

Section 3B



**QCI - AIMED Voluntary Initiative on
Medical Devices**

**Indian Certification of Medical Devices
(ICMED) Scheme**

**Certification Criteria for
ICMED 13485**

Certification Criteria for ICMED 13485

1. Scope

1.1 Scope of Document

This document specifies the requirements for a quality management system for medical device industry which-

- a. needs to demonstrate its ability to consistently provide medical devices /IVD that meets customer and applicable statutory and regulatory requirements, and
- b. aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer well within applicable statutory and regulatory requirements.

1.2 Relationship with other references

The requirements prescribed in this document shall be read with the requirements prescribed in ICMED 2015; ISO13485: 2016 and INDIAN MDR 2017.

1.3 Application

All requirements of this ICMED Standard are generic to organizations providing medical devices / In vitro diagnostics (IVD) regardless of the type or size of the organization. Wherever requirements are specified as applying to medical devices / IVD, the requirements apply equally to associated services as supplied by the organization or being requested by customer within the scope.

This standard specifies requirements for a quality management system (QMS) that shall be used by the manufacturer for Design and Development, packaging, labelling, testing, installation and servicing of medical devices and IVD medical devices. If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the QMS. These regulations can provide alternative arrangements that are to be addressed in the QMS. It is the responsibility of the organization to ensure that claims of conformity with this ICMED Standard reflect exclusion of design and development controls.

If any requirement(s) of this ICMED Standard is (are) not applicable due to the nature of the medical device(s)/IVD for which the QMS is applied, the organization does not need to include such a requirement(s) in its QMS and appropriate justification shall be recorded. The processes required by this Standard, which are applicable to the medical device(s) / IVD, but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's QMS by monitoring, maintaining and controlling the processes.

It is emphasized that the QMS requirements specified are in addition to complementary to technical requirements for products (INDIAN MDR 2017)

Manufacturers of components or parts of finished devices and IVD medical devices are encouraged to use appropriate provisions of the schedule of INDIAN MDR 2017 as guidance.

The provisions of the Standard along with INDIAN MDR 2017 shall be applicable to manufacturers of finished devices IVD medical devices, mechanical contraceptives (condoms, intrauterine devices, tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags with or without anticoagulants (INDIAN MDR 2017)

2. Normative References:

The following referenced documents are indispensable for the application of this document.

- a. ISO 9000 – 2015 *Quality management systems-Fundamentals and vocabulary*
- b. ISO 13485:2016 *Medical devices–Quality management systems*
- c. MDR – 2017 *Medical Devices requirements for regulatory purposes*

3. Terms and Definitions:

For the purposes of this document, the terms and definitions given in ISO 9000 -2015 and ISO 3485 2016 and INDIAN MDR 2017 shall apply.

Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the manufacturing facility.

3.1 Active diagnostic medical device

means any active medical device used, whether alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity (INDIAN MDR 2017)

3.2 Act

means the Drugs and Cosmetics Act, 1940 (23 of 1940) (INDIAN MDR 2017)

3.3 Active implantable medical device

Active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure (INDIAN MDR 2017)

3.4 Active medical device

medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity. (ISO 13485 2016)

3.5 Active therapeutic medical device

means any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap

3.6 Advisory notice

Notice issued by the manufacturer, subsequent to delivery of the medical device and IVD, to provide supplementary information or to advise what action should be taken in or both in:

- a. the use of a medical device, IVD medical devices;
- b. the modification of a medical device and IVD medical devices;
- c. the return of the medical device and IVD medical devices to the organization that supplied it; or
- d. the destruction of a medical device and IVD medical devices (INDIAN MDR 2017)

3.7 Authorized agent

means a person including any firm or organization who has been appointed by an overseas manufacturer through a power of attorney to undertake import of medical device in India (INDIAN MDR 2017).

3.8 Authorized representative

natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation (ISO 13485 2016)

3.9 Body orifice

means any natural opening in a human body including the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy

3.10 Clinical evaluation

assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer (ISO 13485 2016)

3.11 Clinical evidence

means, in relation to -

- i. an IVD 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 (INDIAN MDR 2017)

3.12 Clinical investigation

means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness (INDIAN MDR 2017)

3.13 Clinical investigation plan

means a document which contains the information about the rationale, aims and objective, design and the proposed analysis, conduct, methodology including performance, management, adverse event, withdrawal and statistical consideration and record keeping pertaining to clinical investigation (INDIAN MDR 2017)

3.14 Clinical performance evaluation

means the systematic performance study of a new *IVD* medical device on a specimen collected from human participants to assess its performance (INDIAN MDR 2017)

3.15 Clinical research organization

means any entity to whom a sponsor may transfer or delegate one or more of its functions and duties regarding conduct of clinical investigation or clinical performance evaluation (INDIAN MDR 2017)

3.16 Complaint

written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device / *IVD* that has been released from the organization's control or related to a service that affects the performance of such medical devices / *IVD*. (ISO 13485 2016)

3.17 Custom made medical device

means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialized in the relevant area, under his responsibility for the one use of a particular patient, but does not include a mass production of such device

3.18 Distributor

Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device /*IVD* to the end user.

Note 1: More than one distributor may be involved in the supply chain.

Note 2: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition. (ISO 13485 2016)

3.19 Design input

means the physical and performance requirements of a device that are used as a basis for device design. (INDIAN MDR 2017)

3.20 Design output

means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labelling, and the device master record. (INDIAN MDR 2017)

3.21 Design review

means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems. (INDIAN MDR 2017)

3.22 Ethics Committee

means the committee referred to in rule 50 (INDIAN MDR 2017)

3.23 Finished device

means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labelled or sterilized.

3.24 Implantable medical device.

Medical device intended: -

- a. to be totally or partially introduced into the human or animal body or a natural orifice;
or
- b. to replace an epithelial surface or the surface of the eye; by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention. (ISO 13485 2016)

3.25 Importer

natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed. (ISO 13485 2016)

3.26 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 Central Licensing Authority (INDIAN MDR 2017)

3.27 Labelling

The labelling of medical devices shall follow guidelines prescribed by national /state /scientific recommendations including the mention of shelf life / expiry date of the product;

- a. the extent and type of labelling shall include precautionary material specific to the medical device;
- b. there shall be a system to communicate information on packaging and storing;
- c. there shall be a procedure to ensure that the appropriate documents are accompanied with products for the necessary instructions about installation and usage of the product;
- d. labelling tags for intended use shall be attached according to an appropriate system to each product. (ICMED 2015 – 7.3.2);

CHAPTER VI of INDIAN MDR 2017- Rule 44 and ICMED 2015 - Labelling of Medical Devices - (Annexure 1)

3.28 Life-cycle

all phases in the life of a medical device, from the initial conception to final decommissioning and disposal (ISO 13485 2016)

3.29 Manufacturer

Manufacturer is a person, an enterprise, or an entity who himself makes a product through a process involving raw materials, components, or subassemblies, usually on a large mass production scale with different operations divided among different workers and fulfills the following 2 conditions:

A.

Category of Medical Devices	% of Minimum Local Content*
<i>Medical Disposables and Consumables</i>	50%
<i>Medical Electronics, Hospital Equipment, Surgical Instruments</i>	25%
<i>Implants</i>	40%
<i>Diagnostic Reagents / IVD</i>	25%

*As defined in Guidelines by DOP on Make in India PPO, subject to revision.

B. **Change of Tariff Sub Head (CTSH):** There will be a change of the 8-digit ITC Sub Heading of assembly of inputs for enabling 'Substantial Transformation' to produce the output Product by the Manufacturer in India.

3.30 Medical Device

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,

providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary

intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Note 1: Products which may be considered to be medical devices in some jurisdictions but not in others include: - disinfection substances; - aids for persons with disabilities; devices incorporating animal and/or human tissues; devices for *in vitro* fertilization or assisted reproduction technologies. (ISO 13485 2016)

Medical Device definition as such has not been provided in Indian MDR.

(Rule 3 under chapter I in MDR - Definitions)

“**Medical device**” means,

- A. substances used for IVD and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i),
- B. substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),
- C. devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act;

Explanation: For the purpose of these rules, substances used for *in vitro* diagnosis shall be referred as *IVD* medical device. (INDIAN MDR 2017)

3.31 Medical device family

group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function. (ISO 13485 2016)

3.32 Management with executive responsibility

means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system. (INDIAN MDR 2017)

3.33 Post Marketing Surveillance

means systematic process to collect and analyze information gained from medical device that have been placed in the market (INDIAN MDR 2017)

3.34 Performance evaluation in relation to *IVD* medical device means any systematic investigation by which data is assessed and analyzed to establish or verify performance of the *IVD* medical device for its intended use (INDIAN MDR 2017)

3.35 product

result of a process -

Note 1: There are four generic product categories, as follows:

- a. services (e.g., transport);
- b. software (e.g., computer program, dictionary);
- c. hardware (e.g., engine mechanical part);
- d. processed materials (e.g., lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product “automobile” consists of hardware (e.g., tyres), processed materials (e.g., fuel, cooling liquid), software (e.g., engine control software, driver’s manual), and service (e.g., operating explanations given by the salesman).

