# Central Drugs Standard Control Organization

## (Medical Devices Division)

# Guidance Document

## Title: Guidance document on Medical device software

## Doc No.:

## Draft for stakeholder comments

**Notice:**

This guidance document is aimed only for creating public awareness about Regulations of Medical Device Software and is not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act and the Medical Devices Rules, 2017 and respective Guidelines/Clarifications issued by CDSCO from time to time for all their professional needs.

# INDEX

# ABBREVIATIONS

| | |
|---|---|
| AE | Adverse event |
| ACP | Algorithm Change Protocol |
| AI | Artificial Intelligence |
| API | Application Programming Interface |
| CDSCO | Central Drugs Standard Control Organization |
| CLA | Central Licensing Authority |
| FSC | Free Sale Certificate |
| FSCA | Field Safety Corrective Action |
| IMS | Image Management System |
| IVD | *In vitro* Diagnostic(s) |
| LA | Licensing Authority |
| LIS | Laboratory Information System |
| MSC | Market Standing Certificate |
| MDR | Medical Devices Rules |
| NCC | Non Conviction Certificate |
| PMS | Post Marketing Surveillance |
| PSUR | Periodic Safety Update Report |
| SaMD | Software as a Medical Device |
| SiMD | Software in a Medical Device |
| SUSAR | Suspected Unexpected Serious Adverse Events |
| SLA | State Licensing Authority |
| QMS | Quality Management System |

## 1.0 PURPOSE:

To provide guidance to Indian manufacturers and importers for the submission of application to the Licensing Authority (LA) for obtaining license/permission for manufacturing or import of Medical Device Software (including *In vitro* Diagnostic (IVD) Medical Device Software) under the Medical Devices Rules (MDR), 2017.

## 2.0 SCOPE:

This guidance document applies to Software products which attract the definition of a "Medical Device" as stipulated in the MDR-2017.

This guidance document pertains to the Software categorized as follows:

1) Software in a medical device (SiMD).

2) Software as a medical device (SaMD).

This guideline reflects current practices based on MDR-2017 and should not be misconstrued as a new regulatory control on Medical Device Software (including *In vitro* Diagnostic (IVD) Medical Device Software).

**NOTE:**

*For the purposes of this document, SaMD and SiMD (including IVD medical device software) shall be referred to as "Medical Device Software" hereinafter, unless otherwise specified.*

## 3.0 MODE OF SUBMISSION

- Applications for grant of Test licence for Medical Device Software shall be submitted in the National Single Window System (NSWS) portal, i.e., www.nsws.gov.in.

- Applications for grant of registration/permission/license (other than Test license) for Medical Device Software shall be submitted in the Online system for Medical Devices (MD online portal), i.e., www.cdscomdonline.gov.in.

## 4.0 GUIDANCE

Medical Device Software are regulated under the provisions of the Drugs & Cosmetics Act, 1940 and the MDR-2017, made thereunder. Words and expressions used in this guidance document shall have the meaning respectively assigned to them in the Drugs & Cosmetics Act, 1940 and the MDR-2017 made thereunder.

### 4.1 DEFINITIONS

**4.1.1 "Active medical device"** - means a medical device, the operation of which depends on a source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity.

**4.1.2 "Clinical evidence"** means, in relation to,—

(i) an *in vitro* diagnostic medical device, is all the information derived from specimen collected from human that supports the scientific validity and performance for its intended use;

(ii) a medical device, the clinical data and the clinical evaluation report that supports the scientific validity and performance for its intended use.

**4.1.3 "Clinical investigation"** means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness.

**4.1.4 "Clinical performance evaluation"** means the systematic performance study of a new *in vitro* diagnostic medical device on a specimen collected from human participants to assess its performance.

**4.1.5 "Intended use"** means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling or in the document containing instructions for use [or electronic instructions for use] of such device or in promotional material relating to such device, which is as per approval obtained from the Central Licensing Authority.

**4.1.6 "Investigational medical device"** in relation to a medical device, other than *in vitro* diagnostic medical device, means a medical device which does not have its predicate device or which is licensed under the MDR-2017 however it claims for new intended use or new population or material or major design change and is being assessed for safety or performance or effectiveness in a clinical investigation.

**4.1.7 "Medical Device"** - All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) disinfection of medical devices; and

(vi) control of conception.

**4.1.8 "New *in vitro* diagnostic medical device"** means any medical device used for *in vitro* diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte(s) or other parameter related thereto including details of technology and procedure required.

**4.1.9 "Predicate device"** means a device, first time and first of its kind, approved by the Central Licensing Authority for marketing in the country and has the similar intended use, material of construction, and design characteristics as the device which is proposed for licence in India.

**4.1.10 "Medical purposes"** include, but are not be limited to, diagnosis, prevention, monitoring, mitigation, prediction, treatment, etc., of any disease or pathological condition or state.

## 4.2 TYPES OF MEDICAL DEVICE SOFTWARE

- Generally, Medical Device Software consists of two types:

  **(1) Software in a medical device (SiMD)**
  (also referred to as “embedded” or “part of” a hardware medical device)
  **(2) Software as a medical device (SaMD).**
  (also referred to as “standalone software” or “not embedded/without being a part of” a hardware medical device.)

- Not all software used within healthcare is qualified as a medical device.
- Software can be considered to be active devices because they rely on a source of energy other than energy generated by the human/animal body or gravity.

### 4.2.1 Software in a Medical Device (SiMD)

- SiMD refer to software that are considered as a “part of” the medical device hardware and that drive or influence the use of that medical device. These may also be referred to as “embedded software”, “firmware”, or “micro-code”.
- Embedded software is specialized programming in a microchip or on firmware embedded in a medical device, either as part of a microchip or as part of another application that influences the microchip – to control the functioning of the device. It includes applications, firmware, middleware, and operating systems that execute on a single microprocessor or cluster of microprocessors “embedded” within additional logic.

**NOTE:**

- *Firmware is a type of software that provides control for a device’s specific hardware. It provides the needed instructions and guidance for the device to communicate with other devices or perform a set of basic tasks and functions as intended.*
- *Middleware is a type of software that lies between an operating system and the applications running on it.*

- SiMD also includes software required by a hardware medical device to perform the hardware’s medical device intended use, even if/when sold

separately from the hardware medical device.

- Software that controls a medical device -- some software, including mobile apps, can control or adjust a medical device through a connection, either physical or utilising wireless technology such as Bluetooth or Wi--Fi features.

*Illustration (Examples of SiMD):*

*Example (1):* The embedded software/firmware in a cardiac pacemaker is regulated as a component of that pacemaker, because it is supplied as part of the device and is necessary for the device to function.

*Example (2):* Software that controls an insulin pump – Software that calculates an insulin bolus based on readings from a blood glucose meter. The software controls an insulin pump to deliver the calculated dose.

*Example (3):* Software that is built (pre-installed) into an IVD analyser/instrument (e.g., operating software in a clinical analyser, point of care analyser or personal use IVD such as a glucose meter). In these cases, the software is a part of a device and is not considered to be a separate or distinct device.

*Example (4):* Software that is supplied separately (which is installed on a computer interface) to an IVD analyzer/instrument but intended to operate or influence the IVD. In these cases, the software is a distinct IVD that is separate from the IVD analyser/instrument.

### 4.2.2 Software as a Medical Device (SaMD)

- Software, either alone or in combination, intended to be used to perform one or more medical purposes as specified in S.O. 648(E) dated 11.02.2020 without being part of a hardware medical device, wherein,

"without being part of" means software does not necessarily require a hardware medical device to achieve its intended medical purpose.

- SaMD is capable of running on general purpose (non-medical purpose) computing platforms, wherein

"Computing platforms" include hardware and software resources (e.g. operating system, processing hardware, storage, software libraries, displays, input devices, programming languages, etc.), and "Operating systems" refer to any server, workstation, mobile platform, or any other general purpose hardware platform that may be required by SaMD to run on.

- SaMD may be interfaced with other medical devices (including hardware medical devices and/or other SaMD software) as well as general purpose software.
- Mobile apps that meet the definition stated in **Section 4.1.1** above are considered as SaMD.
- Commercial off-the-Shelf (COTS) software that meet the definition as stated in **Section 4.1.1** shall be considered as medical devices.
- SaMD is often able to attain its intended medical purpose independent of hardware medical devices.
- SaMD is increasingly being deployed on general-purpose (non-medical purpose) hardware and delivered, in diverse care settings, on a multitude of technology platforms (e.g., personal computers, smart phones, and in the cloud) that are easily accessible. It is also being increasingly interconnected to other systems and datasets (e.g., via networks and over the Internet).

*Illustrations (Examples of SaMD):*

*Example (1):* A medical device software application that connects via Bluetooth to a blood pressure cuff to obtain readings used to track blood pressure in the individual wearing the cuff for medical purposes.

*Example (2):* A software intended for image analysis of body fluid preparations or digital slides to perform cell count and morphology reviews.

*Example (3):* A software intended to store medical data (as input by laypersons or health care takers), and analyse and track the data over a period of time to create health-related trend lines or generate alerts relating to a person's health to further aid in clinical decision-making.

