

The "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H through the following:

- Article (8/3) stipulating that "The SFDA may exempt certain medical devices from the condition of obtaining Marketing Authorization for humanitarian and research purposes upon verifying its safety in accordance with the following rules", and mentioned "Custom-Made Medical Device".
- Article (28/2) stipulating that "The Manufacturer, Authorized Representative and Healthcare Provider shall adhere to the Requirements of Post-Market Surveillance of Medical Devices, report to the NCMDR about incidents related to the medical devices and provide the NCMDR with all necessary information and documents including supply and distribution data".

## Requirements & Procedures

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| General | 1 | - Providing a Justification for Manufacturing at the POC rather than purchasing medical devices available in the market. Such a justification shall clearly include patients' specific needs, lead-time, accessibility, cost, or flexibility on the medical device's design.<br>- Manufacturing medical devices inside the healthcare facility for the own use and not transfer them to another facilities. |
| Quality Management System | 2 | Manufacturing medical devices in accordance with the requirements of Medical Devices Quality Management System (ISO 13485). |
| Documentation | 3 | Documenting and submitting the following to the SFDA upon request:<br>a. Name and address of the healthcare facility/POC site<br>b. Details necessary to identify the manufactured medical device<br>c. Identification of the responsible entity and personnel for the POC manufactured medical device<br>d. Healthcare facility's top management approval for the POC medical device manufacturing<br>e. Labelling of the manufactured medical device including the intended use, and -if applicable- the patient identifier and the expiration date.<br>f. The manufacturing processes<br>g. Records of competency, qualification and training of POC manufacturing staff<br>h. design and performance data<br>i. Sterilization processes and applicable standards -if applicable-<br>j. Biocompatibility validation studies -if applicable-<br>k. Records, quality control procedures and other documents related to the POC manufactured medical device. |
| Post-Market Surveillance | 4 | - Implementing a surveillance system to gather experience from the clinical use of the device. |

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| | | - Tracking the medical device throughout its lifecycle.<br>- Conducting preventative and corrective actions to ensure the safety of patients and users of the medical device.<br>- Reporting all incidents, adverse events and complaints to the NCMDR in accordance with the SFDA Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11). |
| 3-D Printed Medical Devices | 5 | - Using medical-grade raw materials and validating them by the supplier.<br>- Obtaining Medical Device Marketing Authorization (MDMA) for the software used for printing the medical device in accordance with the SFDA Requirements for Medical Devices Marketing Authorization (MDS-REQ 1).<br>- Providing and documenting information about the 3D printers, including maintenance records. |
| Medical Device Production System (MDPS) | 6 | - Using medical-grade raw materials and validating them by the supplier.<br>- Obtaining Medical Device Marketing Authorization (MDMA) for the software used for printing the medical device in accordance with the SFDA Requirements for Medical Devices Marketing Authorization (MDS-REQ 1).<br>- Providing and documenting the Medical Device Production System (MDPS) file, which includes information about raw materials, software, equipment, final product, intended use and users. |
| In-House IVD | 7 | - The requirements below are applicable to all In-House IVDs including:<br>• In-House IVD test developed from first principles<br>• IVD test developed or modified from a published source<br>• Modifications to commercially supplied IVDs<br>- Developing/modifying and conducting the IVD test for the own use inside the healthcare facility.<br>- Providing and documenting information about the IVD test that intended to be developed or modified. |
| Implantable Medical Devices and Implant Card | 8 | - Storing one copy of the implant card in the patient file, and providing the patient with another copy.<br>- Accompanying the following information with the implantable device:<br>a. Information allowing the identification of the device which includes the device name and the patient identifier;<br>b. Any warnings, precautions or measures to be taken with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions; |

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| | | c. Any information about the expected lifetime of the device and any necessary follow up;<br>d. Any other information to ensure safe use of the device by the patient, including the overall qualitative and quantitative information on the materials and substances to which patients may exposed. |
| SFDA Prerequisites | 9 | – Submitting the Required Documents by email to POC.MD@sfda.gov.sa.<br>▪ In case of missing documents, SFDA will notify the applicant within (5 days). The application will considered "Void" in case missing documents not submitted within (60 days).<br>▪ In case of completed documents, SFDA will review the request and take a decision within (30 days):<br>o If requirements are satisfied, SFDA will issue a "No Objection Letter".<br>o If requirements are not satisfied, SFDA will issue an "Objection Letter" and notify the applicant with the reasons for rejection.<br>– In case of change or broaden the scope of POC, or addition of extra manufacturing site, the SFDA approval shall be obtained.<br>– In case of ceasing the production, SFDA shall be notified. |
| Monitor the Compliance in the POC Site | 10 | SFDA has the right to monitor the compliance in the POC site without any prior notice. |