Note 2: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

- a. an activity performed on a customer-supplied tangible product (e.g., automobile to be repaired);
- b. an activity performed on a customer-supplied intangible product (e.g., the income statement needed to prepare a tax return);
- c. the delivery of an intangible product (e.g., the delivery of information in the context of knowledge transmission);
- d. the creation of ambience for the customer (e.g., in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. (ISO 13485 2016)

3.36 purchased product

product provided by a party outside the organization’s QMS

Note 1 to entry: The provision of product does not necessarily infer a commercial or financial arrangement. (ISO 13485 2016)

3.37 Quality audit

means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives. (INDIAN MDR 2017)

3.38 Quality policy

means the overall intention and direction of an organization with respect to quality, as established by management with executive responsibility. (INDIAN MDR 2017)

3.39 Quality system

means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management, requirements for manufacturing of medical devices as specified in the Fifth Schedule (INDIAN MDR 2017)

3.40 Reagent

means a chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as *in vitro* diagnostic medical device (INDIAN MDR 2017)

3.41 Rework

means action taken on a nonconforming product that will fulfil the specified Device Master File requirements before it is released for distribution. (INDIAN MDR 2017)

3.42 Risk

combination of the probability of occurrence of harm and the severity of that harm. (ISO 13485 2016)

3.43 Risk management

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk (ISO 13485 2016)

3.44 Specification

means any requirement with which a product, process, service, or other activity must conform. (INDIAN MDR 2017)

3.45 Sterile barrier system

minimum package that prevents ingress of microorganisms and allows aseptic resresentation of the product at the point of use. (ISO 13485 2016)

3.46 Sterile medical device

medical device intended to meet the requirements for sterility (ISO 13485 2016)

Note 1: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards. (ISO 13485 2016)

3.47 Validation

means confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled. (INDIAN MDR 2017)

3.47.1 Process validation

means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

3.47.2 Design validation

means establishing by objective evidence that device specifications conform with user needs and intended use(s).

3.48 Verification

means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. (INDIAN MDR 2017)

		Corresponding		
		Clause of		
4	Quality management system (QMS)	ICMED	INDIA	ISO
4.1	General requirements –	2015	MDR	13485
			2017	2016
a	The medical devices manufacturer shall have an established and documented system for implementation and maintenance of a QMS	4.1(a)		
b	The organization shall maintain the effectiveness of QMS in accordance with the requirements of this Standard and applicable regulatory requirements.			4.1.1
c	QMS processes shall be appropriate to the needs of the Organization	4.2		
d	The organization shall have a n established system to identify all the processes, their sequences, results, and interactions and document as per the requirement of the standard.	4.2(a)		
e	The organization shall identify and document responsibility of individuals for all the processes	4.2.1 €		
f	The various components of all processes required for manufacturing, identification, storing, pre-market authorization, sale, installation, maintenance, repaired disposal shall be defined and documented for every product.	4.2.1(d) &(f)		
g	There shall be defined criteria to monitor, measure the compliance and effectiveness of all the processes.	4.2.1(b)		
h	There shall be a system to measure the adequacy of inputs required for the implementation of all the processes and to improve them based on measurement of defined indicators.	4.2(c) & d)		
i	Implement actions necessary to achieve planned results within stipulated time frame.			4.1.2 (c)
j	There shall be a system to track any delay of time period in the completion of processes	4.2(b)		
k	Apply a risk-based approach to the control of the appropriate processes needed for the Quality Management system			4.1.2 (b)
l	There shall be a system within the organization to measure the correctness of those processes of sub-parts of a process that the organization out sources from agencies external to the organization.	4.2.1 (c)		
m	The organization shall retain responsibility of conformity to this Standard and to customer and applicable regulatory requirements for outsourced processes.			4.1.5

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with. The controls shall include written quality agreements.			4.1.5
n	The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software			4.1.5
	Verification and validation of computer programs (software) prior to be used for product manufacturing shall be performed as per a documented process	7.1.4 (i)		
	Records of such activities shall be maintained			4.1.5
4.2	Documentation requirements:			
	Documents required by the QMS shall be controlled.			4.2
	Records are a special type of document and shall be controlled according to the requirements.			
4.2.1	The organization shall have following minimum documents:	4.3.1		
a	Quality Manual	4.3.1 (a)		4.2.2
b	defined quality policy and quality objectives	4.3.1		
c	documents required to ensure the effective planning, implementation and control of all operations of the organization.	4.3.1		
d	documented product specifications for each category, type and model of medical device / IVD manufactured in the facility	4.3.1 (d)		
e	a procedure shall exist to review, improve and approve, periodically, the quality management system for adequacy.	4.3.1 (e)		
f	Documentation to be done to check the compliance of the quality management system with the national/state regulations on manufacture of medical devices / IVD	4.3.1 (f)		
g	a process shall be available to prevent the use of outdated (obsolete) QMS procedures and documents by having an established system of updating the records.	4.3.1 (g)		
4.2.2	Quality Manual – which has-			4.2.2
i	defined scope, exclusions (if any with justification) and procedures covering all operations of the organization.	4.3.1 (a)		
ii	description of the interaction between the processes of the QMS			4.2.2
iii	outline the structure of the documentation used in the QMS			4.2.2
iv	the documented procedures for the QMS, or reference to them;			4.2.2
4.2.3	The manufacturer / organization shall maintain a Device file to compile or identifying the documents where all relevant information for each		4.2.1 (e)	
	medical device / IVD are available – Refer Device Master file as INDIAN MDR 2017 – Schedule fourth Part III – Appendix II & III and /or medical device file as ISO 13485 -2016 – clause 4.2.3	--		4.2.3
i	The data may be recorded by electronic or other reliable means, access shall be restricted and suitable backup system needs to be there.		4.2.1 (e)	

	Documents shall be available in hard copy also to facilitate checking ...			
ii	The manufacturer shall prepare documentation about specific requirements and refer in a Master Document – Plant Master file - to provide complete profile of organization in brief - Refer schedule fourth of MDR- Part III Appendix I - Contents of a site or plant master file.		4.2.1 (e)	
4.2.4	Control of Documents			4.2.4
	A procedure shall define the Control of Document needed -			4.2.4
a	to review and approve documents for adequacy prior to issue			4.2.4(a)
b	to review and update as necessary and re-approve documents			4.2.4(b)
c	to ensure that changes and the current revision status of documents are identified			4.2.(c)
d	to ensure that relevant versions of applicable documents are available at points of use,			4.2.4(d)
e	to ensure that documents remain legible and readily identifiable,			4.2.4(e)
f	to ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the QMS, are identified and their distribution controlled,			4.2.4(f)
g	prevent deterioration or loss of documents,			4.2.4 g
h	prevent the unintended use of obsolete documents and apply suitable identification to them.			4.2.4(h)
	Changes to document shall be reviewed and approved. Changed records shall be maintained which will include a description of the change, identification of the affected documents, the signature of the approving individual, the approval date, and when the change becomes effective need to be informed to all concerned (a document to record amendments is advised to be maintained as per Annexure no 2– Amendment sheet)		4.2.3	
	The organization shall define the period of retaining a document. This period shall ensure that documents to which medical devices or <i>IVD</i> have been manufactured and tested are retained for at least one year after the date of expiry of the medical device or <i>IVD</i> as defined by the manufacturer.		4.2.3	
4.2.5	Control of records			
	Records are a special type of document and shall be controlled according to the requirements.			4.2.4
	Organization shall maintain a robust records management system	4.3.2.		
a	Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the QMS.			4.2.5
b	Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.			4.2.5
c	The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.			4.2.5

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



d	The manufacturer shall retain the records for a period of time at least one year after the date of expiry of the medical device or <i>in vitro</i> diagnostic medical devices as defined by the manufacturer, but not less than two years from the date of product release by the manufacturer.		4.2.4	4.2.5
e	Responsibility for record maintenance shall be given to identified personnel.	4.3.2.		
f	Records shall be preserved and maintained in environmentally safe conditions	4.3.2		
g	Management shall document and establish a procedure to:	4.3.2		
	(i) access, issue and obtain copy of records;	4.3.2		
	(ii) address theft of records or conducting investigation for missing records.	4.3.2		
	(iii) maintain security and integrity			4.2.5
h	The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.			4.2.5
Record management policy shall support the quality policy of the organization		4.3.2.		
	Following records shall be maintained but not limited to -			
i	records which establish the conformity of the products to product specifications and standards including batch/ sample testing and product verification results	4.3.2.(a)		
ii	records of audits, management reviews and observations of compliance/ non-compliance, preventive and corrective actions performed shall be kept under the supervision of responsible and identified authorized personnel.	4.3.2.(c&g)		
iii	records of compliance to regulatory requirements including certificates required for establishing and running a medical device manufacturing site	4.3.2.(d)		
iv	records of improvisation or change in manufacturing technique, infrastructure, and training of staff	4.3.2.(e)		
v	records of safety management systems and adverse incidents, if any.	4.3.2.(f)		
vi	records of all verifications, validations and calibrations	4.3.2.(h)		
vii	records of all user/customer feedback and complaints	4.3.2.(i)		
viii	records of components used for verification of product quality	4.3.2.(j)		
ix	records of all sale, installation and product commissioning	4.3.2. (k)		
x	records of computer programming (software) activities and review of associated risk	4.3.2.(l)		
5	Management responsibility			
5.1	Commitment			
a	The management shall provide evidence of its resolution to develop, implement and improve the quality management system within the organization by communicating to the organization the importance of meeting customer as well as applicable statutory and regulatory requirements	5.1(a)		