### 4.2.3 Software that are NOT covered under the MDR-2017

- Software that do not attract the definition of a Medical Device (as stated in **Section 4.1.1** above).

*Illustrations (Examples of Software that are not SiMD/SaMD):*

☒ Software that rely on data from a medical device, but do not have a medical purpose, e.g., software that encrypt data for transmission from a medical device.

☒ Software that monitor performance or proper functioning of a medical device for the purpose of servicing the device.

☒ Software that alter the representation of data for embellishment/cosmetic or compatibility purposes.

☒ Software that perform actions such as transfer, storage, archive data, convert, format, communication, simple search, lossless compression.

☒ Hospital/Clinical Information systems that support the process of patient data management (intended only for patient admission, for scheduling patient appointments/visits, for insurance and billing/invoicing purposes, enabling clinical communication such as voice calling, video calling, to store and transfer patient information (patient identification, vital intensive care parameters and other documented clinical observations) generated in association with the patient's intensive care treatment).

☒ Communication systems intended for general purposes, and is used for transferring both medical and non-medical information (e.g. email systems, mobile telecommunication systems, video communication systems, paging, etc.) to transfer electronic information. Different types of messages are sent such as prescription, referrals, images, patient records, etc.

☒ Laboratory Information Systems (LIS) are not qualified as medical devices, wherein the main intended use is the management and validation of incoming information obtained from IVD analyzers connected to the system, such as calibration, quality control, product expiry and feedback (e.g. retesting of samples needed) through

interconnections with various analytical instruments (technical and clinical validation). The post-analytical process allows communication of laboratory results, statistics and optional reporting to external databases.

☒ Image Management System (IMS): a software-based system primarily intended to be networked with digital pathology systems, in order to access, display, annotate, manage, store, archive and share collections of digitised patient images.

**NOTE:**

*The above-mentioned examples are only suggestive of some software that may or may not be classified as Medical Device Software, and are not exhaustive in nature. The classification of a particular software as a Medical Device is subject to its intended use, etc.*

## 4.3 INTENDED USE STATEMENT OF MEDICAL DEVICE SOFTWARE

- The definition of **"Intended use"** means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling or in the document containing instructions for use of such device or in promotional material relating to such device, which is as per approval obtained from the CLA (**Section 4.1**).
- Key elements that may be considered while framing the Intended Use/Intended Purpose statement for the Medical Device Software:
  a) Medical Purposes (*e.g., diagnosis, prevention, monitoring, mitigation prediction, treatment, etc.*)
  b) Intended Disease or Condition (*e.g., critical, serious, non-serious, etc.*)

**NOTE:**

*The specific disease or condition intended to be targeted by the Medical Device Software, if any, should ideally be mentioned in the intended use statement. The state of condition/disease (e.g., chronic or acute) should also be considered.*

c) Intended Patient Populations *(e.g., general population, specific subgroup like pediatric, geriatric, specific age group, ethnicity, etc.)*

d) Intended Users *(e.g., laypersons/non-clinical user/user without a medical qualification, health care professionals that include nurses, radiologists, dentists, primary care physicians, specialist care physicians, etc.)*

e) Intended Use Environment *(e.g., home use, primary care/virtual primary care, hospital, specialty clinics, etc.)*

f) Contraindications *(the specific medical conditions/comorbidities wherein the Medical Device Software should not be used or may provide erroneous results)*

g) Medical device software function, including:
  i. Medical device software inputs (*e.g., from human user, medical device, non-medical device, or consumer product*)
  ii. Medical device software outputs (*e.g., this may include clinical*

*interpretation or intervention (diagnosis, mitigation, treatment, prediction, probability, prognosis, prescription, recommended treatment/therapy, radiation treatment plans, etc.), workflow recommendations (recommended surgical tools, recommended additional tests, recommended imaging modality/parameters, etc.*), or/and data for use in medical purpose (anatomy measurements, volume, or segmentation, image reconstruction/de-noising, processed signals such as ECG, etc.))

iii. Explanation of how the medical device software inputs and outputs fit into the clinical or healthcare workflow (*e.g., output targeted to humans or for other medical devices, whether it informs clinical management, or drives it, etc.*)

**NOTE:**

- *It is pertinent to note that not all elements will be applicable to all Medical Device Software.*
- *For certain Medical Device Software, information such as contraindications, etc. may be included elsewhere and not in the intended use statement.*

h) In addition to the above, the following key elements should be considered in the intended use statement of In-vitro diagnostic (IVD) medical device software:

i. The analyte(s)/parameter(s) being analyzed (*e.g., concentration of anti-HIV antibodies, etc.*)

ii. The type of sample/specimen to be use for analysis (*e.g., blood plasma, urine, etc.*)

iii. Intended diagnostic level (*e.g., screening, diagnosis aid, staging of disease, prognosis, etc.*)

iv. Limitations to the intended use, i.e., the specific conditions/comorbidities/medications/analyte variant for which the software may yield erroneous result, if any, (*e.g., changes in image quality may limit the efficiency by which a software analyzes stained slides; specific subtypes/variants of pathogens for which sensitivity and consequently the software performance may be affected*)

v. Whether the IVD software is intended to yield quantitative, semi-quantitative or qualitative results.

## 4.4 RISK-BASED CLASSIFICATION

- As per Rule 4 in Chapter II of the MDR-2017, all medical devices (including Medical Device Software) are classified as shown in **Table 1**.

**Table 1. Risk classification of medical devices as per the MDR-2017.**

| Degree of risk | Classification |
|---|---|
| **Low risk** | Class A |
| **Low moderate risk** | Class B |
| **Moderate high risk** | Class C |
| **High risk** | Class D |

- The risk class of the Medical Device Software is fundamentally based on the intended use of the software and the applicable rules in First Schedule of MDR-2017, wherein the intended use of the Medical Device Software is normally reflected in various sources such as the labelling details, including instructions for use manuals, websites, promotional material, and other information provided by the manufacturer.
- In effect, a Medical Device Software, which drives a medical device or an IVD medical device, or influences the use of a medical device or an IVD medical device, falls automatically in the same class as the device. It can be inferred that all SiMD intended to drive, control and/or influence the medical device which they are a part of, shall be considered in the same class as the medical device.
- Standalone software (SaMD), which are not incorporated into the medical device itself and provide an analysis based on the results from an analyser (IVD medical device), shall be classified in to the same category as that of the IVD medical device where it controls or influences the intended output of a separate *in vitro* diagnostic medical device.

### 4.4.1 Factors to be considered for risk classification of SaMD

- All SaMD shall be classified using the classification parameters and provisions as specified in the First Schedule of the MDR-2017.
- The intended use of the SaMD as provided by the manufacturer shall be fundamental to the risk classification of SaMD.
- Additionally, subject to the parameters laid out in the First Schedule of MDR-2017 and as specified by the intended use statement, the following factors may be considered in determining the risk class of a SaMD:

**Table 2. Risk classification of SaMD.**

| State of healthcare situation or condition | Significance of information provided by SaMD to health care decision | | |
|---|---|---|---|
| | Treatment or diagnosis | Drive clinical management | Inform clinical management |
| **Critical** | D | C | B |
| **Serious** | C | B | A |
| **Non-serious** | B | A | A |

a) **Significance of information provided by SaMD for health care decision making**, viz. Treatment or diagnosis, Drive clinical management or/and Inform clinical management.

**i. Treatment or diagnosis:** This infers that the information provided by the SaMD will be used to take an immediate or near term action to:

☑ Treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human/animal body, or/and

☑ Diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition).

**ii. Drive clinical management:** This infers that the information provided by the SaMD shall be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition or/and will be used to guide next diagnostics or next treatment

interventions.

- ☑ To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
- ☑ To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis.
- ☑ To triage or identify early signs of a disease or conditions.

**iii. Inform clinical management:** This infers that the information provided by the SaMD will not trigger an immediate or near term action. However, the SaMD shall:

- ☑ Inform of options for treating, diagnosing, preventing, or mitigating a disease or condition, and/or
- ☑ Provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)

b) **The health care situation or condition for which the SaMD is intended to be used**, viz. critical, serious or non-serious situation/condition.

**i. Critical situation/condition:** These refer to situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.

SaMD is considered to be used for a critical situation/condition when:

- ☑ The type of disease/condition is life threatening (including incurable states), requires major therapeutic interventions, and/or time critical (i.e. progression of the disease/condition is such that it may affect the user's ability to reflect on the output information).
- ☑ Intended target population is fragile with respect to the disease or condition (e.g., paediatrics, high risk population, etc.)
- ☑ Intended for use by specialized trained users.

**ii. Serious situation/condition:** This refers to those

situations/conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health. SaMD is considered to be used in a serious situation or condition when:

- ☑ The type of disease/condition is moderate in progression (often curable), does not require major therapeutic interventions, and/or the intervention is not expected to be time critical, in order to avoid death, long term disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations.
- ☑ Intended target population is NOT fragile with respect to the disease or condition.
- ☑ Intended for use by either specialized trained users or lay users.

