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 healthcare facilities for their own use and for non-industrial scale (with regard to the magnitude and methods of production) and (Not for commercial purposes). This document applies to the following activities:

1. Manufacturing a medical device by 3D printing inside a healthcare facility.
2. Manufacturing a medical device by a Medical Device Production System (MDPS) inside a healthcare facility.
3. Developing or modifying In-House IVD kits/reagents.
4. Developing or modifying any medical device inside a healthcare facility.
5. Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing.

Background

The 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 AH 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, in accordance with rules approved by the Board".
- 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 19/2/1443 AH 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

General	1	- Providing a Justification for Manufacturing at the POC rather than purchasing medical devices available in the market. Such justification shall clearly include patients' specific needs, lead-time, accessibility, cost, or flexibility on the medical device's design. - Manufacturing medical devices inside the healthcare facility for their own use and not transfer them to any other facility.
Quality Management System	2	Manufacturing medical devices in accordance with the requirements of Medical Devices Quality Management System (ISO 13485 or equivalent).
Documentation	3	Documenting and submitting the following to the SFDA: a) Name and address of the healthcare facility/POC site b) Details necessary to identify the manufacturing equipment (such as 3D-printer model and brand name) and the manufactured medical device c) Identification of the responsible entity and personnel for the POC medical device manufacturing d) Healthcare facility's top management approval for the POC medical device manufacturing e) Labelling of the manufactured medical device including the intended use, and -if applicable- the patient identifier and the expiration date f) Essential Principles of safety and performance for medical devices checklist in accordance to the Requirements for Medical Devices Marketing Authorization (MDS-REQ 1) and a justification for any principle which is not met by the manufactured medical device g) The manufacturing processes. Documenting and submitting the following to the SFDA upon request: a) Records of competency, qualification and training of POC manufacturing staff b) Design and performance data c) Sterilization processes records and sterilization validation report -if applicable- d) Biocompatibility validation report -if applicable- e) Clinical Evaluation Report f) Records, quality control procedures and other documents related to the POC manufactured medical device.
Post-Market Surveillance	4	- Implementing a surveillance system to monitor the performance of the POC manufactured medical device.

		- Tracking the POC manufactured medical device throughout its lifecycle. - Conducting preventative and corrective actions to ensure the safety of patients and users of the POC manufactured medical device. - Reporting all incidents, adverse events and complaints to the NCMDR in accordance with the Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11).
Manufacturing Medical Device by 3-D Printing	5	- Raw materials used in the manufacturing of medical devices by 3-D printing shall be "Medical-Grade" and shall be validated by the supplying manufacturer. - Obtaining Medical Device Marketing Authorization (MDMA) for the software used for designing or printing the medical device in accordance with the Requirements for Medical Devices Marketing Authorization (MDS-REQ 1). - Providing and documenting information about the 3D printers, including maintenance records.
Manufacturing Medical Device by Medical Device Production System (MDPS)	6	- Raw materials used in the manufacturing of medical devices by MDPS shall be "Medical-Grade" and shall be validated by the supplying manufacturer. - Obtaining Medical Device Marketing Authorization (MDMA) for the MDPS system and software used for printing or designing the medical device in accordance with the Requirements for Medical Devices Marketing Authorization (MDS-REQ 1). - Providing and documenting the Medical Device Production System (MDPS) file, which includes information about raw materials, software, equipment, final product, intended use and users.
Developing or modifying In-House IVD tests	7	The requirements below are applicable to all In-House IVDs including: o Developing In-House IVD test from first principles. o Developing or modifying In-House IVD test based on a published source. o Modifications to commercially supplied IVDs. - Developing/modifying and conducting the IVD test for their own use inside the healthcare facility. - Specifying which part/s of the IVD test is prepared In-House and which part/s were outsourced. - The proof of concept and methodology of developing or modifying In-House IVD test including design control through assignment of the specifications, references, and literature review of published sources. - Full report for verification and validation conducted on the In-House IVD test including clinical performance evaluation and raw data of validation and verification.