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



b	There shall be a defined procedure to update the requirement of QMS, regulatory requirements and product safety guidelines	8.1(e)		
c	Medical device manufacturer shall follow the essential principles of <u>safety and performance</u> of medical devices as may be specified in the guidelines issued by the Ministry of Health and Family Welfare in the Central Government, from time to time keeping in view the contemporary scientific and technological knowledge and development: Provided that the		CHAP	
	guidelines to be so specified shall be in conformity with the provisions of			TER II Rule no 6.
	the Act and these rules. (Essential principles for manufacturing medical devices)			
d	There shall be evidence of management effort to promote quality & safety in all the products	8.1(a)		
e	Established defined quality policy and objectives needs to be there.	4.3.1(b)		
f	There shall be a system to ensure that quality objectives and QMS is communicated to all the divisions of the organization;	5.1(d)		
g	Conducting management reviews, and management reviews of the organization include assessment of the performance of QMS and this assessment is documented.	5.1(b)		5.1(d)
h	The organization shall provide resources specific to the product.	7.1.1(b)		
5.2	Customer focus			
a	Top Management shall establish a procedure to identify customer requirements and to measure the capability of the organization to meet those and applicable regulatory requirements	5(c)		
5.3	Quality policy & objectives			
a	The organization shall have defined quality policy and objectives	4.3.1(b)		
b	Quality policy is applicable to the purpose of the organization			5.3(a)
c	Policy includes a commitment to comply with requirements and to maintain the effectiveness of the QMS			5.3(b)
d	Management Provides a framework for establishing and reviewing quality objectives			5.3(c)
e	These shall be communicated and understood within the organization and being reviewed.			5.3(d)
f	Top management shall ensure that quality objectives meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization.			5.3(e)
g	The quality objectives shall be measurable and consistent with the quality policy			5.3(f)
h	The periodicity of measuring of these indicators (quality objectives) is defined and documented.	4.1(c)		
5.4	Quality Management System Planning			
	Top management shall ensure that:			5.4.2
a	The planning of the QMS is carried out in order to meet the specified requirements given in clause 4.1 as well as the quality objectives; and			5.4.2 a

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



b	Indicators identified to measure the performance of QMS in all the divisions of the organization, which includes collection of suitable data for performance measurement.	5(e)		
c	The integrity of the QMS is maintained when changes to the QMS are planned and implemented.			5.4.2 b
5.5	Responsibility, roles, authority and communication			
5.5.1	Responsibility and authority			
a	There shall be defined and documented roles and responsibilities for every member of organization	8.1(b)		
b	Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.			5.5.1
c	Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.			5.5.1
5.5.2	Management representative			
a	The organization shall identify individuals responsible for all the processes including management representative (M.R.)	4.2.1(e)		
b	Along with other assignments MR is responsible to ensure that QMS processes are documented and that the people in organization are aware about all applicable regulatory requirements.			5.5.2
c	Ensuring that processes needed for the QMS are documented.			5.5.2
d	Reporting to top management on the performance of the QMS and any need for improvement			5.5.2
e	Ensuring the promotion of awareness of applicable regulatory requirements and QMS requirements throughout the organization.			5.5.2
5.5.3	Internal communication			
a	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS			5.5.3
b	There shall be a communication system to exchange information on product, quality, within the various divisions of the organization;	7.2.1(a)		
5.6	Management review			
5.6.1	General			
a	The organization shall document procedures for management review.			5.6.1
b	Top management shall review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness	5(b)		
c	The review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.			5.6.1
d	Records shall be maintained	5(b)		
5.6.2	Review input			
a	The input to management review shall include, but is not limited to–			5.6.2
i	results of audits			5.6.2
ii	feed backs and reports on performance of QMS	8.4(b)		

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



iii	monitoring and measurement of the performance of QMS as well as product	8.1(c)		
iv	corrective and preventive action			5.6.2
v	follow-up actions from previous management reviews			5.6.2
vi	to check the compliance of the QMS with the national / state regulations on manufacture of medical devices, as and when issued.	4.1.3(f)	5.6.2(h)	
vii	complaint handling			5.6.2
viii	reporting to regulatory authorities			5.6.2
ix	follow-up actions from previous management reviews			5.6.2
x	changes that could affect the QMS			5.6.2
xi	recommendations for improvement, and			5.6.2
5.6.3	Review output			
	The output from management review shall be recorded and include the input reviewed and any decisions and actions related to:			5.6.3
a	improvement needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes;			5.6.3
b	improvement of product related to customer requirements, and			5.6.3
c	evidence of management effort to promote quality & safety in all the products	8.1a)		
d	resource requirements			5.6.3
e	changes needed to respond to applicable new or revised regulatory requirements			5.6.3
6	Resource management			
6.1	Provision of resources			
	The <u>organization</u> shall determine and provide the resources needed			6.1
a	to implement the QMS and to maintain its effectiveness, and			6.1
b	to meet applicable regulatory and customer requirements			6.1
c	the reagents, chemicals or other items used for cleaning, fumigation for disinfection and the procedure for their use shall be available	6.3.2.(b)		
6.2	Human resources			
a	Organization shall have appropriate and adequate human resources	6.1		
b	The organization shall comply with statutorily required qualifications and competence levels for performing specific tasks.	6.1 (d)		
c	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.			6.2.1
d	The organization shall have documented information on the skills, trainings and experience required by each category of personnel required in the production process.	6.1b)		
e	The organization shall have a documented procedure for selection, induction, training and performance monitoring and appraisal of each category of personnel	6.1 (c)		
f	Organization shall have defined & documented policy and procedure for training the personnel and ensuring awareness of personnel.	6.2		

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



g	There shall be a procedure to determine the necessary competence for personnel performing work affecting product quality.	6.2(a)		
h	There shall be an established documented procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.		6.2(f)	
i	Training required for performing special tasks or tasks critical to product quality shall be identified.	6.2(d)		
j	Documented training schedule/ calendar for various categories of personnel.	6.2(a)		
k	There shall be procedures to monitor and measure the performance of personnel after the training programs.	6.2(c)		
l	The personnel shall be made aware of duties, responsibilities and expectations so as to promote product quality.	6.1(f)		
m	There shall be defined and documented procedures to take appropriate action for negligence of duty, especially when such negligence adversely affects product quality	6.1 (g)		
n	Maintain appropriate records of education, training, skills and experience for a specified time period			6.2.2(e)
	NOTE - The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.			
o	There shall be defined procedures to address personnel grievances.	6.1(h)		
6.2.1	Organization ensures good health of staff against occupational hazards			
a	Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof.		6.2.1	
b	There shall be a schedule for screening of health effects specially for those who are working in sensitive areas e.g., clean/ aseptic / radiation	6.2.1(b) 6.3.2(i)		
c	In case of any adverse effect if reported on health or life, the procedure to provide adequate compensation shall be there.	6.2.1(c)		
6.3	Infrastructure			
a	The organization has appropriate infrastructure to achieve quality product.	6.3.1		
b	The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product, as appropriate.			6.3
c	Building, fencing, shelter and environment controlling devices shall be installed and operational in the manufacturing facility, as per the requirement of the products and manufacturing processes.	6.3.1(a)		
d	Energy storage and transmission equipment shall be in operational state and national/state	6.3.1(b)		

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	certifications of these installations are valid as on date.			
e	Fire prevention and firefighting installations shall be in functional state in the manufacturing facility.	6.3.1 (c)		
f	The equipment existing in the manufacturing facility (both hardware and software), shall be assessed for their appropriateness for the manufacturing process and is documented.	6.3.1(d)		
g	All such equipment shall comply with national / state/ manufacturer's guidelines for installation, commissioning and functioning	6.3.1(e)		
h	The supporting services shall be available in the manufacturing facility for effective communication within the different sections of the facility.	6.3.1(f)		
6.3.1	Specific area requirements shall be met adequately			
a	The manufacturing area shall be identified into sections of appropriate size so as to prevent mix-up of conforming & non-conforming products.	6.3.1.(a)		
b	The area size and area environment of each section of the manufacturing site dedicated to a specific process /processes shall be conducive for integration of quality components in the product	6.3.1.(b)		
c	Material receipt areas, Storage areas, cleaning and processing areas shall be segregated to avoid mix up of products that may exist during different stages of production	6.3.1.(c)		
d	Areas where products of biological origin are being used shall be segregated physically & environmentally.	6.3.1.(d)		
6.4	Work environment and contamination control			
6.4.1	Work environment			
	The organization shall maintain an environment that supports product quality	6.3.2		
a	There shall be documented information on the environmental requirements of the facility	6.3.2(a)		
b	There shall be a documented process planning to monitor, control and maintain the required environment	6.3.4(b)		
c	Procedures and records shall be maintained to monitor the areas that need special environment conditions due to nature of products or at specific stages of production -	6.3.1(c)		
i	there shall be devices installed to track the trend and regulate the environment conditions (like temperature, pressure, light, humidity, air velocity, particle size etc.) in areas that have special requirement.	6.3.1(d)		
ii	adequate precautions shall be taken by means of appropriate infrastructure to control and prevent pollution, dust, dirt and any other form of contamination to the products / production area as well as personnel.	6.3.1(e)		6.4.2
iii	The manufacturer shall establish documented requirements as per Annexure- 'A' of this Schedule fifth of INDIAN MDR 2017 for the work environment.		6.4(b)	
6.4.2	Contamination control	6.4.2.		
	As appropriate, the organization shall plan and document arrangements for the control of			6.4.2