**NOTE:**

*SaMD intended to be used by lay users in a "serious situation or condition" as described here, without the support from specialized professionals, may be considered as SaMD used in a "critical situation or condition".*

**iii. Non-Serious situation/condition:** This refers to a situation/condition where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health. SaMD is considered to be used in a non-serious situation or condition when:

- ☑ The type of disease/condition is slow with predictable progression disease states (e.g., minor chronic illness or states, etc.), may not be curable but can be managed effectively, requires only minor interventions, and interventions are mostly non-invasive in nature, providing the user the ability to detect erroneous recommendations.

- ☑ Intended target population is individuals who may not always be patients.
- ☑ Intended for use by either specialized trained users or lay users.

- The risk class shall be confirmed by CDSCO upon review of the medical device details such as intended use, design characteristics, etc.
- In exercise of the powers conferred under sub-rule (3) of Rule 4 of MDR-2017, CDSCO has classified a list of Medical Device Software and In-vitro Diagnostic Medical Device Software, which are published on the CDSCO website. This list is dynamic and is subject to revision from time to time under the provisions of MDR-2017.

**NOTE:**

*If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply (First Schedule, MDR-2017).*

## 4.5 APPLICABLE STANDARDS

- The medical device software shall conform to the standards laid down by the Bureau of Indian Standards or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.
- If no such standard(s) are available, the device(s) shall conform to the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopeial standards.
- In case if the standards are not specified under above points, the device shall conform to the validated manufacturer's standards.
- The following standards may be applicable to all medical device software:
  - ☑ IS/ISO 13485 standard (Medical Devices—Quality Management Systems— Requirements for Regulatory Purposes)
  - ☑ IS/ISO 14971 Medical devices — Application of risk management to medical devices.
  - ☑ IEC/TR 80002-1 Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software.
  - ☑ IS/ISO/TR 80002-2 Medical Device Software Part 2 Validation of Software for Medical Device Quality Systems.
  - ☑ IS/IEC/TR 80002-3 Medical device software Part 3: Process reference model of medical device software life cycle processes.
  - ☑ IS/ISO/IEC 62304 Medical device software – Software life cycle processes.
  - ☑ IS/IEC 82304-1 Health software: Part 1 general requirements for product safety.
  - ☑ IEC 81001-5-1 adds requirements about cybersecurity.
  - ☑ IEC 62366-1 adds requirements about man-machine interface ergonomics.
  - ☑ IS 16458/ISO/IEC 16085 — Systems and Software Engineering — Life Cycle Processes — Risk Management
  - ☑ IS/ISO/IEC 23894 — Information Technology — Artificial Intelligence — Guidance on Risk Management

- ☑ IS/ISO/IEC 42001 — Information technology — Artificial intelligence — Management system
- ☑ IS/ISO/IEEE 11073 Health Informatics - Point-of-Care Medical Device Communication
- ☑ ISO 24291 — Health informatics — Applications of machine learning technologies in imaging and other medical applications

**NOTE:**

*The above list mentions some of the standards that may be applicable for Medical Device Software and is not exhaustive in nature.*

## 4.6 REQUIREMENTS FOR QUALITY MANAGEMENT SYSTEM (QMS) FOR MEDICAL DEVICE SOFTWARE

- The manufacturer of a Medical Device Software need to establish Quality Management System (QMS) in respect of the organizational structure and the entire software lifecycle (design, development, product planning, configurations, deployment, maintenance, etc.).

- The indigenous manufacturers are required to establish and maintain procedure and records which demonstrate conformance to the requirements of QMS and submit an undertaking stating compliance with the requirements of QMS as specified in the Fifth Schedule of MDR-2017 as part of their application for grant of manufacturing license.

- In case of import, the overseas manufacturer shall ensure that their manufacturing facility complies with the QMS requirements and need to submit a notarized copy of QMS certificate issued by the National Regulatory Authority or the competent authority in their application for grant of Import license.

## 4.7 REGULATORY PATHWAY FOR MARKETING OF MEDICAL DEVICE SOFTWARE

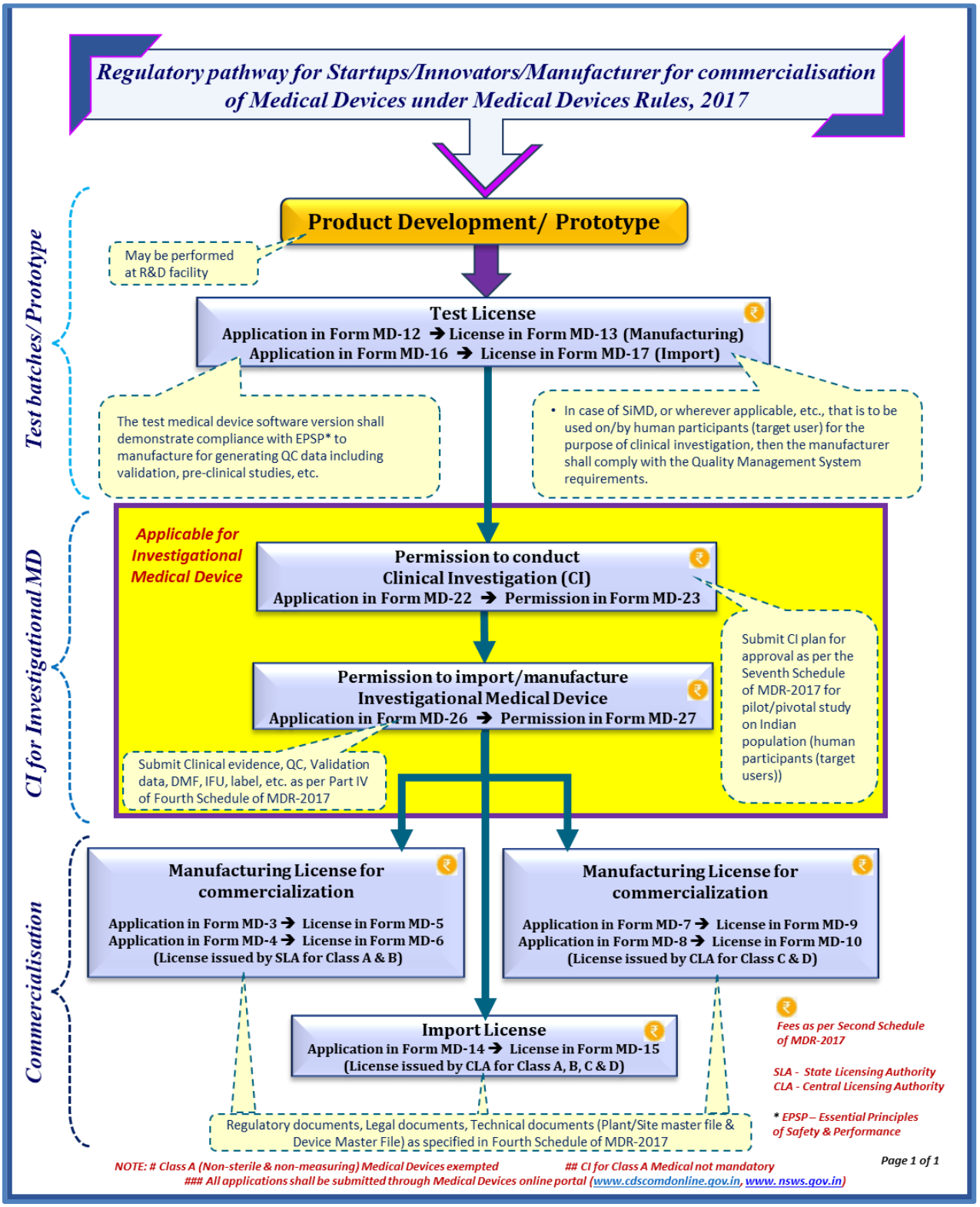


**Figure 1.** Flow chart illustrating the regulatory pathway to be followed for medical device software for marketing in the country.