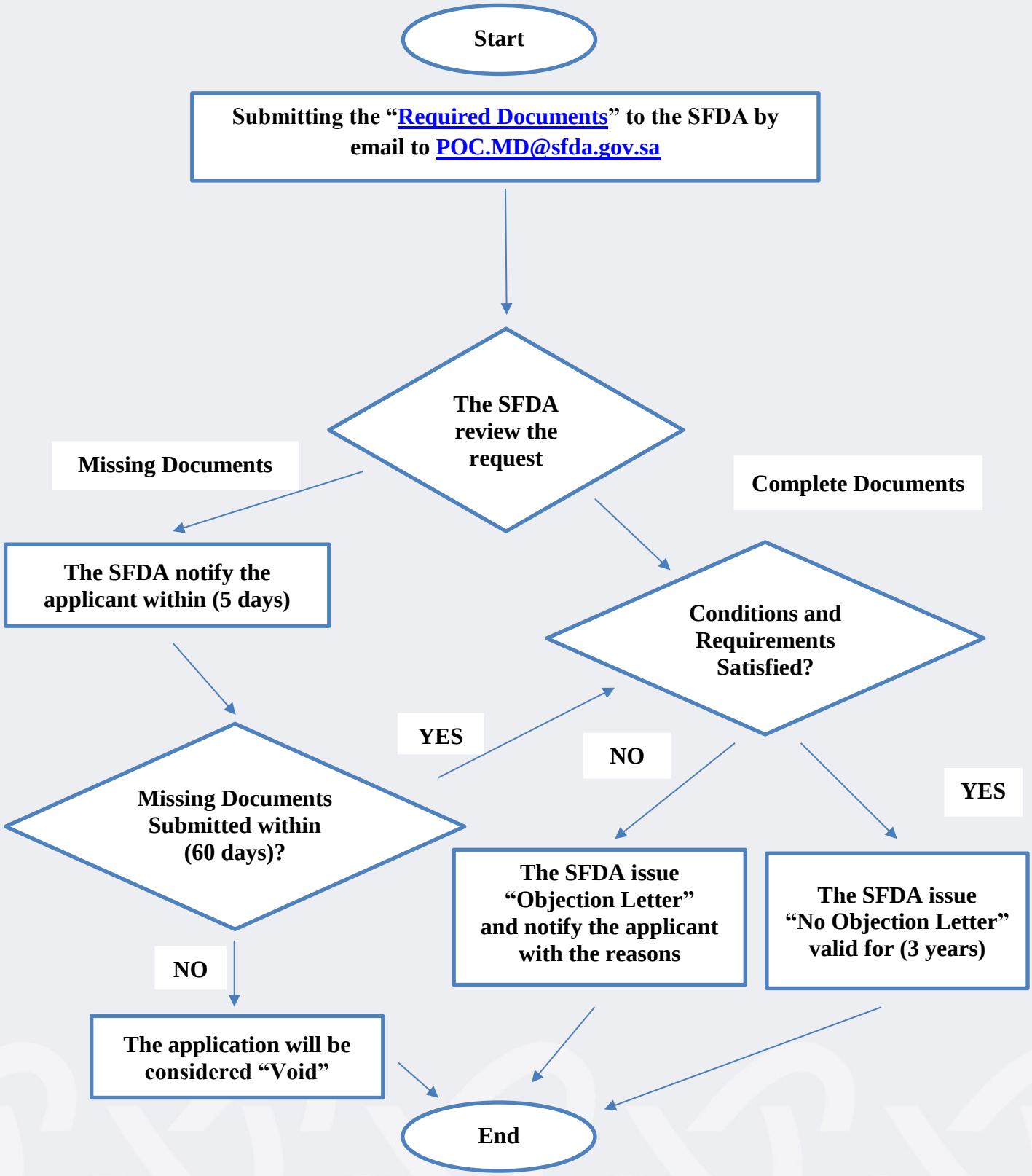
		- Evidence that laboratory where the in-house IVD developed test will be used is compliant with applicable national provisions and have ISO 15189 accreditation or equivalent.
Manufacturing of Implantable Medical Device	8	- Storing one copy of the implant card in the patient file, and providing the patient with another copy. - Containing the following details in the implant card: a) Identification of the device which includes the device name and the patient identifier b) Any warnings, precautions or measures to be taken with respects to cross-interference with anticipated externalities, medical examinations or expected environmental conditions; c) Information on the lifespan of the device and any periodic follow up necessary for the performance of the device 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.
Application Submission	9	- Submitting the Required Documents by email to POC.MD@sfda.gov.sa. • In case of missing documents, the SFDA will notify the applicant within (5 days). The application will be considered "Void" in case missing documents are not submitted within (60 days) from the date of submitting the application. • In case of completed documents, the SFDA will review the request and take a decision within (30 days) and take a decision as follow: o If requirements are satisfied, the SFDA will issue a "No Objection Letter" valid for (3 years). o If requirements are not satisfied, the SFDA will issue an "Objection Letter" and notify the applicant with the reasons for objection. - In case of change or broaden the scope of POC, or addition of extra manufacturing site, the SFDA approval shall be obtained.
Monitor the Compliance in the POC Site	10	- The SFDA conducts annual field visits to monitor the compliance in the POC site. - The SFDA conducts additional field visits to monitor the compliance in the POC site according to its discretion and without any prior notice.
Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing	11	- For importing raw materials/chemicals for the purpose of medical device POC manufacturing, importation license/permission shall be obtained from the SFDA based on the "SFDA No Objection Letter".

