

Schedule M-III

REQUIREMENTS FOR THE MANUFACTURE, IMPORT AND SALE OF MEDICAL DEVICES

Note: The manufacture, import and sale of Medical Devices, which have been notified as drugs are regulated under the Drugs & Cosmetics Act and Rules.

All application of devices for manufacture of devices shall be made in accordance of Rule 76, but in case of inspections and other requirements Schedule M III will apply.

1. General

1.1 For the purposes of this Schedule any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article shall be deemed to be a Device under the meaning of Section 3 (b) (iv), which is:

- (a) intended by the manufacturer to be used alone or in combination for human beings for one or more specific purpose(s) of;
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
 - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process,
 - (iv) supporting or sustaining life,
 - (v) control of conception,
 - (vi) disinfection of medical devices,
 - (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

- (b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Note 1: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control

materials and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. *In vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations under D&C Act.

Note 2: Accessories intended specifically by manufacturers to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose are subject to the same procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the ‘parent’ device.

Note 3: Components to medical devices are generally controlled through the manufacturer’s quality management system and the conformity assessment procedures for the device.

Note 3a: Semi-finished products, in specific processes performed by sub contractors are to be generally controlled through the manufacturer’s quality management system and the conformity assessment procedures for the device.

Note 4: (1) ‘accessory’ means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

(2) ‘*in vitro* diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donation from the human body, solely or principally for the purpose of providing information:

- (a) concerning a physiological or pathological state, or
- (b) concerning a congenital abnormality, or
- (c) to determine the safety and compatibility with potential recipients, or
- (d) to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and

preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination. Products for general laboratory use are not *in vitro* diagnostic medical devices

(3) 'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;

(4) 'device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner or by paramedical personnel when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(5) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

(6) 'clinical data' means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

- (a) clinical investigation(s) of the device concerned; or
- (b) clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- (c) published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

(7) 'device subcategory' means a set of devices having common areas of intended use or common technology;

(8) 'generic device group' means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(9) 'single use device' means a device intended to be used once only for a single patient.

(10) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use in the market, regardless of whether it is new or fully/partly refurbished;

(11) 'putting into service' means the stage at which a device is ready for use in the market for the first time for its intended purpose.

(12) Notified Body is a formally designated conformity assessment body which verifies the product and reviews the technical documentation and assesses whether the product and technical documentation in respect of a product demonstrates that the relevant essential requirements have been met. The Notified Body may also audit the manufacturer's quality management system according to regulatory requirements. As appropriate, the Notified Body issues certificates of conformity.

(13) 'Authorized Representative' means any natural or legal person established within India who has received a 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.

(14) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name,(regardless of whether these operations are carried out by that person himself or on his behalf by a third party). The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

(16) Active medical device: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change, are not considered to be active medical devices.

(17) Active therapeutic device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

(18) Active device intended for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

1.2 a) Where a device is intended to administer a medicinal product within the meaning of D&C Act relating to medicinal products for human use it shall be governed by this schedule. If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall not be governed by this Schedule. The relevant essential requirements of Annex I shall apply to that product as far as safety and performance related device features are concerned. (Eg : Prefilled Insulin Syringe)

b) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of the D&C Act and which is liable to act upon the body with action ancillary to that of the device, that device shall be assessed and authorized in accordance with this schedule.

(Eg : Drug Eluting Stent.)

c) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of the D&C Act and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a 'human blood derivative', that device shall be assessed and authorized in accordance with this schedule. (Eg : .Cord blood coated stent)

d) This Schedule shall not apply to:

(i) medicinal products covered by D&C Act. In deciding whether a product falls under the drug category under D&C Act or Medical Devices under this Schedule, particular account shall be taken of the principal mode of action of the product;

(ii) cosmetic products covered by D&C Act

(iii) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, ;

(iv) transplants or tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin,;

(v) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma.

2. Classification:

Medical Devices shall be classified as per their risk level and intended use . They shall be divided into Classes A,B,C,D. Classification shall be carried out in accordance with Annex IX.

The classification rules set out in Annex IX may be adapted by CLAA in accordance in the light of technical progress and any information which becomes available under the information system provided for in 10. (Information on incidents occurring following placing of devices on the market)

Whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices;

2.1 Risk Level

Medical Devices shall be classified as per the Figure 1 mentioned below. The examples given are for illustration only and the classification of Medical Devices must be done as per the classification rules for each medical device according to its intended purpose.