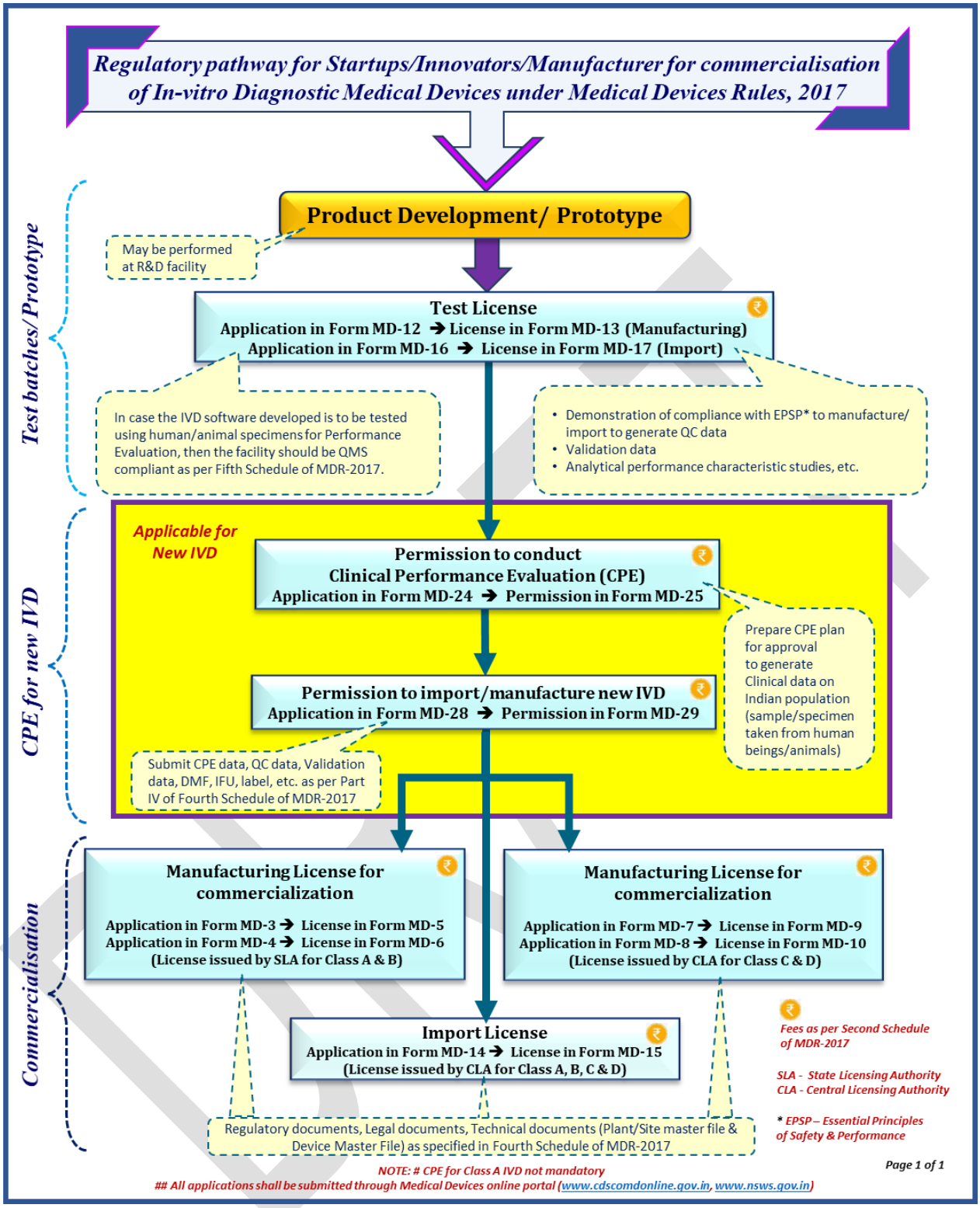


**Figure 2.** Flow chart illustrating the regulatory pathway to be followed for IVD medical device software for marketing in the country.

## 4.8 LICENSING AUTHORITIES FOR MEDICAL DEVICE SOFTWARE

- The Medical device software are required to be licenced for its manufacture or import for sale and marketing in the country by the LA as per the provisions prescribed under the MDR-2017.

**Table 3.** Licensing Authority for grant of license/ permission for medical devices in the country.

| Licenses/Permissions under MDR-2017 | Class A | Class B | Class C | Class D |
|---|---|---|---|---|
| **Test license** | CLA | CLA | CLA | CLA |
| **Manufacturing license** | SLA | SLA | CLA | CLA |
| **Import license** | CLA | CLA | CLA | CLA |
| **Clinical Investigation of MDs** | CLA | CLA | CLA | CLA |
| **Clinical Performance Evaluation of IVDs** | CLA | CLA | CLA | CLA |
| **Sale and distribution** | SLA | SLA | SLA | SLA |
| **MSC /NCC /FSC** | SLA | SLA | CLA | CLA |
| **Special Code/Neutral Code** | CLA | CLA | CLA | CLA |

**Abbreviations:** MD: Medical Device, CLA: Central Licensing Authority, SLA: State Licensing Authority, MSC: Market Standing Certificate, NCC: Non-conviction certificate, FSC: Free Sale Certificate.
**NOTE 1:** Class A (non-sterile and non-measuring) medical devices are exempted from the licensing requirements under MDR-2017, such medical device software shall be registered as per Chapter IIIb of MDR-2017 in the MD online portal.
**NOTE 2:** The time line required for processing various license applications is mentioned in the MDR-2017.

**NOTE:**

- *The applicant(s) may ensure whether the medical device software, for which application is to be submitted, is listed in the risk classification lists published by the CLA. If so, the same may be followed as risk classification for the applied devices.*
- *In case the medical device software has a similar intended use as the device mentioned in the published risk classification lists, they may follow the same risk classification for the applied medical device software.*
- *In case the medical device software is not listed in the published risk classification lists, they may seek clarification from the CLA regarding its*

*risk classification.*

- *In case the medical software falls in the category of an investigational medical device (IMD) or new IVD medical device, the applicant(s) may obtain prior permission of IMD/new IVD from the CLA under the MDR-2017.*
- *It may also be ensured that the medical device software that attract the definition of IMD or new IVD do not get approved for marketing in the country without prior permission from the CLA under the MDR-2017.*

## 4.9 DOCUMENTS REQUIRED FOR GRANT OF TEST LICENCE FOR THE PURPOSE OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING OF MEDICAL DEVICE SOFTWARE, NOT FOR COMMERCIALIZATION

- In order to obtain a Test licence (Form MD-13) to manufacture small quantities of medical device(s) for the purpose of Clinical Investigations or Test or Evaluation or Demonstration or Training, the applicant need to submit an online application in Form MD-12 in NSWS portal along with the requisite documents as per Rule 31 and fee as specified in the Second Schedule of MDR-2017.
- In order to obtain a Test licence (Form MD-17) to import small quantities of medical device(s) for the purpose of Clinical Investigations or Test or Evaluation or Demonstration or Training, the applicant need to submit an online application in Form MD-16 in NSWS portal along with the requisite documents as per Rule 40 and fee as specified in the Second Schedule of MDR-2017.
- The list of documents required for such applications is available in the NSWS portal.

**NOTE:**

*The applicant may mention number of installations/number of copies/ number of downloads of the medical device software as the quantity proposed for obtaining test license.*

## 4.10 CLINICAL INVESTIGATION OF INVESTIGATIONAL MEDICAL DEVICE SOFTWARE AND CLINICAL PERFORMANCE EVALUATION OF NEW IN VITRO DIAGNOSTICS MEDICAL DEVICE SOFTWARE

- No person or sponsor shall conduct any Clinical Investigation of an Investigational Medical device (IMD) or Clinical Performance Evaluation of new IVD on human participants or on any specimen derived from human body, respectively, except in accordance with the permission granted by the CLA as specified in MDR-2017.
- A Medical Device Software will be considered as an **"Investigational medical device"**, where the device:

  (i) does not have its predicate device, or

  (ii) is licensed and claims for new intended use or new population or new material or major design change, and is being assessed for safety or performance or effectiveness in a clinical investigation (**Section 4.1**).

- Clinical investigation is the systematic study of an investigational medical device in or on human participants to assess its safety performance or effectiveness.

- A Medical Device Software will be considered as a **"new in vitro diagnostic medical device"** where the device is used for *in vitro* diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required (**Section 4.1**).

- Clinical performance evaluation is the systematic performance study of a new IVD on a specimen collected from human participants to assess its performance (**Section 4.1**).

- In case the Medical Device software falls under the definition of an IMD or new IVD medical device, then permission to conduct Clinical investigation (Form MD-23) or Clinical Performance Evaluation (Form MD-25), respectively, is required to be obtained by the CLA by submitting an

application in the MD online portal with requisite documents (Refer Rule 51 and Rule 59) and fee as specified in the Second Schedule of MDR-2017.

- In case the clinical study data generated on Indian population is to be used for regulatory submission for obtaining manufacturing/import licence, then a permission to manufacture/import such Investigational medical device is required to be obtained from the CLA, by submitting an application (in Form MD-27) through the MD online portal with requisite documents (Refer Rule 63) and fee as specified in the Second Schedule of MDR-2017, prior to obtaining manufacturing/import licence for marketing in the country.

- In case the clinical performance evaluation data generated on Indian population is to be used for regulatory submission for obtaining manufacturing/import licence, then the applicant shall obtain permission to manufacture/import (Form MD-29) such new IVD is required to be obtained from the CLA, by submitting an application in the MD online portal with requisite documents (Refer Rule 64) and fee as specified in the Second Schedule of MDR-2017, prior to obtaining manufacturing/import licence for marketing in the country.

**NOTE:**

*For more details, please refer to Chapter VII and Chapter VIII of MDR-2017.*

## 4.11 DOCUMENTS REQUIRED FOR GRANT OF MANUFACTURING/IMPORT LICENCE FOR SALE OR FOR DISTRIBUTION OF MEDICAL DEVICE SOFTWARE

- The requisite document checklists (specific to the type of licence application) for Medical Device Software and IVD Medical Device Software are given in **Annexure A**.
- The applicants may refer to **Figure 1** and **Figure 2** for determining the corresponding Application Form (Legal form) number.
- In case, any of the documents specified in the checklist is deemed not applicable, then the applicant needs to submit the rationale/justification for the non-applicability of such document/requirement for Medical Device Software.
- Also, the applicant may refer the Tool Tips for information that needs to be filled in the Legal Form and also the technical documents that need to be uploaded as part of a checklist for review by the LA. The Tool Tips are published on the CDSCO website (www.cdsco.gov.in)

### 4.11.1 Guidance on the legal documentation applicable for medical device software

- For obtaining a licence to manufacture or import for sale and/or marketing of medical device software in the country, the applicant(s) shall submit an online application in MD online portal with the requisite fee, as specified in the Second Schedule along with respective documents as per the Fourth Schedule of MDR-2017.
- If any of the points in the Legal form is not applicable, then the applicant may mention “Not applicable” or “NA” (e.g, if shelf life is not applicable, it should be mentioned as “NA” in the Legal Form).
- The Site/Plant master file may outline the infrastructure and work environment (such as equipment, information, communication networks, tools, and the physical facility, etc.) used to support the development, production, and maintenance of the Medical Device Software. The said details need to be maintained and submitted as part of the Site/Plant Master File.
- In addition, the organization chart and personnel qualification details

of the organization is also required to be submitted.