		- Quantity of raw materials/chemicals shall be corresponding to the production output. - Abiding to the declaration specified in the Required Documents. - Importation license/permission application shall be submitted via GHAD system with providing the below mentioned Required Documents from (3) to (9). - Once satisfied, the SFDA issue an importation license/permission, valid for (One Year). Note: The validity of importation license/permission can be extended for an extra period not exceeding the validity of "No Objection Letter". - To obtain the SFDA Approval for releasing shipment before it arrives at a port of entry, the applicant shall: • Submit the application via Faseh Services System. • Submit the application via the FASAH (Tabadul) platform. • Provide the following documents: o No Objection Letter o Purchase Invoice o Bill Of Lading o Customs Declaration o Importation License/Permission.

Required Documents

	Required Documents	Notes
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 3-D designing or printing of the medical device, or for the MDPS system. – In accordance with the Requirements for Medical Devices Marketing Authorization (MDS-REQ 1).
For importing raw materials/chemicals for POC Medical Devices Manufacturing		
3	Declaration of Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing	– See Annex 2. – It shall be signed by authorized person identified in GHAD system.
4	Purchase Invoice	– If it is not available, provide the Pro Forma. – It shall include invoice reference number, manufacturer name, product name, model number, lot/serial numbers, quantity, and expiry date (if applicable) in the purchase invoice or packing list. – It shall be issued by the manufacturer, if it is not, the applicant shall provide a copy of the agreement/authorization letter between the manufacturer and the establishment that issued the invoice. – It shall be stamped by the concerned authority for trade in the country of origin (if applicable).
5	Bill of Lading	If any.
6	Country of Origin Certificate	If any.
7	Material Safety Data Sheet	It shall be issued by the manufacturer.
8	Chemical details in terms of weight or volume	– If the raw material is a chemical substances under MOI control. – It shall be issued by the manufacturer. – Measuring unit shall be in Kilogram or Liter.
9	Application and attestation forms specified in Article Two of "The Implementing regulations of the chemicals import Law"	– If the raw material is a chemical substances under MOI control. – The attestation of responsible person for chemical warehouse shall contain his/her contact information. – They shall contain storage warehouse location (Sketch).