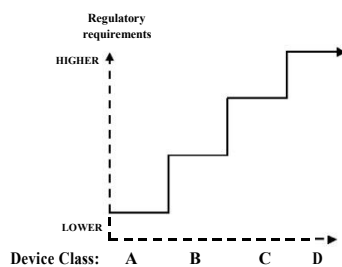
Figure 1: ..General classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Thermometers / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment

C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example: -

- operation of a quality system (recommended for all devices);
- technical data;
- product testing using in-house or independent resources;
- documentation of clinical evidence to support the manufacturer’s claims;
- the need for and frequency of independent external audit of the manufacturer’s quality system; and
- Independent external review of the manufacturer’s technical data.



The classification rules generally enable medical devices to be appropriately classified.

In view of the diverse nature of the devices and technological progress in this field, steps must be taken to include amongst the implementing powers conferred on the CLAA the decisions to be taken with regard to the proper classification or reclassification or confirmation of the classification of the devices or, where appropriate, the adjustment of the classification rules themselves;

The confirmation of compliance with the essential requirements may mean that clinical investigations have to be carried out by the manufacturer; as per requirements of clinical investigation of this schedule.

For the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;

If a manufacturer desires to reclassify a device to a lower class, it must submit justification to the CLAA for evaluation that less stringent class requirement will assure sufficient safety and effectiveness of the device.

3. Placing on the market and putting into service:

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the country is one of the essential objectives of this Schedule;

Whereas, for the purpose of this Schedule Compliance with the essential requirements shall be presumed in respect of devices when the manufacturer relies on relevant latest BIS standard(s) or ISO standard(s) or any other official standard(s) or the manufacturer's own validated standard(s).

Harmonized conformity assessment procedures shall be the responsibility of manufacturers and notified bodies for carrying out conformity assessment on the basis of the type of devices intended to be manufactured.

Whereas the details added to these procedures are justified by the nature of the verification required for medical devices;

Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes;

The conformity assessment procedures for Class A devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; The manufacturers are not required to obtain manufacturing license from Central Licensing Authority CLAA. Class A device manufacturer shall register with the CLAA.

For Class B devices, a notified body should assess and certify the manufacturing facility quality management system. Based on the assessment by Notified body CLAA shall have no objection to manufacture such device(s). Class B device manufacturers shall register with the CLAA.

For device(s) falling under Class C which constitute a medium high risk potential, certification by a notified body is required with regard to the design and manufacture of the device(s). The manufacturers are required to apply for a

license along with supportive documents with respect to safety and effectiveness of these devices to CLAA. Based on these documents and certificate issued by the Notified body, the manufacturing license will be issued by CLAA.

For devices falling under Class D which constitute a high risk potential, certification by a notified body is required with regard to the design and manufacture of the devices. The manufacturers are required to apply for a license along with the supportive documents in respect of safety and effectiveness of these devices to CLAA. The class D devices manufacturing facility will also be inspected jointly by CLAA and state licensing authority. Based on the recommendations of joint inspections report and the certification by the Notified body, the manufacturing license will be issued by CLAA.

The manufacturer which has already gone through Quality Management system (QMS) and product certification through a Notified body elsewhere need to produce approval documents for consideration of registration or licensing of Quality Management system and product.

Any expenses incurred by an applicant for assessment and certification by the notified body shall be borne by the manufacturer only.

Fees required to be paid for obtaining a license in this schedule shall be as specified in relevant D&C Act Rules.

Medical devices sold in this country should, as a general rule, bear the ICAC mark (Indian Conformity Assessment Certificate) to indicate their conformity with the provisions of this schedule to enable them to move freely within the Country and to be put into service in accordance with their intended purpose;

Wherever possible sampling of a medical devices shall be carried out in accordance of the procedure laid down in Drugs and Cosmetics Act, 1940. In case the nature of the devices is such that above procedure cannot be adopted, CLAA may take samples for evaluation from experts in the field or take any other measure to verify the claim of the manufacturer.