- If any of the contents of the Site or Plant master file (as specified in Appendix I, Part III of Fourth Schedule of MDR-2017) is deemed not applicable, then the applicant(s) needs to submit the rationale/justification for the non-applicability of such requirement for Medical Device Software.
- The manufacturers shall furnish details on company/firm constitution along with a copy of the establishment/site ownership/tenancy agreement. These documents shall be duly notarized.
- In case of import, the applicant shall furnish a Power of Attorney (PoA) along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017. The PoA must be duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille.
- The importer(s) are also required to submit a copy of the Wholesale licence/Manufacturing licence/Registration Certificate in Form MD-42 among other requirements.
- The applicants are advised to go through the document checklists available on the CDSCO MD Online portal (also provided in **Annexure A**) for a complete list of legal documentation requirements.

### 4.11.2 Guidance on the technical documentation applicable for medical device software

**(A) Executive Summary – Device description, intended use, specifications including variants, etc.**

***Software/Firmware Description***

Software description, including overview of operationally significant software features, analyses, inputs and outputs is required to be added in the Device Master File (DMF).

a) Specify the name of the software

b) Specify the version of the software, provide a statement about software version naming (specify all fields and their meanings)

c) Provide a description of the software including the identification of the

device features that are controlled by the software, the programming language/compiler versions used, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process.

d) Intended User/operator of the software

*[Examples: patient (self-use), primary caregiver, primary care physicians, specialist physicians, radiologists, laypersons (non-clinical user), etc.]*

e) Intended patient population

*[Examples: general population, specific vulnerable groups (pediatrics, geriatrics), specific age group, specific ethnicity, etc.]*

f) Intended user environment, or the setting within which the software is intended to be used

*[Examples: non-clinical environment (home use, etc.), general health care (dental/general physician's clinics, primary care centers, etc.), specialty health care (emergency rooms, operation theaters, oncology departments, etc.)]*

g) Analysis methodology used (if any)

*[Examples: Rule-based calculations, online test administration, artificial intelligence (AI)/machine learning (ML), neural networks, fixed or adaptive algorithms]*

h) Role of software and its output within the health care intervention

i. Whether the software impacts/influences or replaces any otherwise manual or clinician performed actions?

   *[Examples: automated steps, triages patients, provides a definite diagnosis or suggests likely diagnosis for further confirmation by physician, performs or recommends treatment, identifies a region of interest for further review]*

ii. Contribution to the clinical decision

   *[Examples: intended as an aid to current practice, intended to replace all or a part of a current practice, etc.]*

iii. Whether the intended software output is dependent on other steps during the health care intervention

*[Examples: software that use output/clinical decisions from prior steps such as medical image overlays and reconstruction]*

i) Software inputs and outputs

i. Inputs and their format to the Medical Device Software

*[Examples: data, images (specify modality), measurements (specify units), sensor/attachments, report, questionnaire]*

ii. Source of the inputs.

*[Examples: user, other medical devices, other nonmedical devices or software.]*

iii. If the software is designed to be interoperable and transmit, exchange, and/or use information through an electronic interface with another medical/nonmedical product, system, or device – specify the methods, standards, and specifications used.

iv. Outputs and their formats: include test setup, acceptance criteria, and results

*[Examples: testing for accuracy and repeatability of output measurements, parametric analyses, model outputs, device generated segmentation contours, medical image enhancements]*

v. To whom are the outputs provided (output targets)?

*[Examples: patients, caregivers, healthcare professionals, technicians, researchers, health records, interoperable systems, medical devices, etc.]*

vi. Data or information flow of the software

*[Examples: inputs or outputs transmitted locally, via cloud storage, by disk drive, or wirelessly]*

vii. Whether the software interacts with any networked devices.

viii. Whether cloud or network storage is used.

ix. Degree of autonomy of software (i.e., whether its output impacts subsequent clinical action/decision without user intervention (autonomous), or requires a user supervision (supervised autonomy), or only intended as an aid for the user in clinical decision making (non-autonomous).

j) Software change management

i. Degree of learning, i.e., change autonomy

*[Examples: self-learning (autonomous updates effectuated and controlled from within the software, externally controlled changes (non-autonomous updates either effectuated by the user or the manufacturer)*

ii. Domain of learning or change implementation

*[Examples: international, national, regional, patient-specific, site-specific, etc.]*

iii. Infrastructure for installation, updates and error corrections

*[Examples: distribution channels such as app stores, web pages, web application, etc., and installation locations such as mobile phones, hardware medical devices, wearable devices, cloud, personal computers, etc.]*

**(B) Substantial equivalence with predicate medical device software**

- The applicant(s) shall submit a substantial equivalence evidence in tabular format between applied software and predicate software in respect to the intended use, risk class, applicable standards, design characteristics (*e.g., the type of algorithm/technology used to code the software (whether self-trainable, passive, machine-learning-based, procedural languages, etc.), platforms for operation, nature and type of output, target user of software output, training models used, if any, etc.*), manufacturing and testing process, performance, safety, effectiveness, and other characteristics (as applicable).

**(C) Essential Principles of safety and performance**

- The applicant shall refer to the Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the Medical Device, published on the CDSCO website.
- While demonstrating the conformance to the essential principles, the manufacturer shall ensure the following for Medical Devices Software:

a) The software should be developed, manufactured and maintained in accordance with the state of the art taking into account the principles of development life cycle (e.g., rapid development cycles, frequent changes, the cumulative effect of changes), risk management (e.g., changes to system, environment, and data), including information security (e.g., safely implement updates), verification and validation (e.g., change management process).

b) Software that is intended to be used in combination with mobile computing platforms should be designed and developed taking into account the platform itself (e.g. size and contrast ratio of the screen, connectivity, memory, etc.) and the external factors related to their use (varying environment as regards level of light or noise).

c) Manufacturers should set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.

**(D) Risk management**

The Medical Device Software are associated with some unique challenges that are generally not evident for other medical devices, which are summarized below:

a) Direct benefit and risks for patients are not always present.
b) Deployed on a multitude of technology/hardware platforms.
c) Interconnected to other systems and datasets.
d) Rapid development cycles and frequent changes.
e) Often an update made available by the manufacturer is left to the user of the medical device software to install.

f) Deployment at scale and at pace, outside control of manufacturer.
g) Information security with respect to safety considerations (e.g., Cyber security, preservation of patient confidentiality and privacy, integrity and availability of information). Local legislation and regulations on data protection and privacy should be complied with.
h) Computer-human interaction.

Considering this, the manufacturers/importers need to consider and comply with the following:

- Applicable standards such as IS/ISO 14971, IS/ISO 62304, etc. need to be followed and complied to.
- The risk management plan/protocol should be devised and the Risk Management Report generated by the manufacturer as per the IS/ISO 14971 (and other applicable standards) shall be submitted as part of the license application.
- The manufacturer/importer is required to consider and ensure implementation of surveillance/monitoring mechanisms for the risks associated with Medical device software, in relation to injury or damage to the health of people and reduction of effectiveness, wherein “reduction of effectiveness” can result from inadequate, incorrect, or absent data supplied to a human or product at an inappropriate time, rate, or with an inadequate method.
- The manufacturers/importers are required to consider and ensure implementation of surveillance/monitoring mechanisms for indirect harms associated with Medical Device Software (e.g., introduction of unintended bias in clinical decision-making because of a Medical Device Software output may be considered as an indirect harm to the patient).
- The risk management process should be integrated across the entire lifecycle of the Medical Device Software.
- Software change management should be ensured and properly documented as part of the risk management plan by the manufacturer/importer.
- Details on periodic updation of the Medical Device Software and corrections/changes associated with risks should be added in the risk management plan.

- In this regard, an Algorithm Change Protocol (ACP) may be devised, which shall include an overview of all the procedures to be followed so that any changes/modifications made in the Medical Device Software do not compromise its safety and intended use. The ACP may contain the following information:

  a) A data management plan that includes a data management protocol, risk assessment plan, new data collection protocols, and quality assurance process.
  b) A performance evaluation and monitoring plan, describing assessment metrics, a statistical analysis plan, assessment frequency, performance targets, and post market monitoring overview.
  c) An algorithm retraining plan (if applicable) to described retraining objectives, methods that will be employed to improve algorithm performance, the approach to performance evaluation, and potential impacts to intended purpose.
  d) A software update plan, describing version tracking, verification and validation methods, update triggers, update procedures, and approaches to transparently communicating updates to end users.
  e) A rollback plan, describing triggers, backup and recovery procedures, and communication to users.