## Required Documents

| | Required Documents | Notes |
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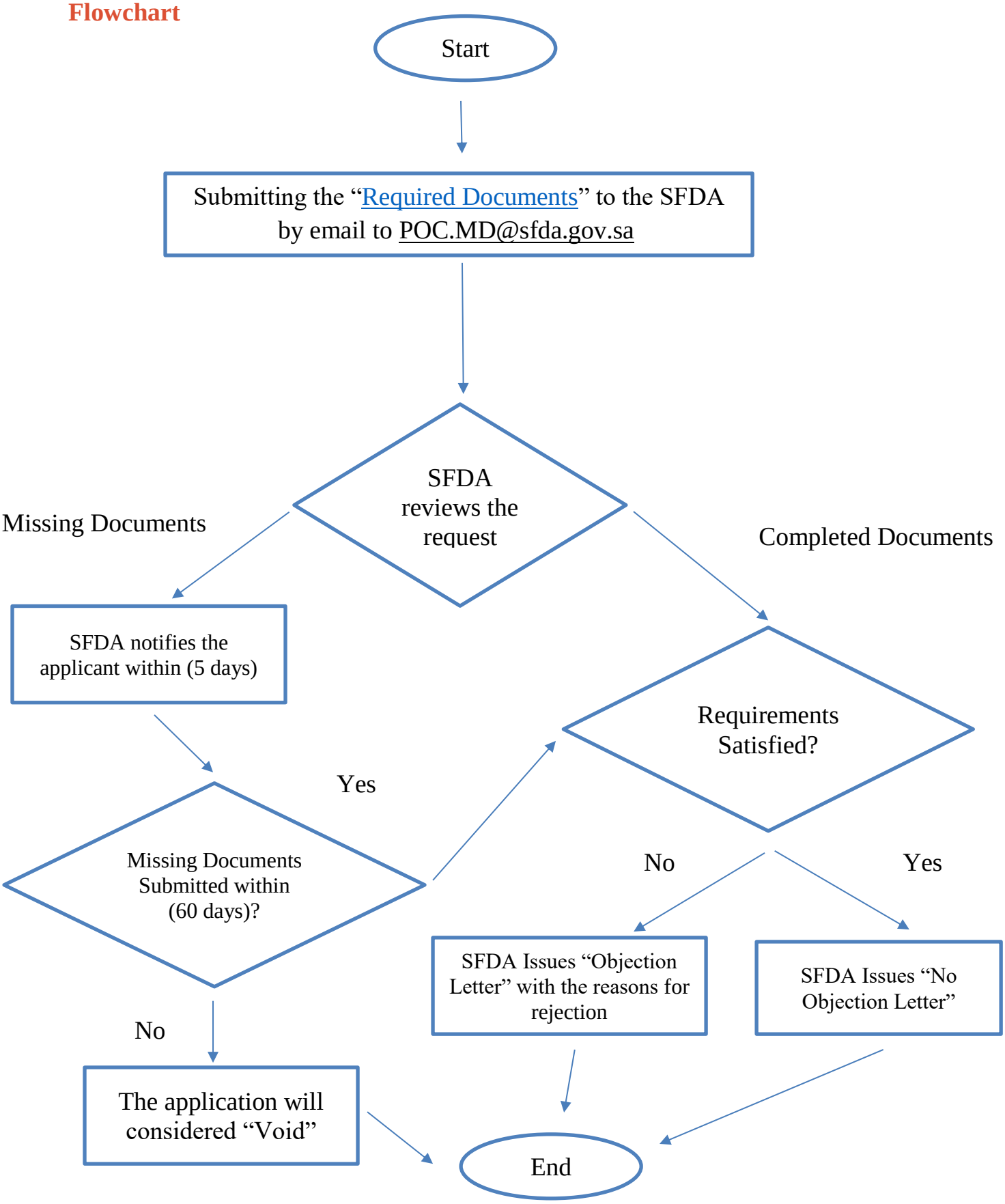
| 1 | Application Form for Points of Care (POC) Medical Devices Manufacturing | See Annex 1. |
| 2 | Medical Device Marketing Authorization (MDMA) | – For the software used for printing the medical device.<br>– In accordance with the SFDA Requirements for Medical Devices Marketing Authorization (MDS-REQ 1) |

## Flowchart


Start
Submitting the "Required Documents" to the SFDA by email to POC.MD@sfda.gov.sa
SFDA reviews the request
Missing Documents
Completed Documents
SFDA notifies the applicant within (5 days)
Requirements Satisfied?
Yes
Missing Documents Submitted within (60 days)?
No
Yes
SFDA Issues "Objection Letter" with the reasons for rejection
SFDA Issues "No Objection Letter"
No
The application will considered "Void"
End