Flowchart


Start
Submitting the "Required Documents" to the SFDA by email to POC.MD@sfda.gov.sa
The SFDA review the request
Missing Documents
Complete Documents
The SFDA notify the applicant within (5 days)
Conditions and Requirements Satisfied?
YES
NO
YES
Missing Documents Submitted within (60 days)?
The SFDA issue "Objection Letter" and notify the applicant with the reasons
The SFDA issue "No Objection Letter" valid for (3 years)
NO
The application will be considered "Void"
End

Annexes

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

Saudi Food and Drug Authority Medical Devices Application		DATE RECEIVED: (For SFDA Use Only) APPLICATION NUMBER: (For SFDA Use Only)
FACILITY INFORMATION		
Name of Healthcare Facility:		
Responsible Personnel:	Phone:	Email:
Address:		
MEDICAL DEVICE/IVD TEST INFORMATION		
Description:		
Intended Use:		
Manufacturing equipment brand/model number:		
JUSTIFICATION FOR MD MANUFACTURING/IVD TEST DEVELOPING AT THE POC		
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 any other facility.
- The SFDA has the right to monitor the compliance in the POC site at any time without prior notice.
- The information provided in this application is true and accurate.

Name:

Position:

Date:

Signature:

Annex (2): Declaration and Attestation of Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing

[To be printed on Healthcare Provider Letterhead]

أ) بيانات المنشأة		
اسم مرفق الرعاية الصحية		
رقم المعرف في نظام غد		
ب) المادة الخام		
هل المادة الخام:	نعم أو لا؟	اسم المادة (عند الإجابة بنعم)
مادة مشعة		
مادة كيميائية خاضعة لرقابة وزارة الداخلية		
مادة مخدرة		
ج) الغرض من الاستيراد ومنفذ الدخول		
الغرض من الاستيراد		
منفذ الدخول الجمركي		
د) الإقرار والتعهد:		

نقر ونتعهد نحن المدونة بياناتنا أعلاه بالآتي:

١) مطابقة بنود الإرسالية (الشحنة) الواردة في الفاتورة مع الشروط والمعايير الدولية والمتطلبات الواردة في "نظام الأجهزة والمستلزمات الطبية" ولائحته التنفيذية.
٢) الالتزام بـ "نظام الأجهزة والمستلزمات الطبية" ولائحته التنفيذية والمتطلبات ذات العلاقة.
٣) جميع البيانات المدخلة في الطلب في نظام غد الالكتروني صحيحة وعلى مسؤولية مقدم الطلب.
٤) جميع المستندات المرفقة في الطلب متعلقة بالبنود المطلوبة.
٥) أن تتوافق كمية المواد الخام/الكيميائية المراد استيرادها مع مخرجات الإنتاج.

اسم الشخص المسؤول	
المسمى الوظيفي	
التاريخ	
التوقيع	

Annex (3): List of Changes on the Previous Version

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 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.
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.
Clinical Performance	The ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer
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.
Accidents of Medical Devices and Supplies	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 medical device inside a healthcare facility which may include:

	- Putting together of a medical device from raw materials or component parts; - The complete rebuilding of an existing medical device; or - Medical device software development (including AI)
3 D - Printing	A process that creates a three-dimensional object by building successive layers of raw material. Each new layer is attached to the previous one until the object is complete. Objects are 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. - A MDPS includes the medical device it is intended to produce and the intended use for the device validated in accordance with essential principles of safety and performance for medical devices published by the SFDA. - The 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 must be validated as a production process to consistently produce the intended medical device with the use of the supplied instructions.
In-House IVD	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	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 (4): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 08/01/2023	• Editorial modifications on the clause “Scope”. • Modifications on the clause “Requirements & Procedures”, subclause “Documentation”. • Modifications on the clause “Requirements & Procedures” subclause “Developing or modifying In-House IVD tests”. • Modifications on the clause “Requirements & Procedures” subclause “Application Submission”. • Addition of the subclause “Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing” to the clause “Requirements & Procedures”. • Addition of the subclauses from (3) to (9) related to “Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing” to the clause “Required Documents”. • Editorial modifications on the clause “Flowchart”. • Modifications on “Annex (1) Application Form for Points of Care (POC) Medical Devices Manufacturing”. • Addition of “Annex (2): Declaration and Attestation of Importing Raw Materials/Chemicals for POC Medical Devices Manufacturing”. • Modifications on “Annex (3) Definitions & Abbreviations”.
2.0 25/01/2024	• Editorial modifications on the clause “Scope”.