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



	contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product			
	A document is required for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance. Accordingly, the organization shall have a plan for the cleanliness of the facility.	6.3.2		6.4.1 (a)
a	There shall be a documented procedures and schedule for cleaning, fumigation, disinfection of various parts of the manufacturing facility as per requirements of the production process and compliance records are maintained.	6.3.2(a) & (c)		
b	There agents, chemicals or other items used for cleaning, fumigation or disinfection and the procedure for their use shall be available	6.3.2 (b)		
c	The procedure(s) to protect specific manufacturing equipment from contamination shall be documented.	6.3.2€		
e	All personnel shall bear clean body covering appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production, laboratory and storage areas		6.4 (e)	
f	There shall be a documented code for hand washing, clothing, masking, gowning for personnel who are required to work in clean /aseptic areas.	6.3.2(i)		
g	For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.			6.4.2
h	Areas where products of biological origin are being used shall be segregated physically & environmentally.	6.3.1(d)		
6.4.3	The organization shall maintain proper waste management & disposal system	6.3.2.		
a	The waste management regulations as per national /state regulations shall be complied with.	6.3.2.1(a)		
b	The infrastructure for waste management& disposal systems shall be checked by an appropriate authority and records maintained	6.3.2.1(b)		
c	The waste management & disposal system shall not endanger the quality or conformity of the product	6.3.2.1(c)		
d	The personnel shall be adequately trained to follow a documented waste management & disposal system	6.3.2.1(d)		
e	Any rejected or non-conforming product when disposed, the record of the identity of such a product shall be maintained to avoid it's re - use	6.3.2.1.(e)		
6.4.4	Resources (man-made or natural) required to maintain appropriate environment shall be available in proper quality & quantity	6.3.3		
a	The quality and quantity of water available in the facility shall be appropriate for the production process and this appropriateness is scientifically established and observations recorded.	6.3.3(a)		

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



b	The quality of air available in the facility shall be appropriate for the production process and this appropriateness is scientifically established and observations recorded	6.3.3(b)		
c	The air velocity and direction shall be appropriate for the production process	6.3.3(c)		
d	Records of trends of controlled environment shall be maintained for a specified time period	6.3.3(d)		
e	Lighting requirements shall be specified and complied for various stages of production.	6.3.3 (e)		
6.4.5	Organization shall plan for maintenance of all components of infrastructure	6.3.3.1		
a	There shall be documented periodic preventive maintenance plans for building, equipment and energy installations in the facility.	6.3.3.1(a)		
b	The records of preventive maintenance shall be maintained as per specified period.	6.3.3.1(b)		
c	Organization shall identify person(s) who is (are) responsible for carrying out the maintenance.	6.3.3.1(c)		
d	Maintenance procedure shall be documented, the lapses, delays and /or exclusions in maintenance schedule shall be documented and brought to the notice of identified personnel	6.3.3.1(d)		
	The recommendations for conducting major repair that may arise during such maintenance shall be documented along with action taken report.	6.3.3.1(e)		
7	Product realization			
7.1	Planning of product realization			
7.1.1	Organization shall plan for all the phases of product realization	7.1.1		
a	There shall be a system to identify and provide all inputs required for the various phases of product realization	7.1.1 (a)		
b	The organization shall provide resources specific to the product including infrastructure and work environment	7.1.1(b)		7.1 (b)
c	The objectives of QMS shall be integrated throughout product realization	7.1.1(d)		7.1 (a)
d	The organization shall document verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product and the criteria for product acceptance	7.1.1 (c)		7.1 (c)
e	The organization shall maintain a production schedule	7.1.1(f)		
f	The organization shall have documented procedure to identify risks to product quality and to manage it during the phases of product realization and also to minimize the same.	7.1.1(e)		7.1
	Records of risk management activities shall be maintained.			
g	The organization shall keep records needed to provide evidence that the realization processes and resulting product meet requirements.	7.1.1(h)		
h	The records of past production schedules shall be maintained as per a defined and documented policy of the organization	7.1.1(g)		
	The output of this planning shall be in a form suitable for the organization's method of operations.			7.1

7.1.2	Organization has established criteria for product acceptance	7.1.2		
	There shall be system to measure conformance of products throughout the product realization process.	7.1.2(a)		
	The product shall be verified and validated against pre-determined standards	7.1.2(b)		
	A documented acceptance and rejection criteria for all products shall be there.	7.1.2(c)		
	A system shall be there for monitoring and testing of all processes that can influence product quality, acceptance and rejection	7.1.2(d)		
7.2	Customer-related processes			
7.2.1	Product realization meets intended and implied requirements.	7.1.3		
a	Customer requirements related to the products shall be defined, reviewed and documented.	7.1.3 (a)		
b	The products shall meet the requirements of the customer from the point of completion of the product still the point of final use and is documented.	7.1.3 (b)		
c	The organization shall determine, requirements not stated by the customer but necessary for specified or intended use, where known			7.2.1(b)
d	The product shall meet national /state regulations.	7.1.3(c)		
e	Adequate information shall be provided to the customer/ user about scope, limitations and jurisdiction of any legal dispute that may arise about the product	8.3(e)		
f	Any additional requirements determined by the organization needs to be communicated to customer			7.2.1 (e)
g	Changes in product specifications shall be brought to the knowledge of users/Customers.			7.2 .2
	Any user training needed to ensure specified performance and safe use of the medical device			7.2.1(d)
7.2.2	Review of requirements related to the product			
	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that -			7.2.2
a	product requirements are defined and documented			7.2.2(a)
b	contract or order requirements differing from those previously expressed are resolved			7.2.2(b)
c	the organization has the ability to meet the defined requirements.			7.2.2(e)
	Records of the results of the review and actions arising from the review shall be maintained			7.2.2
d	applicable regulatory requirements are met			7.2.2(c)
e	any user training identified in accordance with 7.2.1 is available or planned to be available			7.2.2(d)
f	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.			7.2.2

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



g	when product requirements change (by law or by any other reason), the product specifications shall be reassessed for its intended or specified use and documented	7.1.3(d)		
7.2.3	Communication			
	The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.			7.2.3
	The organization shall determine and implement effective arrangements for communication within organization and with customers in relation to:	7.2.1		
a	A change in product specifications shall be brought to the knowledge of users/ Customers.	7.1.3(e)		
b	product quality, precautions, product installation, maintenance and use shall be done under an established procedure	7.2.1(c)		
c	enquiries, contracts or order handling, including amendments	7.2.1(d)		7.2.3
d	customer feedback, including complaints	7.2.1(e)		7.2.3
e	information crucial to product quality shall be communicated within a specified time period as per a defined and documented policy	7.2.1(b)		
f	there shall be a system to communicate information on packaging and storing	7.3.2(c)		
g	there shall be a documented policy that would prescribe procedure for communication of changes in uses and precautions to the existing users.	7.4.1(c)		
h	adequate information shall be provided to the customer / user about scope, limitations and jurisdiction of any legal dispute that may arise about the product	8.3(e)		
i	there shall be special instructions for use of the product for special groups of users like neonates, children, elderly, physically and /or mentally differently able users of the product	8.3 (i)		
7.3	Design and development			
7.3.1	General			
a	The organization shall document procedures for design and development.			
b	The manufacturing plan incorporates product quality & safety	7.1.4		
c	The entire plan for product realization from design to dispatch shall be documented including Design Input Review, Design Output Review, Design Verification, Design Validation and Design Changes, If any.	7.1.4(d)		
d	The various phases of manufacturing shall be identified	7.1.4(a)		
7.3.2	Design and development planning			
	During design and development planning, the organization shall document:			7.3.2
a	the design and development stages			7.3.2 (a)
b	the review(s) needed at each design and development stage			7.3.2(b)
c	the verification, validation, and design transfer activities that are appropriate at each design and development stage			7.3.2 (c)
d	the responsibilities and authorities for design and development.			7.3.2(d)