# Annexes

# Annex (1) Application Form for Points of Care (POC) Medical Devices Manufacturing

| Saudi Food and Drug Authority<br>Medical Devices Application | DATE RECEIVED: (For SFDA Use Only)<br>APPLICATION NUMBER: (For SFDA Use Only) |
|---|---|

| FACILITY INFORMATION | | |
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| Name of Healthcare Facility: | | |
| Responsible Personnel: | Phone: | Email: |
| Address: | | |

| MEDICAL DEVICE/IVD TEST INFORMATION |
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| Description: |
| Intended Use: |

| JUSTIFICATION FOR MD MANUFACTURING/IVD TEST DEVELOPMENT OR MODIFICATION AT THE POC |
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**DECLARATION**

I, the POC manufacturer of medical device defined in this application declare that:

- POC Manufactured medical devices are for the healthcare facility's own use and not to be transferred to other facilities.
- SFDA has the right to monitor the compliance in the POC site at any time without prior notification.
- The information provided in this application is true and accurate.

Name:

Position:

Date:

Signature:

# Annex (2) Abbreviations and Definitions

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| SFDA | Saudi Food and Drug Authority |
| MDS | Medical Devices Sector |
| MDMA | Medical Devices Marketing Authorization |
| NCMDR | The National Center for Medical Devices Reporting |
| Healthcare Providers | Any government or private establishment that provides healthcare services. |
| Medical device | Any machine, instrument, application device, culture device, laboratory reagents, laboratory calibration materials, software or operating materials for medical devices, or any similar or related device manufactured alone or in combination with other devices.<br><br>It is used in the diagnosis, prevention, monitor, control, treatment, mitigation, palliation, or compensation of injuries, as well as in an examination, replacement, modification, anatomical support, influence on the functions of body organs, support or enablement of life (vital functions for humans) to continue, organize or assist pregnancy, sterilize medical devices and supplies, and give information - for a medical or diagnostic purpose - extracted from laboratory tests of samples taken from the human body, as well as that cannot achieve the goal for which they were made in or on the human body. It is mediated by the drug or the immune factor or metabolic transformations but only helps achieve their interactions. |
| Quality Management System | A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device in accordance with the latest edition of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations. |
| Intended Use | The purpose specified by the manufacturer for the use of a medical device. |
| Labelling | Any written statement, information, or illustration printed on a medical device, including identifying information, technical description, method of use, and manner of storage and transportation. |
| Standards | Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements. |
| Surveillance | A group of procedures to control safety, efficiency, quality and effectiveness of medical devices while circulated in the Kingdom. |
| User | A person, whether a professional, non-professional, or patient, who uses a medical device or supply. |
| Adverse event | Any defect or change in the characteristics or performance of a medical device or supply that may directly or indirectly cause or contribute to the death or serious injury of a user. |
| POC Manufacturing | Manufacturing a device by healthcare facilities which may include:<br>- Putting together of a device from raw materials or component parts;<br>- The complete rebuilding of an existing device; or<br>- Device software development (including AI) |
| 3 D - Printing | A process that creates a three-dimensional object by building successive |

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| | layers of raw material. Each new layer attached to the previous one until the object is complete. Objects produced from a digital 3D file, such as a computer-aided design (CAD) drawing or a Magnetic Resonance Image (MRI). |
| Medical device production system (MDPS) | A collection of the raw materials, software and digital files, and main production and post-processing (if applicable) equipment intended to be used by a healthcare provider, or healthcare facility, to produce a specific type of medical device at the point of care, for treating their patients.<br><br>MDPS includes the medical device it is intended to produce and the intended use for the device.<br><br>MDPS may require the use of ancillary equipment, human factors considerations, technical capability requirements, or other specified input and design limit controls; however, all components shall be validated as a production process to consistently produce the intended medical device with the use of the supplied instructions. |
| In-House IVD | A pathology tests that have been developed (or modified) within a laboratory (or laboratory network) to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or be used in making decisions concerning clinical management. |
| Medical Device Marketing Authorization (MDMA) | A document issued by the SFDA permitting the circulation of a medical device or supply in the market. |
| Implantable Medical Device | Any device that is totally introduced into the human body surgically, replace a superficial/epithelial surface of the body, or placed on the surface of the eye. Including those partially or wholly absorbed by the body and remain in place after the medical surgical intervention, and include devices that partially introduced surgically for a purpose of (30) days or more of usage. |

# Annex (3): List of Changes

| Changes Description |
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| • Replace the following document:<br>Guidance on Patient-matched Medical Devices Using 3D Printers (MDS-G30) |