- Risks associated with process validation and benchmarking should be carefully documented and assessed – including the decisions for selecting specific datasets, reference standards, parameters and metrics to justify such validation processes.

  *[For example, in case of AI-based SaMD, careful consideration needs to be given to documenting how and why specific data or datasets are selected to train, externally validate and retrain the model (e.g. post-deployment retraining).]*

**(E) Device Design**

***System and Software Architecture Design/Diagram:***

- Detailed depiction of functional units and software modules may include

state diagrams as well as flow charts to present a roadmap of the device design to facilitate a clear understanding of:

a) The modules and layers that make up the system and software.

b) The relationships among the modules and layers.

c) How users or external products, including IT infrastructure and peripherals (e.g. wirelessly connected medical devices) interact with the system and software.

d) How users or external products, including IT infrastructure and peripherals (e.g., wirelessly connected medical devices) interact with the system and software.

*[Example: A module could represent – a finished hardware device within a system of hardware and software products, a hardware component within a finished hardware device, a finished software product within a system of software products, or a software function within a finished software product. A module is not specifically meant to describe code-level software functions.]*

***Software Requirement Specifications:***

- The software requirement specifications (SRS) document the requirements of the software. This typically includes functional performance, interface design, developmental, and other requirements for the software. In effect, this document describes what the Medical Device Software is supposed to do.

*[Example: Hardware requirements, programming language requirements, interface requirements, performance and functional requirements]*

***Software Design Specifications:***

- The software design specifications (SDS) describe the implementation of the requirements for the Medical Software Device. The SDS describes how the requirements in the SRS are implemented.

**(F) Software versioning and traceability**

- The applicant(s) shall ensure traceability of the Medical Device Software – this is essential for identification (e.g. software version) for the post-market traceability/ follow-up (track and trace) of the software to the users (e.g. physicians or patients) in the event of a Field Safety Corrective Action (FSCA) or product defect in post market phase.

- A detailed procedure/plan should be devised for post-market surveillance (PMS) and response. The manufacturer/importer needs to ensure that they have the ability to handle product recalls and implement corrective actions (e.g. bug fixes, cyber alerts, software patches) in a timely and effective manner (Planning, conducting and reporting of corrective action), and to identify any recurring problems requiring attention.

- Description of software versioning and traceability system implemented for the software may be included in the Device Master File.

**(G) Software verification and validation**

The Device Master File should contain information on:

- The software design and development process.
- Evidence of the validation of the software, as used in the finished device.
- Summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.
- For Medical Device Software that work together or in conjunction with other medical devices or systems, issues relating to the interoperability have to be carefully considered and addressed as appropriate.
- Implemented cyber security risk control methods that should be verified and validated against specified design requirements or specifications prior to implementation.

**(H) Clinical Evidence**

- Medical Device Software may function in a way that instead of yielding a direct clinical output, they provide indirect clinical benefits to the subject such as:

  a) Improving quality and consistency of care
  b) Enhancing human abilities and mental health support
  c) Removing administration burden
  d) Timely care, informed decision
  e) Earlier diagnosis and prevention
  f) Reducing cognitive errors
  g) Reducing burden of diagnostic and treatment activities for a patient

- The applicant(s) shall ensure the determination of the valid clinical association/scientific validity of a Medical Device software, demonstrating that it corresponds to the clinical situation, condition, indication or parameter defined in its intended purpose.
- Types of data to support valid clinical association/scientific validity may include:

  a) Technical Standards, Literature searches
  b) Professional medical society guidelines
  c) Systematic scientific literature review
  d) Clinical Investigation/Clinical performance studies
  e) Published Clinical data
  f) Secondary data analysis

- Validation of technical performance/analytical performance – to demonstrate the ability of a Medical Device Software to accurately, reliably and precisely generate the intended output, from the input data. Evidence supporting Technical Performance/Analytical Performance should be generated through verification and validation activities.
- Validation of the Clinical Performance is the demonstration of the ability of a Medical Device Software to yield clinically relevant output in accordance with the intended purpose.
- Details of the Clinical Investigation/Clinical Performance evaluation

(including study outcomes) of Medical Device Software may be submitted as part of the Device Master File, if applicable.

**(I) Software Labelling**

- The Device Master File should typically contain a complete set of labelling information associated with the device as per the requirements of Chapter VI of MDR-2017.
- Generally, device labelling information includes the following:

  a) Copy of original label of the device, including accessories if any, and its packaging configuration;
  b) Instructions for use (Prescriber's/User manual);
  c) Product brochure; and
  d) Promotional material.
  e) Whether standalone or intended to be used with a specific medical device, especially when it influences/controls another medical device's programming or function.

- The Medical Device Software should be identified with an identifier, such as version, revision level and date of build release/issue.
- Software can be supplied in different forms and there may be difficulties in presenting device information for certain forms (e.g. web-based software). Generally, software can be broadly categorised into two groups based on the mode of supply:

  a) supplied in physical form, or
  b) supplied without a physical form

- If the software is delivered on a physical medium, e.g. CD or DVD, each packaging level shall bear particulars printed in indelible ink on the label, as specified in Chapter VI of MDR-2017.
- For Medical Device Software without a physical form or packaging, the instructions for use may be available electronically. In this situation, as a good practice, the device may incorporate a means for the user to easily access the electronic label via the software itself or via inclusion of a web address or other means.

- The developer may display the regulatory requirement (Please refer Chapter VI, MDR-2017) on the primary landing page and as a screen shot in any app store.
- A screenshot of the software graphical interface (e.g., splash screen) which displays the elements for identification, including software version number, may be submitted as a part of Device Master File.
- For downloadable software where the downloading and installation is to be done by the end-user, it may be ensured that the user is provided with sufficient information (e.g., Internet address/weblink to download the software, software installation guide or procedure, etc.) for proper installation of such downloadable software.
- An appropriate system for version controls and access rights controls should be in place to allow timely tracing of the software versions.
- Software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the label information through an Application Programming Interface (API).

## 4.12 POST MARKETING REGULATORY REQUIREMENTS

### 4.12.1 Fulfillment of conditions of license/permissions

- The applicant(s) is(are) required to comply with the conditions of the licence/permission as prescribed in the MDR-2017 with respect to the post marketing requirements for medical devices.
- In case any special (additional) conditions are imposed by the Licensing Authority at the time of approval of the licence/permission, then the applicant(s) shall submit a condition fulfilment application through the MD Online portal accompanied with supporting documents within the time period specified by the Licensing Authority.

### 4.12.2 Post approval change notification

- Changes to a Medical Device Software refer to any modifications made throughout its lifecycle, including the maintenance phase.
- Medical Device Software may undergo a number of changes throughout its product life cycle.

- The changes are typically meant to:
  a) Correct faults,
  b) Improve the software functionality and performance to meet customer demands,
  c) Keep a software product usable in a changed or changing environment.
  d) Ensure safety and effectiveness of the device is not compromised (e.g. security patch).
- Due to the non-physical nature of software, a software change management process needs specific considerations to achieve the intended result regarding traceability and documentation.
- Major changes and minor changes to medical devices are specified in the Sixth Schedule of MDR-2017.
- Subject to the provisions laid out in the Sixth Schedule of the MDR-2017, changes in respect of following shall be considered as major change in respect of Medical Device Software:
  a) Design characteristics which shall affect quality in respect of its specifications, indication for use, and performance;
  b) the intended use or indication for use;
  c) the name and address of, -
     i. the domestic manufacturer or its manufacturing site;
     ii. overseas manufacturer or its manufacturing site (for import only);
     iii. authorized agent (for import only).
  d) Label excluding change in font size, font type, colour, label design.
  e) Manufacturing process, equipment or testing which shall affect quality of the device
- Subject to the provisions laid out in the Sixth Schedule of the MDR-2017, changes in respect of following shall be considered as minor change in respect of Medical Device Software:
  a) Design which shall not affect quality in respect of its specifications, indications for use, performance and stability of the medical device.
  b) in the manufacturing process, equipment, or testing which shall not

affect quality of the device.

c) Revisions for bug fixes and security patches, etc., which does not affect intended use, safety and performance of the medical device software.

- In case of change in constitution of the firm, which is considered as a major change, the same shall be notified to the LA as per the stipulated timeline specified under the MDR-2017 and the applicant shall submit a fresh application along with the requisite documents to obtain a new licence for marketing of Medical Device Software in the country under the MDR-2017.
- The licence holder shall submit a Post Approval Change (PAC) notification/request through the MD Online portal to the Central Licensing Authority or the State Licensing Authority, as the case may be, for any major/minor changes (including those mentioned above) to Medical Device Software, as specified above.