4. Essential requirements:

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

5. Post-Marketing Surveillance and Adverse Event (Vigilance) Reporting:

Once a medical device is placed on the market in India, the manufacturer shall adhere to requirements of post-marketing surveillance (PMS) to systematically monitor the performance of the device during use. As appropriate, events meeting certain criteria should be analyzed and reported to a designated authority (“vigilance reports”). As part of the manufacturer’s Quality Management System, appropriate corrective and preventive actions may be applied to prevent the recurrence of adverse events. Medical device manufacturers should comply with post-marketing surveillance and vigilance reporting guidance provided hereinafter. In addition, the manufacturer should submit to CLAA vigilance reports for analysis. The Manufacturer shall follow the procedure referred to in Annex XII in respect of Adverse Event Reporting.

6. Free movement, devices intended for special purposes:

6.1 CLAA shall not create any obstacle to the placing on the market or the putting into service within the country devices bearing the ICAC marking provided for in ICAC marking which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Conformity Assessment procedure (11)

Note : It should be understood the requirement to bear the ICAC mark also applies to devices in Classes A and B (which do not require conformity assessment by a Notified Body.

6.2 CLAA shall not create any obstacle to:

Devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Clinical Investigation (14) and in Declaration of Conformity (Annex VII) and bear form 12 License under D&C Act.

Custom-made devices being placed on the market and put into service if they meet the conditions laid down; Class B, C and D devices shall be accompanied by the statement, which shall be available to the particular patient or user identified by name, an acronym or a numerical code.

These devices may not bear the ICAC marking.

6.2 At trade fairs, exhibitions, demonstrations, etc. there shall not be any obstacle to the showing of devices which do not conform to this Schedule, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply and the manufacturer has permission under appropriate Rules of the D&C Act.

7. Reference to standards:

7.1 Standards:

1. In order for the manufacturer to demonstrate conformity with the relevant regulatory requirements, the CLAA shall adopt and recognize BIS 15575 or its revisions and ISO 13485 in respect of the specifications to be followed for Quality Management Systems.

2. For the purposes of this Schedule, reference to harmonized standards also includes the monographs of the Indian *Pharmacopoeia and US, EU pharmacopoeia wherever applicable*, notably on surgical sutures and on combination of pharmaceutical and devices.

7.2 Labelling:

The packaging of medical devices shall be labelled as per the Annex XIII and relevant ISO standards .

Additionally relevant internationally accepted symbols denoting sterilization, single use etc, as per ISO 15223-1:2007 shall also be depicted.

Note 1: Medical Devices shall be exempted from mentioning Date of manufacture in labelling.

Note 2: In case of medical devices sold in bulk packaging without any primary packaging, labelling shall be on the bulk package.

Note 3: In case of Medical Devices imported to the country, the importer can take permission for further labelling of the package under provision of Rule 104A of the drugs and cosmetic rules from the CLAA before release for sale in the market.

Note 4: The rules for labelling specified as per Rule 109A shall not be applicable to medical devices

7.3 Shelf Life: In special circumstances to be mentioned in writing and permission taken thereof from the CLAA, shelf life of imported medical devices may not be covered under Rule 31 of the D&C Rules.

8. Expert Committee on Medical Devices:

An Expert Committee consisting of experts of relevant fields of the devices constituted by the Government shall assist CLAA in evaluation of application of devices.

9. Safeguard Clause:

Where CLAA ascertains that the devices, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.

The CLAA shall immediately inform the manufacturer or importer of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance is due to:

(a) failure to meet the essential requirements referred to in. 6 (Free movement, devices

intended for special purposes)

(b) incorrect application of the standards referred to in 7.(Reference to standards)

(c) Shortcomings in standard themselves

10. Information on incidents occurring following placing of devices on the market:

10.1. CLAA shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Schedule, regarding the incidents mentioned below involving a Class A, B, C or D device is recorded and evaluated centrally:

(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

10.2. Where the CLAA requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative is also informed of the incident.

10.3. After carrying out an assessment if possible together with, the manufacturer or his authorized representative, without prejudice to Safe Guard (9) Clause shall immediately inform the CLAA of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 10.1, including information on the underlying incidents.

10.4. Any appropriate measures to adopt procedures to implement this action shall be taken in accordance to the Dugs & Cosmetic Rules.