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



e	personnel shall be made aware of the manufacturing plan, of their roles and interactions during the various stages of the plan, selection needs to be with necessary competence.	7.1.4(f)		
f	verification and validation of following shall be performed as per a documented process - quality parameters for the product	7.1.4		
i		(g)		
ii	measuring instruments used for product manufacturing	7.1.4(g)		
iii	computer programs used for product manufacturing	7.1.4(h)		
g	validation of processes of production shall be performed as per a documented process.	7.1.4(i)		
h	records of all calibrations, verification and validations shall be maintained as per a defined policy	7.1.4(k)		
7.3.3	Design and development inputs			
	Inputs relating to product requirements shall be determined and records maintained.			7.3.3
	The design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patients		7.3.2	
	These inputs shall include –			
a	functional, performance, usability and safety requirements, according to the intended use			7.3.3 a
b	the product shall meet national /state regulations	7.1.3(c)		
c	as appropriate, information derived from previous similar designs			7.3.3d
d	other requirements essential for design and development of the product and processes.			7.3.3 e
e	applicable output(s) of risk management			7.3.3c
	These inputs shall be reviewed for adequacy and approved by designated individual		7..3.2(e)	
	Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other			7.3.3
7.3.3.1	Traceability, labelling, cleaning and/or sterilization for products shall be ensured			
7.3.3.19(a)	Traceability			
7.5.9	The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.			7.5.9
a	There shall be a defined policy to ensure traceability of all input components used for product manufacturing and to ensure various final product.	7.3.1 (a)		
b	The methods to ensure traceability of design and development outputs to design and development inputs.			7.3.2
c	There exists a system to initiate appropriate action whenever traceability is compromised.	7.3.1(b)		
d	For specific products or as per regulatory requirements, the unique identification of product shall be maintained throughout the sales, delivery, installation process and after installation	7.4.2(c)		
e	Where traceability is a requirement, the organization shall control and record the unique identification of the product			
7.3.3.1 (b)	Labelling			

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



a	The labelling of medical devices shall follow guidelines prescribed by national/ state/ scientific recommendations including the mention of shelf life/ expiry date of the product.	7.3.2(a)		
b	The extent and type of labelling shall include precautionary material specific to the medical device	7.3.2(b)		
c	There shall be a system to communicate information on packaging and storing	7.3.2(c)		
d	There shall be a procedure to ensure that the appropriate documents are accompanied with products for the necessary instructions about installation and usage of the product	7.3.2(d)		
e	Labelling tags for intended use shall be attached according to an appropriate system to each product.	7.3.2(e)		
	CHAPTER VI -Rule 44. Labelling of medical devices – INDIAN MDR 2017	7.3.2	7.5.1.	
	LABELLING OF MEDICAL DEVICES – ICMED		1	
	(Refer Annexure no 1 – Labelling)			
7.3.3.1(c)	Cleaning and /or sterilization			
a	There shall be defined and documented policy specific to the products for performing the cleaning and/or sterilization of the product at appropriate stages of the manufacturing, whether the –	7.3.3(a)		
i	product is cleaned by the organization prior to sterilization and/or its use, or			7.5.2(a)
ii	product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or			7.5.2(b)
iii	product is supplied to be used non-sterile and its cleanliness is of significance in use, or			7.5.2(d)
iv	process agents are to be removed from product during manufacture			7.5.2 (e)
c	There shall be a documented criteria based on which the cleaning and /or sterilization completion is evaluated, maintained and records maintained.	7.3.3(c)		
d	Guidelines shall accompany the products that are to be subjected to cleaning / sterilization before their final use for intended purposes	7.3.3(d)		
e	There shall be procedures to prevent contamination of the products by other potentially contaminated products	7.3.3 (e)		
f	The suitability of all input components that could influence the sterility of products shall be assessed.	7.3.3(f)		
	Sterilization records shall be traceable to each production batch of medical devices.			7.5.5
g	Particular requirements for validation of processes for sterilization and sterile barrier systems :			7.5.7
i	there shall be defined & documented process based on which cleaning and /or sterilization and sterile barrier system is performed and validated prior to market release following product or process changes, as appropriate.	7.3.3 (b)		7.5.7
	NOTE - Further information can be found in ISO 11607-1 and ISO 11607-2.			

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



	Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained			7.5.7
7.3.4	Design and development outputs			
	The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.			7.3.4
a	Design and development outputs shall:			
i	meet the input requirements for design and development,			7.3.4(a)
ii	provide appropriate information for purchasing, production and for service provision,			7.3.4(b)
iii	contain or reference product acceptance criteria, and			7.3.4(c)
b	monitor and test the accuracy in design and specifications of the products during the various phases of manufacturing	7.1.4(c)		
c	Specify the characteristics of the product that are essential for its safe and proper use.			7.3.4(d)
d	the organization shall document verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance	7.1.1 (c)		
e	there shall be system of monitoring and testing of all processes that can influence product quality, acceptance and rejection.	7.1.29(d)		
	Records of the design and development outputs shall be maintained			7.3.4
	Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks		7.3.3	
7.3.5	Design and development review			
	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to :			7.3.5
a	evaluate the ability of the results of design and development to meet requirements, and			7.3.5(a)
b	identify any problems and propose necessary actions.			7.3.5(b)
	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel			7.3.5
	Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review.			7.3.5
7.3.6	Design and development verification			
a	Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.			7.3.6
b	The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.			7.3.6

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



c	If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.			7.3.6
	Records of the results and conclusions of the verification and necessary actions shall be maintained			7.3.6
7.3.7	Design and development validation			
a	Validation of the product shall be performed according to an established procedure and results shall be documented	7.4.5 (c)		
b	Arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use			7.3.7
c	Design validation shall be performed under defined operating conditions on initial production units, lots, or batches or their equivalence. Design validation shall include software validation and risk analysis, where appropriate validation shall be completed prior to the delivery or implementation of the product.		7.3.6	
d	As part of design and development validation, the <u>manufacturer</u> shall perform clinical evaluations and/or evaluation of performance of the medical device or <i>in vitro</i> diagnostic medical devices.		7.3.6	
e	There shall be a policy to take appropriate permission from national /state			
	/Regulatory authority, before including a medical device product for any clinical trial that needs to be conducted to establish the efficacy of effect of the medical device. Not applicable for clinical evaluation & investigations.	8.3 (h)		
	NOTE 1 If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.		7.3.6	
	NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery		7.3.6	
	If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.			7.3.7
7.3.8	Design and development transfer			
	The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.			7.3.8
	Results and conclusions of the transfer shall be recorded.			
7.3.9	Control of design and development changes			

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



a	The organization shall document procedures to control design and development changes.			7.3.9
b	The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before implementation, the changes shall be reviewed, verified and validated, as appropriate, and approved.			7.3.9
c	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.			7.3.9
d	There shall be a documented policy that would prescribe procedure for communication of changes in uses and precautions to the existing users	7.4.1(c)		
e	Any change in product specifications, uses and precautions related to product use shall be incorporated in the relevant documents	7.4.1(b)		
7.3.10	Design and development files			
	Note. -Each manufacturer shall establish and maintain a Design History File for each type of device. The Design History File shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of design & development and records for design and development if changes made.		7.3.7	
7.3.11	Operational Life Cycle Management	7.4		
a	Organization shall ensure consistency in product characteristics	7.4.1		
b	The output of the planning shall be in a form suitable for the manufacturer's method of operations		7.1 -	
c	Installation procedures shall be determined by the organization (Refer Annexure no 3 – MD Installation)	7.4.2		
d	Organization shall maintain after sale documents (reference is available in the installation procedure Annexure no 3)	7.4.3		
e	Non-conformity after dispatch and maintenance procedures shall be determined by the organization (reference is available in the installation procedure Annexure no 3)	7.4.4		
f	The organization shall arrange for post-production requirements (reference is available in the installation procedure Annexure no 3)	7.4.5		
7.4	Purchasing			
7.4.1	Organization shall have a documented procurement system that ensures and conforms the purchased product quality	7.5.1		
a	There shall be a system to select and evaluate suppliers -	7.5.1		
i	based on their ability to supply product as per product/ organization requirements	7.5.1		7.4.1(a)
ii	based on the performance of the supplier			7.4.1(b)

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



iii	based on the effect of the purchased product on the quality of the medical device			7.4.1(c)
iv	proportionate to the risk associated with the medical device.			7.4.1(d)
b	The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.			7.4.1
c	Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.			7.4.1
	Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained.			7.4.1
7.4.2	Purchasing information			
	Purchasing information shall describe -			
a	purchase requirements including purchase product specification before placing the order.	7.5.1(b)		7.4.2 a
b	requirements for approval of product, procedures, processes and equipment			7.4.2 b
c	requirements for qualification of supplier personnel, and			7.4.2 c
d	QMS requirements.			7.4.2d
e	To the extent required for traceability given in 7.3.3.1 (a), the organization shall maintain relevant purchasing information in the form of documents.			7.4.2
7.4.3	Verification of purchased product			
a	The input components shall be selected based on pre-defined and documented criteria and undergo verification before usage.	7.5.1(d)		
b	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.			7.4.3
c	The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.			7.4.3
d	When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.			7.4.3
e	The suitability of all input components that could influence the sterility of products shall be assessed.	4.3.3(f)		
	Records of all verifications, validations and calibrations shall be maintained	4.3.2.(h)		
7.5	Production and service provision			
7.5.1	Control of production and service provision			
a	The manufacturing plan incorporates product quality & safety	7.1.4		
b	Defined controls shall exist at various stages to check and ensure product conformity	7.1.4(b)		
c	As appropriate, production controls shall include but are not limited to -			7.5.1