**NOTE**:

*If the Medical Device Software has been updated such that it significantly changes the indications for use and/or the intended use of the Medical Device Software (and subsequently its risk class), then the applicant shall need to apply for a fresh licence for the same.*

### 4.12.3 Post marketing surveillance (PMS)

Once the Medical Device Software is in the market, the manufacturer/importer shall maintain vigilance for any direct/indirect harm to the user/patient(s), reduction in effectiveness, and any vulnerability to intentional and unintentional security threats as part of PMS. Manufacturers/importers should maintain documented procedure for PMS and consider the following as part of their PMS:

- Corrections and corrective actions may be required when a process is not correctly followed or the Medical Device Software does not meet its specified requirements (i.e., when a nonconforming process or product exists).
- Non-conforming Medical Device Software should be contained to prevent unintended use or delivery. The detected nonconformity should be analyzed and actions taken to eliminate the detected nonconformity (i.e., correction); and to identify and eliminate the cause(s) of the detected nonconformity (i.e., corrective action) to prevent recurrence of the detected nonconformity in the future. In some cases, a potential nonconformity may be identified, and actions such as safeguards and process changes can be taken, to prevent nonconformities from occurring (i.e., preventive action).
- Nonconformities in a Medical Device Software may lead to inaccurate or incorrect test results, mixing up of patient results, failure to deliver therapy, calibration errors resulting in incorrect patient positioning during therapy, incorrect image display, calculation errors, software bugs leading to malfunction, etc.
- A Field Safety Corrective Action (FSCA) may be initiated when the manufacturer/importer becomes aware of such nonconformities/certain risks associated with use of the Medical Device Software through post-market monitoring and surveillance, such as through tracking of product complaints/feedback.
- Adverse events (AE) for Medical Device Software may arise due to:
  a) Shortcomings in the design of the software
  b) Inadequate verification and validation of the software code

c) Inadequate instructions for use

d) Software bugs introduced during implementation of new features

- The license holder shall inform the SLA or the CLA, as the case may be, of the occurrence of any suspected unexpected serious adverse event (SUSAR) and action taken thereon including any product recall within 15 days of such event coming to the notice of the license holder.
- The importer shall inform the Licensing Authority, within a period of 15 days of any administrative action taken on account of any adverse reaction, such as market withdrawal, regulatory restrictions, cancellation of authorization or declaration of the medical device as not of standard quality by the regulatory authority of the country of origin or by any regulatory authority of any other country, where the medical device is marketed, sold or distributed.
- The manufacturer/importer shall immediately inform SLA or CLA, as the case may be, if there are reasons to believe that a Medical Device Software which has been placed in the market, may be unsafe for the patients, wherein unsafe in terms of Medical Device Software refers to erroneous results leading to negative impact (whether direct or indirect) on patient health or/and introduction of bias in clinical decision-making to the extent that it may negatively impact the health of user.

  *[Examples: malfunction of an implanted pulse generator because of erroneous control/influence by the respective software; erroneous calculations in radiation therapy planning leading to exposure to incorrect radiation intensities, etc.]*.
- The manufacturer/importer shall ensure availability of sufficient infrastructure/mechanisms and resources for receiving continuous customer/user feedback for the Medical Device Software in terms of its performance, safety and efficacy.
- The manufacturer/importer may recall a Medical Device Software from the market, subject to the conditions laid down in the MDR-2017, wherein product recall in the case of Medical Device Software may refer to a complete or partial halt in distribution of the medical device software from some or all channels/domains, uninstalling/decommissioning the Medical Device Software from some

or all available networks and hardware devices.

- Medical Device Software that are approved for marketing after clinical investigation(s) (such as medical devices that do not have a predicate device), shall be closely monitored for their clinical safety once they are marketed. The manufacturer/importer(s) shall furnish Periodic Safety Update Reports (PSURs) as per the conditions laid out in the MDR-2017, in order to —
  a) Report all the relevant new information from appropriate sources;
  b) Relate these data to patient exposure;
  c) Summarize the market authorization status in different countries, if applicable, and any significant variations related to safety; and
  d) Indicate whether changes will be made to product information in order to optimize the use of the product.

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# Annexure A: Document Checklists

**(A)** Checklist for the grant of manufacturing license for Class A (other than Class A (non-sterile and non-measuring) medical devices) Medical Devices under Medical Devices Rules, 2017

| **Form Type:** | **Fresh (Form MD-3/MD-4) common checklist** | |
|---|---|---|
| **Section no.** | **Checklist Name** | **Applicability** |
| 1.0 | Covering Letter | Applicable |
| 2.0 | Application (Form MD-3/MD-4) | Applicable |
| 3.0 | Fee Challan | Applicable |
| 4.0 | Details of the constitution of the firm along with the relevant documents | Applicable |
| 5.0 | The Establishment /Site ownership/Tenancy Agreement | Applicable |
| **6.0** | **Plant Master file as per Appendix I of Fourth Schedule of MDR, 2017** | |
| 6.1 | General Information of the facility | Applicable |
| 6.2 | Personnel- Organisation chart | Applicable |
| 6.3 | Personnel -Qualification, Experience and responsibilities | Applicable |
| 6.4 | Premises and Facilities | Applicable |
| 6.5 | Plant Layout of premise with indication of scale | Applicable |
| 6.6 | List of equipment and instruments used for manufacturing and testing | Applicable |
| 6.7 | Sanitation | May not be applicable |
| 6.8 | Production | Applicable |
| 6.9 | Quality Assurance | Applicable |
| 6.10 | Storage | Applicable |
| 6.11 | Documentation | Applicable |
| **7** | **Quality Management System Requirements** | |
| 7.1 | Undertaking from the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017 | Applicable |
| 7.2 | Quality Manual | Applicable |
| 7.3 | Control of Documents | Applicable |
| 7.4 | Control of Records | Applicable |
| 7.5 | Management Responsibility | Applicable |
| 7.6 | Resource management | Applicable |
| 7.7 | Control of production and service provision | Applicable |
| 7.8 | Internal Audit System | Applicable |
| 7.9 | Control of non-conforming product | Applicable |
| 7.10 | Corrective Action and Preventive Action | Applicable |

| | | |
|---|---|---|
| 7.11 | Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of MDR, 2017. | Applicable |
| **8.0** | Copy of Type approval obtained from AERB in case of radiation emitting devices | May not be applicable |
| **9.0** | Copy of approval obtained from DAHD in case of devices intended for veterinary use | Applicable |
| **10.0** | Any other additional documents (if any) | Applicable |
| **11.0** | Test License obtained in Form MD-13 for the applied devices (if any) | Applicable |
| **12.0** | Copy of Permission in Form MD-27 (in case of Medical device which does not have Predicate medical device) | Applicable |
| 13.0 | Device description including Intended use of the device, Material of construction (if applicable), Working principle, specification including variants and accessories etc., | Applicable |
| 14.0 | Labelling information (Labels, Instruction for Use, etc.) | Applicable |
| 15.0 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the applied device Medical Device | Applicable |

**(B)** Checklist for the grant of manufacturing licence for Class B Medical Devices under Medical Devices Rules, 2017

| **Form Type:** | **Fresh (Form MD-3/MD-4) common checklist** | |
|---|---|---|
| **Section no.** | **Checklist Name** | **Applicability** |
| 1.0 | Covering Letter | Applicable |
| 2.0 | Application (Form MD-3/MD-4) | Applicable |
| 3.0 | Fee Challan | Applicable |
| 4.0 | Details of the constitution of the firm along with the relevant documents | Applicable |
| 5.0 | The Establishment /Site ownership/Tenancy Agreement | Applicable |
| **6.0** | **Plant Master file as per Appendix I of Fourth Schedule of MDR, 2017** | |
| 6.1 | General Information of the facility | Applicable |
| 6.2 | Personnel- Organisation chart | Applicable |
| 6.3 | Personnel -Qualification, Experience and responsibilities | Applicable |
| 6.4 | Premises and Facilities | Applicable |
| 6.5 | Plant Layout of premise with indication of scale | Applicable |
| 6.6 | List of equipment and instruments used for manufacturing and testing | Applicable |
| 6.7 | Sanitation | May not be applicable |
| 6.8 | Production | Applicable |
| 6.9 | Quality Assurance | Applicable |
| 6.10 | Storage | Applicable |
| 6.11 | Documentation | Applicable |
| **7** | **Quality Management System Requirements** | |
| 7.1 | Undertaking from the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017 | Applicable |
| 7.2 | Quality Manual | Applicable |
| 7.3 | Control of Documents | Applicable |
| 7.4 | Control of Records | Applicable |
| 7.5 | Management Responsibility | Applicable |
| 7.6 | Resource management | Applicable |
| 7.7 | Control of production and service provision | Applicable |
| 7.8 | Internal Audit System | Applicable |
| 7.9 | Control of non-conforming product | Applicable |
| 7.10 | Corrective Action and Preventive Action | Applicable |
| 7.11 | Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of MDR, 2017. | Applicable |
| **8.0** | Copy of Type approval obtained from AERB in case of radiation emitting devices | May not be applicable |
| **9.0** | Copy of approval obtained from DAHD in case of devices intended for veterinary use | Applicable |