11. Conformity assessment procedures:

11.1. In the case of devices falling within Class B, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the ICAC marking, follow the procedure relating to the ICAC declaration of conformity set out in Annex VII and coupled with either:

(a) the procedure relating to the ICAC verification set out in Annex IV or

(b) the procedure relating to the ICAC declaration of conformity production quality assurance set out in Annex V

or

(c) the procedure relating to the ICAC declaration of conformity in product quality assurance set out in Annex VI.

(d) Instead of applying this procedure the manufacturer may also follow the procedure referred to in the paragraph 11.2 (a).

11.2. In the case of devices falling within Class C, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the ICAC marking, either:

(a) follow the procedure relating to the ICAC declaration of conformity full quality assurance set out in Annex II; in this case point 4 of Annexure II is not applicable.

Or

(b) follow the procedure relating to the ICAC type-examination set out in Annex III coupled with:

(i) the procedure relating to the ICAC verification set out in Annex IV or

(ii) the procedure relating to the ICAC declaration of conformity- production quality assurance set out in Annex V; or

(iii) the procedure relating to the ICAC declaration of conformity - product quality assurance set out in Annex VI.

11.3. In the case of devices falling within Class D, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the ICAC marking, either:

(a) follow the procedure relating to the ICAC declaration of conformity full quality assurance set out in Annex II; or

(b) follow the procedure relating to the ICAC type-examination set out in Annex III coupled with:

(i) the procedure relating to the ICAC verification set out in Annex IV or

(ii) the procedure relating to the ICAC declaration of conformity production quality assurance set out in Annex V.

11.4. In the case of devices falling within Class A, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the ICAC marking, follow the procedure referred to in Annex VII and draw up the ICAC declaration of conformity required before placing the device on the market.

11.5. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

CLAA may require that the manufacturer shall submit a list of such devices which have been put into service in the country .

11.6. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Schedule at an intermediate stage of manufacture.

11.7. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative may apply to a body of his choice within the framework of the tasks for which the body has been notified.

11.8. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

11.9 Certificate issued by the notified bodies in accordance with this Schedule shall be valid for a maximum of five years.

By derogation from above mentioned cases,(11.1 to 11.5) the CLAA may authorize, on duly justified request, the placing on the market and putting into service, within the country, of individual devices for which the procedures referred to in above paragraphs ,(11.1 to 11.5) have not been carried out and the use of which is in the interest of protection of health.

11.10 Any manufacturer or authorized agent who wants to market in the India a Class B, C, and D device intended for human use, which if proved to be substantially equivalent at least as safe and effective to a legally marketed device or if device is already approved by CE/USFDA or any other major regulatory body may be considered for a manufacturing license based on supportive documents submitted to CLAA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate."

Before marketing a device, each submitter must receive an order, in the form of a Registration Certificate, from CLAA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in India. This order "clears" the device for commercial distribution.

11.11: Periodic Safety Update data compilation and submission (PSUR) / Clinical Registry method of clinical data compilation need not be approved by CLAA.

11.12 The periodicity of surveillance audit will be annual .

12. Particular procedure for systems , procedure packs and procedure for Sterilisation:

By way of derogation from 11 the following paragraphs shall apply to systems and procedure packs.

12.1 Any manufacturer who puts devices bearing the ICAC marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

- (a) he has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and
- (b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- (c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a ICAC mark or

Where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such subjected to the relevant procedure pursuant to 11.

12.2 Any Licensed firm /entity who sterilizes, for the purpose of placing on the market, systems or procedure packs referred to in 12.1 or other ICAC-marked medical devices designed by their manufacturers to be sterilized before use, shall, at his choice, follow one of the procedures referred to in the quality systems as per Annex IV,V or VI and relevant BIS and ISO standards. The application of the abovementioned and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration

stating that sterilisation has been carried out in accordance with the manufacturer's instructions.

The products referred to in paragraphs 12.1 and 12.2 themselves shall not bear an additional ICAC marking. They shall be accompanied by the information referred to point 13 of Annex I which includes where appropriate, the information supplied by the manufacturer of the devices which have been put together.. If the labelled intended use(s) of the system or procedure pack differs from that of the original device(s), then it should require a new conformity assessment procedure and a new ICAC mark.

12.3 The declarations referred to in paragraphs 12.1 and 12.2 shall be kept at the disposal of the CLAA. for a period of 5 years.

13. Particular health monitoring measures:

Where CLAA considers in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. CLAA shall then inform the Notified Body, manufacturer and all other Stakeholders, giving the reasons for its decision. The CLAA shall, whenever possible, consult the interested Parties.