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	- documentation of procedures and methods for the control of production			7.5.1(a)
	- qualification of infrastructure -			7.5.1(b)
i	to ensure the use of proper instruments and equipment for the manufacturing, monitoring and measurement	7.5.1(f)		7.5.1(d)
ii	to identify and separate the non-conforming input components and to prevent their unintended use in the manufacturing process	7.5.1(e)		
	-to check the quality and specifications of input components that are used in the manufacturing of the final product	7.5.1(c)		
	- implementation of product release, delivery and post-delivery activities			7.5.1(f)
	- the implementation of defined operations for labelling and packaging.			7.5.1(e)
	(Refer Annexure no 1 for labelling) (see clause 7.3.3.1 (b))			
d	The manufacturer shall establish and maintain a record for each batch of medical device or <i>in vitro</i> diagnostic medical devices that provides traceability and identifies the amount manufactured and amount approved for distribution.		7.5.1	
	(Regarding traceability refer clause 7.3.3.1(a))			
e	The entire plan for product realization from design to dispatch shall be documented including Design Input Review, Design Output Review, Design Verification, Design Validation and Design Changes, If any.	7.1.4 (d)		
	Records of all sale, installation and product commissioning shall be maintained	4.3.2.(k)		
	NOTE - A batch can be a single medical device.			7.5.1
7.5.2	Cleanliness of product (Refer clause 7.3.3.1 (c))			7.5.2
7.5.3	Installation activities (Refer annexure no.3 - installation)			7.5.3
	There shall be a system to maintain records of completion of installation and successful operation of the medical device.	7.4.2(k)		7.5.3
7.5.4	Servicing activities (Not covered in MDR)			
	Included in the procedure Installation- refer annex no 3			
	If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.			
	The organization shall analyze records of servicing activities carried out by the organization or its supplier and records shall be maintained.			
7.5.5	Particular requirements for sterile medical devices			
	(Refer – clause 7.3.3.1.(c))			
7.5.6	Validation of processes for production and service provision			
	Validation of processes of production shall be performed as per a documented process.	7.1.4(k)		
	The organization shall validate any processes for production and service provision where the resulting			7.5.6

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	output cannot be verified by subsequent monitoring or measurement as a consequence deficiencies become apparent only after the product is in use or the service has been delivered.			
	Validation shall demonstrate the ability of these processes to achieve planned results consistently.			7.5.6
	The organization shall document procedures for validation of processes, including-			7.5.6
a	defined criteria for review and approval of the processes			7.5.6 a
b	equipment qualification and qualification of personnel.			7.5.6 b
	All such equipment shall comply with national / state / manufacturer's guidelines for installation, commissioning and functioning	6.3.1 (e)		
c	use of specific methods, procedures and acceptance criteria.			7.5.6 c
d	as appropriate, statistical techniques with rationale for sample sizes			7.5.6d
e	requirements for records			7.5.6 e
f	revalidation, including criteria for revalidation			7.5.6 f
g	approval of changes to the processes			7.5.6g
h	validation of computer programs used for product manufacturing and service provision shall be performed as per a documented process.	7.1.4(i)		7.5.6
	Such software applications shall be validated prior to initial use and as appropriate, after changes to such software or its application.			
	The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.			7.5.6
	Records of the results and conclusion of validation and necessary actions from the validation shall be maintained			7.5.6
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems			
	(Refer clause 7.3.3.1(c))			
7.5.8	Identification			
a	Product identification shall be done based on specified criteria	7.1.4e		
b	The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization.			7.5.8
c	Identification of product status shall be maintained throughout production, storage, implant, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.			7.5.8
d	If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.			7.5.8
	The unique identification of product shall be maintained throughout the sales, delivery, installation process and after installation;	7.4.2		
		(c)		

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



	The manufacturer shall establish documented procedures to ensure that medical devices and <i>in vitro</i> diagnostic medical devices returned to the manufacturer are identified and distinguished from conforming product.		7.5.3.	
			1	
7.5.9	Traceability			
7.5.9.1	General			
	Refer clause 7.3.3.1(a)			
7.5.9.2	Particular requirements for implantable medical devices (<u>active implantable medical devices are not covered in ISO 13485 – 2016</u>)			
	Particular requirements for active implantable medical devices and implantable medical devices.			
			7.5.3.	
			2.2	
a	The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.			7.5.9.
				2
b	The manufacturer shall require that its agents or distributors maintain records of the distribution of <u>active implantable medical devices and implantable medical devices</u> to allow traceability and that such records are available for inspection.		7.5.3.	
			2.2	
c	Records of the name and address of the shipping package consignee shall be maintained			7.5.9.
				2
7.5.10	7.5.10 Customer Property			
a	The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization.			7.5.10
b	The property of the customer that is handled by the organization during the installation shall be conserved against undue damages and this responsibility shall be defined in product installation policy.	7.4.2(e)		
c	If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records.			7.5. 10
	NOTE Customer property can include intellectual property or confidential health information.		7.5.4	
7.5.11	7.5.11 Preservation of product			
a	There shall be a documented management policy for preserving and promoting products quality.	8.3(a)		
b	The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.			7.5. 11
c	The organization shall protect product from alteration, contamination or damage when exposed			7.5. 11

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	to expected conditions and hazards during processing, storage, handling, and distribution by:			
i	designing and constructing suitable packaging and shipping containers for safe transit and delivery to the intended destination.	7.4.4(f)		7.5.11(a)
ii	documenting requirements for special conditions needed if packaging alone cannot provide preservation.			7.5.11(b)
iii	adopting procedures to prevent contamination of the products by other potentially contaminated products.	7.3.3(e)		
d	Areas where products of biological originate being used shall be segregated physically & environmentally.	6.3.3.1(d)		
e	Organization ensures product safety, reliability and credibility	8.3		
f	If special conditions are required, they shall be controlled and recorded			7.5.11
7.6	7.6 Control of monitoring and measuring equipment			
a	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements			7.6
b	Verification and validation of measuring instruments (equipment) used shall be performed as per a documented process	7.1.4(h)		
c	As necessary to ensure valid results, measuring equipment shall –			
i	be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards - Bureau of Indian Standards wherever available, where no such standards exist, the basis used for calibration or verification shall be recorded.		7.6(a)	7.6
ii	be adjusted or re-adjusted as necessary: such adjustments or re- adjustments shall be recorded			7.6
iii	have identification in order to determine its calibration status;			7.6
iv	be safeguarded from adjustments that would invalidate the measurement result;			7.6
v	be protected from damage and deterioration during handling, maintenance and storage.			7.6
d	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.			7.6
e	Verification and validation of computer programs if used shall be performed as per a documented process. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.	7.1.4(i)		7.6
f	The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of			7.6

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



	the software, including the effect on the ability of the product to conform to specifications.			
g	Records of results and conclusion of all calibrations, verification and validation and necessary actions shall be maintained as per a defined policy	7.1.4(j)		7.6
	NOTE Further information can be found in ISO 10012 for guidance related to measurement management systems.			7.6
8	Measurement, analysis and improvement			
8.1	General			
a	Organization shall be led by a management which promotes quality in products and consistency in processes and the efforts shall be evident.	8.1		
b	There shall be documented procedures to monitor and measure the performance of quality management system (conformity and effectiveness) and the conformity of product.	8.1(c)		
c	This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.			8.1
	Note. -If relevant Indian standards are not available, international standards are applicable. In case no Indian or International standards are available, validated testing process of the manufacturer is applicable.		8.1	
8.2	Monitoring and measurement:			
8.2.1	Feedback			
a	As one of the measurements of the effectiveness of the QMS – the organization shall have a procedure to collect, analyze and incorporate customer /user feedback whether the organization has met customer requirements and the data may be used in enhancing the product quality.	8.3(d)		
b	There shall be a documented procedure to collect view, feedbacks and reports on performance of QMS	8.4(b)		
c	The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.			8.2.1
d	If applicable regulatory requirements require the organization to gain specific experience from post production activities, the review of this experience shall form part of the feedback process.			8.2.1
8.2.2	Complaint handling			
	The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.			8.2.2
	These procedures shall include at a minimum requirements and responsibilities for:			8.2.2
a	receiving and recording information;			8.2.2
b	evaluating information to determine if the feedback constitutes a complaint;			
c	investigating complaints;			8.2.2
d	determining the need to report the information to the appropriate regulatory authorities;			8.2.2
e	handling of complaint-related product;			8.2.2