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|---|---|---|
| **10.0** | Any other additional documents (if any) | Applicable |
| **11.0** | Test License obtained in Form MD-13 for the applied devices (if any) | Applicable |
| **12.0** | Copy of Permission in Form MD-27 (in case of Medical device which does not have Predicate medical device) | Applicable |
| **13.0** | **Device Master file in the line of Appendix II of Forth Schedule of Medical Devices Rules, 2017** | |
| 13.1 | Executive Summary | Applicable |
| 13.2 | Descriptive information of the device | Applicable |
| 13.3 | Justification for the Medical Device Grouping | Applicable |
| 13.4 | Product Specification, including variants and accessories | Applicable |
| 13.5 | Substantial equivalence with reference to the predicate device or previous generations of the device | Applicable |
| 13.6 | Labelling information (Labels, Instruction for Use, etc) | Applicable |
| 13.7 | Device Design and Manufacturing Information | Applicable |
| 13.8 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device | Applicable |
| 13.9 | Risk analysis and control summary | Applicable |
| 13.10 | Verification and validation of the medical device | Applicable |
| 13.11 | Biocompatibility validation data (if applicable) | May not be applicable |
| 13.12 | Medicinal substances data (if device contains Drug) | May not be applicable |
| 13.13 | Biological Safety (if applicable) | May not be applicable |
| 13.14 | Sterilization Validation data (if applicable) | May not be applicable |
| 13.15 | Software verification and validation (if software used) | Applicable |
| 13.16 | Animal studies – Preclinical data (if any) | May not be applicable |
| 13.17 | Stability study data (Real-time and Accelerated conditions) | May not be applicable |
| 13.18 | Clinical evidence (if any) | Applicable |
| 13.19 | Post Marketing Surveillance data (Vigilance reporting) duly authenticated by the manufacturer | Applicable |
| 13.20 | Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate | Applicable |

**(C)** Checklist for the grant of manufacturing license for Class C and Class D Medical Devices under Medical Devices Rules, 2017

| **Form Type:** | **Fresh (Form MD-7/MD-8) Class C and D MDs** | |
|---|---|---|
| **Section No.** | **Checklist Name** | **Applicability** |
| 1.0 | Covering Letter | Applicable |
| 2.0 | Application (Form MD-7/MD-8) | Applicable |
| 3.0 | Fee Challan | Applicable |
| 4.0 | Details of the constitution of the firm along with the relevant documents | Applicable |
| 5.0 | The Establishment /Site ownership /Tenancy Agreement | Applicable |
| **6.0** | **Plant Master file as per Appendix I of Fourth Schedule of MDR, 2017** | |
| 6.1 | General Information of the facility | Applicable |
| 6.2 | Personnel- Organisation chart | Applicable |
| 6.3 | Personnel -Qualification, Experience and responsibilities | Applicable |
| 6.4 | Premises and Facilities | Applicable |
| 6.5 | Plant Layout of premise with indication of scale | Applicable |
| 6.6 | List of equipment and instruments used for manufacturing and testing | Applicable |
| 6.7 | Sanitation | May not be applicable |
| 6.8 | Production | Applicable |
| 6.9 | Quality Assurance | Applicable |
| 6.10. | Storage | Applicable |
| 6.11 | Documentation | Applicable |
| **7.0** | **Quality Management System Requirements** | |
| 7.1 | Undertaking from the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017 | Applicable |
| 7.2 | Quality Manual | Applicable |
| 7.3 | Control of Documents | Applicable |
| 7.4 | Control of Records | Applicable |
| 7.5 | Management Responsibility | Applicable |
| 7.6 | Resource management | Applicable |
| 7.7 | Control of production and service provision | Applicable |
| 7.8 | Internal Audit System | Applicable |
| 7.9 | Control of nonconforming product | Applicable |
| 7.10 | Corrective Action and Preventive Action | Applicable |
| 7.11 | Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of MDR, 2017. | May not be applicable for SaMD |
| **8.0** | **Device Master file in the line of Appendix II of Fourth Schedule of MDR, 2017** | |

| | | |
|---|---|---|
| 8.1 | Executive Summary | Applicable |
| 8.2 | Descriptive information of the device | Applicable |
| 8.3 | Justification for the Medical Device Grouping | Applicable |
| 8.4 | Product Specification, including variants and accessories | Applicable |
| 8.5 | Substantial equivalence with reference to the predicate device or previous generations of the device | Applicable |
| 8.6 | Labelling information (Labels, Instruction for Use, etc) | Applicable |
| 8.7 | Device Design and Manufacturing Information | Applicable |
| 8.8 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device | Applicable |
| 8.9 | Risk analysis and control summary | Applicable |
| 8.1 | Verification and validation of the medical device | Applicable |
| 8.11 | Biocompatibility validation data (if applicable) | May not be applicable |
| 8.12 | Medicinal substances data (if device contains Drug) | May not be applicable |
| 8.13 | Biological Safety (if applicable) | May not be applicable |
| 8.14 | Sterilization Validation data (if applicable) | May not be applicable |
| 8.15 | Software verification and validation (if software used) | Applicable |
| 8.16 | Animal studies – Preclinical data (if any) | May not be applicable |
| 8.17 | Stability study data (Real-time and Accelerated conditions) | May not be applicable |
| 8.18 | Clinical evidence (if any) | Applicable |
| 8.19 | Post Marketing Surveillance data (Vigilance reporting) | Applicable |
| 8.20 | Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate | Applicable |
| 9.0 | Copy of Type approval obtained from AERB in case of radiation emitting devices | May not be applicable |
| 10.0 | Copy of approval obtained from DAHD in case of devices intended for veterinary use | Applicable |
| 11.0 | Any other additional documents (if any) | Applicable |
| 12.0 | Test License obtained in Form MD-13 for the applied devices (if any) | Applicable |
| 13.0 | Copy of Permission in Form MD-27 (in case of Medical device which does not have Predicate medical device) | Applicable |

**(D)** Checklist for the grant of Import license for Medical Device Software under Medical Devices Rules, 2017

| **Form Type:** | **Fresh application in Form MD-14** | |
|---|---|---|
| **Section no.** | **Checklist Name** | **Applicability** |
| 1 | Covering Letter | Applicable |
| 2 | Application (Form MD-14) | Applicable |
| 3 | Fee Challan | Applicable |
| 4 | Power of Attorney along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille) | Applicable |
| 5 | Copy of Whole Sale licence / Manufacturing licence/ Registration Certificate in Form MD-42 of the Authorized agent | Applicable |
| 6 | Constitution details of the authorized agent | Applicable |
| **7** | **Regulatory Certificate** | |
| 7.1 | Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any) (duly notarized) | Applicable |
| 7.2 | Copy of Free Sale Certificate Marketing Authorization of the product issued from National Regulatory Authority of any of the following countries viz., USA, UK, EU, Canada, Japan or Australia (duly notarized) | Applicable |
| 7.3 | Copy of overseas manufacturing site / establishment / plant registration, by whatever name called, in the country of origin issued by the competent authority (duly notarized) | Applicable |
| 7.4 | Copy of latest inspection or audit report carried out by the Competent Authority within last 3 years, if any. | Applicable |
| **8** | **Quality Certificate in respect of the actual manufacturing site, as applicable** | |
| 8.1 | Copy of Certificate supporting Quality Management System (duly notarized) | Applicable |
| 8.2 | Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality assurance certificate, CE design Certificate, etc. as applicable (duly notarized) | Applicable |
| 8.3 | Declaration of conformity issued by the manufacturer | Applicable |
| **9** | Plant Master file from the Manufacturer as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017 | Applicable |
| **10** | **Device Master file from the Manufacturer as per Appendix II of Fourth Schedule of Medical Devices Rules, 2017** | |
| 10.1 | Executive Summary | Applicable |
| 10.2 | Descriptive information of the device | Applicable |

| | | |
|---|---|---|
| 10.3 | Justification for the Medical Device Grouping | Applicable |
| 10.4 | Product Specification, including variants, accessories, etc. | Applicable |
| 10.5 | Substantial equivalence with reference to the predicate device or previous generations of the device | Applicable |
| 10.6 | Labelling information (Labels, Instruction for Use, etc.) | Applicable |
| 10.7 | Device Design and Manufacturing Information | Applicable |
| 10.8 | Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device | Applicable |
| 10.9 | Risk analysis and control summary | Applicable |
| 10.1 | Verification and validation of the medical device | Applicable |
| 10.11 | Biocompatibility validation data (if applicable) | May not be applicable |
| 10.12 | Medicinal substances data (if device contains Drug) | May not be applicable |
| 10.13 | Biological Safety (TSE/BSE), if applicable | May not be applicable |
| 10.14 | Sterilization Validation data (if applicable) | May not be applicable |
| 10.15 | Software verification and validation (if software used) | Applicable |
| 10.16 | Animal studies – Preclinical data (if any) | May not be applicable |
| 10.17 | Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable) | May not be applicable |
| 10.18 | Clinical evidence (if any) | Applicable |
| 10.19 | Post Marketing Surveillance data (Vigilance reporting) | Applicable |
| 10.20 | Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate | Applicable |
| **11** | Any other additional documents | Applicable |
| **12** | Copy of Permission in Form MD-27 (in case of Investigational Medical Device ) | Applicable |

**Note:**

1. In case of loan licence, the applicant may submit only the applicable relevant information along with the proper justification for non-submission of particular documents.

2. In case of Class A (non-sterile and non-measuring) medical devices, the applicant may obtain the registration number from the CDSCO MD Online portal to fulfil the regulatory requirements for marketing in the country.