The CLAA shall adopt its opinion, indicating whether the national measures are justified or not. The CLAA shall inform all the stakeholders and the consulted interested Parties thereof. When appropriate, the necessary measures designed to amend non- essential elements of this Schedule MIII, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in D&C Act. On imperative grounds of urgency, the CLAA may exceptionally use the urgency procedure referred to in D&C Act.

14. Clinical investigation:

14.1. In the case of devices intended for clinical investigations, the manufacturer or the authorized representative of the manufacturer shall follow the procedure referred to in Annex VIII and notify the CLAA

14.2. In the case of devices falling within Class D and implantable and long-term invasive devices falling within Class B or C, the manufacturer may commence the relevant clinical investigation after obtaining approval from CLAA.

14.3. In the case of devices other than those referred to in paragraph 14.2, CLAA may authorize manufacturers to commence clinical investigations immediately after the date of information and submission to CLAA, provided that the ethics committee concerned has issued a favourable opinion on the program of investigation in question including its review of the clinical investigation plan.

14.4. Clinical investigation shall be conducted in accordance with provisions of Annex X and in the manner provided in ISO 14155.

14.4. The manufacturer or his authorized representative shall notify the CLAA of the end of the clinical investigation, with a justification in case of early termination.

14.5. The provisions of paragraphs 14.1 and 14.2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with conformity assessment to bear the ICAC mark unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant procedure of Annex X remains applicable.

15. Notified bodies:

Notified bodies for conformity assessment and /or ICAC certification of the medical devices shall be listed by the CLAA in consultation with the BIS or any other such competent body and publicly circulated for the benefit of the users of such services.

1. Manufacturer shall notify the CLAA of the Accredited Notified Bodies which they have selected for carrying out the tasks pertaining to the procedures referred to in conformity assessment and the specific tasks for which the Notified Bodies have been designated.

2. The appointed Notified bodies by the Manufacturer shall be compliant with the criteria set out in this Schedule (Annex XI).

3. After manufacturer has notified a notified body to CLAA, it shall withdraw that notification if it finds that the body no longer meets the criteria set out.

4. The notified body and the manufacturer, or his authorized representative, shall lay down, by common accord, the time limits for completion of the

assessment and verification operations referred to in Annexes relating to Declaration of Conformity to Quality Assurance Systems for Production, Declaration of Conformity to Quality Assurance Systems for Product, Type Examination and Verification.

5. The notified body shall inform the CLAA about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Schedule M III about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.

6. Where a notified body finds that pertinent requirements of this Schedule M III have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the CLAA may become necessary, the notified body shall inform CLAA thereof.

7. The notified body shall, on request, supply all relevant information and documents, required to enable the CLAA to verify compliance with Annex XI requirements of Schedule M III.

8. CLAA will have the its right to review the functioning of the Notified body either pro actively or with respect to complaint redressal.

9. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the CLAA.

10. Change of Notified body can be after obtaining No objection certificate from existing one.

16. Indian Conformity Assessment Certificate (ICAC):

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Rule 3 must bear the ICAC marking of conformity when they are placed on the market.

2. The ICAC marking of conformity, consisting of the initials 'IC' must appear in a visible, legible and indelible form on its packaging, where practicable and appropriate, and on the instructions for use. Where applicable, the ICAC marking must also appear on the sales packaging.

The various components of the 'IC' marking must be vertical, and may not be less than 5mm in height.

It shall be accompanied by the identification number of the notified body issued by CLAA responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the ICAC marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the ICAC marking is not thereby reduced.

17. Wrongly affixed ICAC marking:

(a) where CLAA establishes that the ICAC marking has been affixed unduly or is missing in violation of the Schedule M III, the manufacturer or his authorized representative shall be obliged to end the infringement under conditions imposed by the CLAA;

(b) where non-compliance continues, the CLAA must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in this Schedule. (No 9).

Those provisions shall also apply where the ICAC marking has been affixed in accordance with the procedures in this Schedule M III, but inappropriately, on products that are not covered by this Schedule M III.