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



f	determining the need to initiate corrections or corrective actions;			8.2.2
g	if any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. Manufacturer shall notify the adverse event to the regulatory authority and establish documented procedures for the same;		8.5.1	
h	adequate information shall be provided to the customer /user about scope, limitations and jurisdiction of any legal dispute that may arise about the product;	8.3(e)		
i	if an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved;			8.2.2
	Complaint handling records shall be maintained			8.2.2
8.2.3	Reporting to regulatory authorities			
a	There shall be a policy to bring to the notice of appropriate national / state / regulatory authority, any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold.	8.3(g)		
b	Manufacturer shall notify the adverse event to the regulatory authority and establish documented procedures for the same.		8.5.1	
	Records of reporting to regulatory authorities shall be maintained			8.2.3
c	There shall be a policy to bring to public notice or advisory notice any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold	8.3(f)		
8.2.4	Internal audit			
a	There shall be documented procedures to conduct audits to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.	8.2(a)		8.2.4
b	An audit programme shall be planned (needs to be informed in advance to all concerned) taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.			8.2.4
c	Organization shall have appropriate and adequate number of audits at planned intervals to determine whether the QMS:	8.2		
i	conforms to the planned arrangements to the requirements of this <u>Standard</u> and to the QMS requirements established by the <u>organization</u> , and applicable regulatory requirements.			8.2.4
ii	is effectively implemented and maintained.			8.2.4
d	audits shall be conducted by qualified and competent auditors, independent of the area of their activity	8.2(b)		
e	The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.			8.2.4

Section 3B Certification Criteria for ICMED 13485
PADD: ICMED: Section 3B: SD: 02: ICMED 13485



f	There shall be evidence for the action taken on the recommendations of the audit findings along with reasons for not taking action (if any) within stipulated time.	8.2(c)		
g	There shall be records of internal and/or external audits of the processes of the facility and the records are preserved for a specified time period.	8.2(d)		
h	Follow-up activities shall include the verification of the actions taken and the reporting of verification results.			8.2.4
	NOTE - Further information can be found in ISO 19011			
8.2.5	Monitoring and measurement of processes			
a	The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the QMS processes.			8.2.5
b	These methods shall demonstrate the ability of the processes to achieve planned results.			8.2.5
c	When planned results are not achieved, there shall be a system for detection of failures /non conformities in QMS, correction and corrective action shall be taken, as appropriate.	8.4(c)		8.2.5
8.2.6	Monitoring and measurement of product			
a	There shall be system of monitoring and testing of all processes that can influence product quality, acceptance and rejection.	7.1.2(d)		
b	This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and procedures.			8.2.6
c	There shall be a system to evaluate the ability of the product to meet intended use	7.4.5(a)		
d	Verification and validation of quality parameters for the product shall be performed according to an established procedure and results shall be documented	7.4.5(b)		
e	There shall be documented acceptance and rejection criteria for all products.	7.1.2(c)		
f	Records which establish the conformity of the products to product specifications and standards shall be maintained including batch / sample testing and product verification results.	4.3.2.(a)		
g	Records of components / equipment used for verification of product quality shall be maintained	4.3.2.(j)		
h	Organization ensures product safety, reliability and credibility.	8.3		
i	The identity of the person authorizing release of product shall be recorded			8.2.6
j	Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.			8.2.6
k	There shall be evidence of compliance to the market authorization regulations for all the products.	8.1(f)		
	Particular requirement for active implantable medical devices and implantable medical devices, wherever applicable		8.2.4.2	
	The manufacturer shall record the identity of personnel performing any inspection or testing.		8.2.4.	

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



8.3	Control of nonconforming product			
8.3.1	General			
a	The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification of any deviations in the product as compared the documented characteristics defined for that product, documentation, segregation, evaluation and disposition of nonconforming product.	7.4.5(e)		8.3.1
b	The manufacturing area shall be identified into sections of appropriate size so as to prevent mix-up of conforming & non- conforming products	6.3.1.(a)		
c	Any rejected or non-conforming product when disposed, the record of the identity of such a product shall be maintained to avoid t's re- use.	6.3.2.(e)		
8.3.2	Actions in response to non-conforming product detected before delivery			
a	Records that do not establish the conformity of the products to product specifications and standards shall also be maintained	4.3.2.(b)		
b	There shall be a system to handle unintended acceptance and /or use of non-conforming products by one or more of the following ways:	7.4.5(f)		
i	taking action to eliminate the detected nonconformity;			8.3.2
ii	taking action to preclude its original intended use or application;			8.3.2
iii	authorizing its use, release or acceptance under concession			8.3.2
c	The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met.			8.3.2
	Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained.			8.3.2
	Records of the nature of the non conformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained.			8.3.1
	The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.			8.3.1
8.3.3	8.3.3 Actions in response to nonconforming product detected after delivery.			
	(Annexure no 3 for installation shall be referred).			
a	When nonconforming product is corrected it shall be subject to re- verification to demonstrate conformity to the requirements.		8.3	
b	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.			8.3.3
c	If defects or non-conformity is detected in the product after receipt of the product at the installation site, there shall be an established and documented procedures to initiate return/ repair of the product	7.4.3(a)		

Section 3B Certification Criteria for IC MED 13485
PADD: IC MED: Section 3B: SD: 02: IC MED 13485



d	Rejected /returned products to the manufacturer shall be kept separate from the conforming products	7.4.3(c)		
	Records of actions taken shall be maintained.			8.3.3
e	There shall be a policy to bring to the notice of appropriate national/ state/ regulatory authority, any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold	8.3(g)		
	Records of actions relating to the issuance of advisory notices shall be maintained in accordance with regulatory requirements			8.3.3
8.3.4	Rework			
	(Please refer Annexure no 3 - Installation)			
8.4	Analysis of data			
	There shall be a system to evaluate and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the QMS and improve the processes based on measurement of defined indicators as input like -	4.2(d)		
	a) <i>feedback</i> ; b) conformity to product requirements; c) characteristics and trends of processes and products including opportunities for preventive action, and for improvement; d) Suppliers; e) audits; f) service reports, as appropriate	8.4		
	The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.	8.4		
	Records of the results of analyses shall be maintained.			
8.5	Improvement			
8.5.1	General			
	There shall be a system for the assessment and improvement and maintain the continued Suitability, adequacy and effectiveness of the QMS as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review, Post Market surveillance.	8.4(a)		8.5.1
	The organization shall have established procedures for incorporating continuous quality improvement in the product.	8.3(j)		
8.5.2	Corrective action			
a	There shall be a system to initiate action to rectify the failures/non conformities identified in the QMS and prevent it's reoccurrence.	8.4(d)		
b	Any necessary corrective actions shall be taken without undue delay.			8.5.2
c	Corrective actions shall be proportionate to the effects of the nonconformities encountered.			8.5.2
d	The organization shall document a procedure to define requirements for reviewing nonconformities (including complaints);			8.5.2 a
	There shall be a system to initiate investigation of the cause of non- conformity, evaluating the need for action, and procedures to prevent re- occurrence.	7.4.3(d)		8.5.2c
	Records of the results of any investigation and of action taken shall be maintained.			8.5.2

	Reviewing the effectiveness of corrective action taken.			8.5.2(f)
	Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;			8.5.2.(e)
8.5.3	Preventive action			
	The organization shall determine action to eliminate the causes of potential non conformities in order to prevent their occurrence.			8.5.3
	Preventive actions shall be proportionate to the effects of the potential problems			8.5.3
	The organization shall document a procedure to describe requirements for:			8.5.3
a	determining potential nonconformities and their causes;			8.5.3(a)
b	evaluating the need for action to prevent occurrence of nonconformities;			8.5.3 (b)
c	planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;			8.5.3(c)
d	verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;			8.5.3(d)
e	reviewing the effectiveness of the preventive action taken, as appropriate.			8.5.3(e)
	Records of all preventive and corrective actions performed shall be maintained.	4.3.2.(g)		

ANNEXURE -I

Bibliography

1. ISO 9000:2015, Quality Management Systems - Fundamentals and Vocabulary.
2. ISO 9001:2015, Quality management Systems - Requirements
3. ISO 10001, Quality management - Customer satisfaction - Guidelines for codes of conduct for organizations
4. ISO 10002, Quality management - Customer satisfaction - Guidelines for complaints handling in organizations
5. ISO 10012, Measurement management systems - Requirements for measurement processes and measuring equipment
6. ISO 10015, Quality management - Guidelines for training
7. ISO 14001, Environmental management systems - Requirements with guidance for use
8. ISO 19011, Guidelines for quality and/or environmental management systems auditing
9. ISO 11134, Sterilization of healthcare products - Requirements for validation and routine control- Industrial moist heat sterilization
10. ISO 11135, Medical devices - Validation and routine control of ethylene oxide sterilization (Corrigendum 1 published 1994)
11. ISO 11137, Sterilization of healthcare products - Requirements for validation and routine control- Radiation sterilization (Corrigendum 1 published 1995; Amendment 1 published 2001)
12. ISO 13641, Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
13. ISO 13683, Sterilization of healthcare products- Requirement for validation and routine control of moist heat sterilization in health care facilities
14. ISO 14155-1, Clinical investigation of medical devices for human subjects - Part 1: General requirements
15. ISO 14155-2, Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans
16. ISO 14160, Sterilization of medical devices- Validation and routine control of sterilization of Single-use medical devices incorporating materials of animal origin by liquid chemical sterilant

17. ISO 14937, Sterilization of healthcare products- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilizing agent
18. ISO / TR 14969: -1), Medical devices - Quality management systems Guidance on the application of ISO13485:2003
19. ISO 14971, Medical devices - Application of risk management to medical devices
20. ISO 15223-1, Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

ANNEXURE -II CHAPTER VI (MDR 2017) LABELLING OF MEDICAL DEVICES

44. Labelling of medical devices. - The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely, -

- a. name of the medical device;
- b. the details necessary for the user to identify the device and its use;
- c. the name of manufacturer and address of manufacturing premises where the device has been manufactured;
- d. the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system;
- e. the month and year of manufacture and expiry (alternately the label shall bear the shelf life of the product):

Provided that in case of sterile devices, the date of sterilization may be given as date of manufacture of the device:

Provided further that where the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile or in case of medical equipment or instruments or apparatus, the date of expiry may not be necessary.

Explanation. - For the purposes of this clause, the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life";

- f. to provide, wherever required, an indication that the device contains medicinal or biological substance;
- g. to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." Or "B. No.";
- h. to indicate, wherever required, any special storage or handling conditions applicable to the device;
- i. to indicate, if the device is supplied as a sterile product, its sterile state and the sterilization method;
- j. to give, if considered relevant, warnings or precautions to draw the attention of the user of medical device;
- k. to label the device appropriately, if the device is intended for single use;
- l. to overprint on the label of the device, the words "Physician's Sample—Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample;

- m. to provide, except for imported devices, the manufacturing license number by preceding the words "Manufacturing License Number" or "Mfg. Lic. No." or "M. L";
- n. to provide on the label, in case of imported devices, by way of stickering, where such details are not already printed, the import license number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture:

Provided that the label may bear symbols recognized by the Bureau of Indian Standards or International Organization for Standardization (ISO) *in lieu* of the text and the device safety is not compromised by a lack of understanding on the part of the user, in case the meaning of the symbol is not obvious to the device user;

- o. in case of small sized medical devices on which information cannot be printed legibly, shall include the information necessary for product identification and safety such as information covered by clauses (a), (b), (c), (d), (e), (g), (k), and (m) shall be included.

ICMED

LABELLING CHECKLIST REQUIREMENTS FOR MEDICAL DEVICES

A. Information mandatory to be marked on the 'Unit pack for sale' of Device.

1. Name / Trade Name of the device.
2. The Name & Address of manufacturer
3. Lot / Batch No.
4. Date of Expiry
5. Indication for single use (if applicable)
6. The word "STERILE" (For Sterile Devices)
7. Caution in event of damage to sterile pack
8. Max. Retail Price

B. If space constraint "unit pack for sale", the following information is also mandatory on secondary pack of Device, user/ consumer can be cautioned by use of caution symbol on the unit pack.

1. Device description
2. Mfg. Lic. No. (if applicable)
3. Date of Mfg.
4. Storage / handling instruction
5. Operating instruction / Instruction for use, where appropriate
6. Method of sterilization (For Sterile Devices)
7. Warning / Precautions & Symbols (if applicable)
8. Customer- care –Contact Detail.

Note 1. As far as it is practicable and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and/or on the packaging for each unit, and/or on the packaging of multiples devices.

Note 2. As far as practicable and appropriate, the information needed to use the Device safely to be given on the Device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information to be given in the leaflet/ Information to Use supplied with one or more Devices.

Note 3. Each Device to be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

Note 4. Where appropriate, the information should take the form of symbols. Any symbol or identification Colour used must conform to the harmonized Standards. In areas for which no Standards exist, the symbols and colors must be described in the documentation supplied with the Device”. Graphical symbol as per ISO 15223 can be used as appropriate for all of above. Any additional labeling requirement specified in related product standard to be included appropriately.

Note 5. The unit pack can be containing more than one number or type of medical devices.

ANNEXURE- III

**Installation / Maintenance/ Service/ Repair/ Rework of
Medical Device / IVD**

I	Installation Activity
	Installation procedures shall be determined by the organization. The requirements for product installation that are expected from the customer's end shall be specified beforehand giving customer a time period as per the defined policy. Clause 7.4.2 (d) – ICMED
	The organization shall document requirements for medical device /IVD installation and acceptance criteria for verification of installation, as appropriate. Clause 7.5.3 - 13485 -2016
	If the agreed customer requirements allow installation of the medical device / IVD to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Clause 7.5.3 - 13485 -2016
	The installation protocols shall include briefing to the customer and inspection of the site of installation. Clause 7.4.2 (a) - ICMED
	There shall be a system to maintain the details of transportation of medical devices / IVD and record of the same for a defined period. Clause 7.4.2 (b) – ICMED
	For specific products as per defined policy, the unique identification (SN/ Batch No /Lot No/ Software version) of product shall be maintained throughout the sales, delivery, installation process and after installation. Clause 7.4.2 (c) – ICMED
	The property of the customer that is handled by the organization during installation shall be kept safely against undue damages and this responsibility shall be defined in product installation policy. Clause 7.4.2 (e) – ICMED
	The instructions for installation of the product shall be communicated with adequate documentation Clause 7.4.2 (f) – ICMED
	The shelf life of the product, including its warranty /guarantee period shall be mentioned in the documents supplied to the customer with the product. Clause 7.4.2 (g) – ICMED
	There shall be a defined policy for the financial responsibility of any damage to the product from the point of dispatch to the point of receipt at the installation site. Clause 7.4.2 (h) – ICMED
	The organisation shall ensure that the requirements (infra structure / energy / man power requirements etc.) of installation and commissioning are completed before the installation phase begins. Clause 7.4.2 (i) – ICMED
	There shall be a documented system to ensure the compliance of all regulatory requirements necessary for the medical device / IVD installation and scheduled operation before the installation begins. Clause 7.4.2 (j) – ICMED
	Records shall be maintained for completion of installation and successful operation of the medical device / IVD. Clause 7.4.2 (k) – ICMED
II	Servicing and Maintenance after dispatch
	The maintenance manual a n d I F U m a n u a l shall be included as per a defined policy for every specified category of products. Clause 7.4.4 (a) – ICMED

	Any non-conformity arising during the transit shall be brought to the notice of the manufacturer and the customer based on a specific procedure. Clause 7.4.4 (g) – ICMED
	If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. Clause 7.5.4 – ISO 13485 – 2016
	Records of servicing activities performed by the manufacturer shall be documented Clause 7.4.4 (b) – ICMED
	The unique identification (SN/Batch No/Lot No/Software version) of product shall be maintained after installation for further maintenance works– for specific products as per a defined policy. Clause 7.4.4 (c) – ICMED
III	Non-conformity detected after dispatch
	During Guarantee / Warranty Period
	Maintenance / Repair /Rework procedures shall be determined by the organization
	The organization shall establish a procedure to initiate return / repair of the product if any non-conformity is detected in the product post installation (after delivery or use has started). Clause 7.4.3 (a) – ICMED
	Rejected/ returned products from customer to the manufacturer shall undergo a process of identification and shall be kept separate from the conforming products. Clause 7.4.3 (b) &(c)– ICMED
	There shall be a system to initiate investigation of the cause of non- conformity and procedures to prevent re-occurrence. Clause 7.4.3 (d) – ICMED
	Effects and impacts, if detected, due to such non – conformity shall be documented. Clause 7.4.4 (e) – ICMED
	There shall be a policy to bring to the notice of appropriate national/ state/regulatory authority, any adverse events or potentially adverse events that could arise due to manufacturing fault in the product that are already sold; the records of actions relating to the issuance of advisory notices shall be maintained. Clause 8.3(g) -ICMED Clause 8.3.3 -134852016
	If the investigation for the cause of non-conformity is not performed, the reason for not performing such investigation shall be documented. Clause 7.4.4 (d) – ICMED
	Repair / Rework
	Prior to approval for rework, any adverse effect if predicted due to repair or rework, the same shall be documented and authorized. – modified from clause 8.3 - 13485 -2003
	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Clause 8.3– 13485 – 2003
	The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. Clause 8.3.4 – 13485 -2016
	If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Clause- 8.3 -13485 -2003
	After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Clause 8.3.4 – 13485 – 2016

	Records of rework shall be maintained Clause 8.3.4 – 13485 -2016
IV	Service / Rework / Repair
	Post Guarantee / Warranty Period
	Annual Maintenance Contract (AMC) and Comprehensive Maintenance Contract (CMC) between manufacturer and customer (based on customer need and product type) shall be done.
	If servicing / repair of the medical device /IVD after warranty period is a specified requirement of the client, the organization shall provide documented procedures, feasible rate contracts and approximate time period. The manufacturer shall responsible to support the customers with required spare parts and service support within the shelf life of device.
	After satisfactory rework /repair within the warranty period with demonstration of proper intended use, the manufacturer shall renew further warranty period, failing which may be liable for some penalty clause.

Amendment Sheet

Record of Current Status of the Technical Criteria for Certification of Medical Devices

The current status of each page and the history of change of the Technical Criteria for Certification of Medical Devices are set out below:

S. No.	Date Of Amendment	Page No.	Amendment details
01	August 2016	All	Issue 01
02	Mar 2019	All	Issue 02 updated to include requirements of ISO13485: 2016 and INDIAN MDR 2017

- Highlighting is used within the text of the Requirements to identify current amendments with any deleted text shown with a strikethrough.
- Previous amendments or revisions are incorporated into the text. Where text on an individual page is amended the page will be reissued.
- Each reissued page is identified in the header as a 'page amendment' making reference to the "revision number" and the "revision issue date".