18. Decision in respect of refusal or restriction:

1. Any decision taken pursuant to this Schedule M III:

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

(b) to withdraw devices from the market, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party

concerned, who shall at the same time be informed of the remedies available to him under the Drugs & Cosmetics Act in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken

In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

19. Confidentiality:

1. Without prejudice to the existing national provisions and practices on medical confidentiality, CLAA shall ensure that all the Parties involved in the application of this Schedule M III are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of CLAA and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:

(a) information on the registration of persons responsible for placing devices on the market in accordance with Schedule;

(b) information to users sent out by the manufacturer, authorized representative or distributor in relation to a measure according to Schedule

(c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

3. The measures designed to amend non-essential elements of this Schedule M III inter-alia by supplementing it, relating to determination of the conditions under which other information may be made publicly available, and in particular for Class D and above devices to any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Schedule and D&C Act.

ANNEX I

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),

- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be

adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

7. Chemical, physical and biological properties

7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:

- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.

7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.

7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods.

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.

7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

8. Infection and microbial contamination

8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Notified bodies shall retain information on the geographical origin of the animals.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.

8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.

8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

9. Construction and environmental properties

9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe

and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,
- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

10. Devices with a measuring function

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Weights and Measures Act 1977.

11. Protection against radiation

11.1. General

11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far

as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2. Intended radiation

11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3. Unintended radiation

11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

11.4. Instructions

11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5. Ionizing radiation

11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.

11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.

12. Requirements for medical devices connected to or equipped with an energy source

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.

12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.

12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

12.6. Protection against electrical risks

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.

12.7. Protection against mechanical and thermal risks

12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise,

particularly at source, unless the noise emitted is part of the specified performance.

12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.

12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

12.8. Protection against the risks posed to the patient by energy supplies or substances

12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

12.9. The function of the controls and indicators must be clearly specified on the devices.

Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. Information to be submitted by the manufacturer

13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out 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 must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class A or B if they can be used safely without any such instructions.

13.2. Where appropriate, this 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 colours must be described in the documentation supplied with the device.

13.3. The label must bear the following particulars: Also adhere to RULE 96

(a) the name or trade name and address of the manufacturer. For devices imported into the Country, in view of their distribution in the Country, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the Authorized Agent responsible or of the authorized representative of the manufacturer established within the Country or of the importer established within the Country, as appropriate;

(b) the details strictly necessary for the user to identify the device and the contents of the packaging;

(c) where appropriate, the word 'STERILE';

(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

(f) where appropriate, an indication that the device is for single use;

(g) if the device is custom-made, the words 'custom-made device';

(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';

(i) any special storage and/or handling conditions;

(j) any special operating instructions;

(k) any warnings and/or precautions to take;

(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;

(m) where applicable, method of sterilization.

13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

13.6. Where appropriate, the instructions for use must contain the following particulars:

(a) the details referred to in Section 13.3, with the exception of (d) and (e);

(b) any undesirable side-effects;

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

(d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

(e) where appropriate, information to avoid certain risks in connection with implantation of the device;

(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I;

(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

(k) precautions to be taken in the event of changes in the performance of the device;

(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

(n) precautions to be taken against any special, unusual risks related to the disposal of the device;

(o) medicinal substances incorporated into the device as an integral part in accordance with Section 7.4;

(p) degree of accuracy claimed for devices with a measuring function.

14. Where conformity with the essential requirements must be based on clinical data, such data must be established in accordance with Annex X.

ANNEX II

ICAC DECLARATION OF CONFORMITY (Full quality assurance system)

1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3 and 4 and to surveillance as specified in Section 5.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Schedule which apply to them.

The manufacturer must affix the ICA marking in and draw up a written declaration of conformity. This declaration must cover a given number of the products manufactured and be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body and must submit a copy of under-mentioned documents to the competent authority in case of Class C and D devices.

The application must include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality system,**
- all the relevant information on the product or product category covered by the procedure,**
- a written declaration that no application has been lodged with any other notified body for the same product-related quality system,**
- the documentation on the quality system,**
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,**
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,**
- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:**
 - (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;**
 - (ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.**

3.2. Application of the quality system must ensure that the products conform to the provisions of this Schedule which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,

- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform;

(c) the procedures for monitoring and verifying the design of the products and in particular:

- a general description of the product, including any variants planned,

- the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,

- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,

- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

- a statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex I and data on the tests conducted in this connection,

- the clinical data referred to in Annex ,

- the draft label and, where appropriate, instructions for use;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must verify that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.

4. Examination of the design of the product

4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this schedule, as referred to in Section 3.2 (c).

4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Schedule, issue the application with an design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the

requirements of the Schedule. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product.

In the case of devices referred to in Annex I, paragraph 7.4, the notified body shall, in view of the aspects addressed in that paragraph, consult one of the competent bodies in the country before taking a decision.

The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

4.4. Changes to the approved design must receive further approval from the notified body which issued the design-examination certificate wherever the changes could affect conformity with the essential requirements of the Schedule or with the conditions prescribed for use of the product. The applicant shall inform the notified body which issued the design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the ICA design-examination certificate.

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular:

- the documentation on the quality system,
- the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculation tests, etc.,
- the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. Administrative provisions

6.1. The manufacturer must, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1,
- the changes referred to in Section 3.4,
- the documentation referred to in Section 4.2, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

6.2. The notified body must make available to the other notified bodies and the competent authority, on request, all relevant information concerning quality system approvals issued, refused or withdrawn.

6.3. In respect of devices subject to the procedure in Section 4, when neither the manufacturer nor his authorized representative, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the market or the importer referred to in Annex I, Section 13.3 (a).

7. Application to devices in Classes B and C

This Annex may apply to products in Classes A and B. Section 4, however, does not apply.

ANNEX III

ICAC Type-Examination

1. Type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Schedule.

2. The application includes:

- the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative,
- the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to

as the 'type', with the requirements of this Schedule. The applicant must make a 'type' available to the notified body. The notified body may request other samples as necessary,

- a written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

- a general description of the type, including any variants planned,
- design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,
- the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,
- a statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex I and data on the tests conducted in this connection,
- the clinical data referred to in Annex ,
- the draft label and, where appropriate, instructions for use.

4. The notified body must:

4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Schedule if the standards referred to in Article 5 have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential

requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. If the type conforms to the provisions of this Schedule, the notified body issues the applicant with an ICA type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

In the case of devices referred to in Annex I, paragraph 7.4, the notified body shall, in view of the aspects addressed in that paragraph, consult one of the competent bodies established in the country before taking a decision.

The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

6. The applicant must inform the notified body which issued the type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the ICA type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial ICA type-examination certificate.

7. Administrative provisions

7.1. The notified body must make available to the other notified bodies on request, all relevant information on ICA type-examination certificates and supplements issued, refused or withdrawn.

7.2. Other notified bodies may obtain a copy of the ICA type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed.

7.3. The manufacturer or his authorized representative must keep with the technical documentation copies of ICA type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured.

7.4. When neither the manufacturer nor his authorized representative approved in the Country, the obligation to keep available the technical documentation shall fall to the person responsible for placing the device on the Indian market or the importer referred to in Annex I, Section 13.3 (a).

ANNEX IV

ICAC Verification

1. ICAC verification is the procedure whereby the manufacturer or his authorized representative established in the Country ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the IC type-examination certificate and meet the requirements of this Schedule which apply to them.

2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the IC type-examination certificate and to the requirements of the Schedule which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the IC type-examination certificate and with the requirements of this Schedule which apply to them. The manufacturer must affix the ICA marking in accordance with Article 17 and draw up a declaration of conformity.

In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 4.

3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use

which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Schedule either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify, where appropriate, the conformity of the products with the IC type described in the type-examination certificate and with the requirements of the Schedule which apply to them.

5.2. The notified body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the IC type-examination certificate and with the requirements of the Schedule which apply to them in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes, entailing a sampling system ensuring a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %. The sampling method will be established by the harmonized standards referred to in Article 5, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

7. Administrative provisions

The manufacturer or his authorized representative must, for a period ending at least five years after the last product has been manufactured, make available to the CLAA:

- the declaration of conformity,**
 - the documentation referred to in Section 2,**
 - the certificates referred to in Sections 5.2 and 6.4,**
 - where appropriate, the type-examination certificate referred to in Annex III.**
- ### **8. Application to devices in Class B**

In line with Article 11 (2), this Annex may apply to products in Class B, subject to the following exemptions:

8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class B are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Schedule which apply to them;

8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class B with the technical documentation referred to in Section 3 of Annex VII.

ANNEX V

ICAC DECLARATION OF CONFORMITY (Production quality assurance)

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