

	Moulding	Well ventilated Area with minimum 5 micron filter
	Vulcanising	Normal Air
	Primary Packing	Air conditioned
Intra Uterine Devices	Moulding	Well ventilated Area with minimum 5 micron filter
	Assembling	7
	Primary Packaging	7
Tubal ring	Extrusion	7
	Cutting and Assembly	7
	Primary Packaging	7
Blood bags	Moulding/Extrusion of components	8
	Assembly	7
	Filing	5
Suture	Extrusion	9
	Assembly	8
	Primary Packing	8
Staplers	Staple formation	9
	Staple assembly	8
	Staple Primary pack	8
Ligatures	Extrusion	9
	Cutting and assembly	8
	Final Primary Packing	8
Surgical dressings	Weaving	9
	Assembly and Gauzing	9
	Final Primary Packing	9
<i>In vitro</i> diagnostic medical devices (Kit/Reagents)	Dry, Liquid Reagent Preparation	Well Lighted and Ventilated controlled temperature & humidity as per process or product requirement
	Coating of sheets etc.	
	Assembly and primary packing	
	Filling	Well Lighted and Ventilated controlled temperature and humidity as per process or product requirement. Provision of Laminar hood if required, Clean Room class 8 or class 9 as per product/process requirement
	Secondary Packing	Well Lighted and Ventilated controlled temperature if required
	Storage	As per recommended storage condition of the product

Sixth Schedule

[See rules 26(iii), 26(iv), 38(v) and 38(vii)]

Post approval change

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device;
3. the intended use or indication for use ;
4. the method of sterilization;
5. the approved Shelf life;
6. the name or address of,-
 - (i) the domestic manufacturer or its manufacturing site;
 - (ii) overseas manufacturer or its manufacturing site (for import only);
 - (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

(B) Changes in respect of following shall be considered as minor change in,-

1. design which shall not affect quality in respect of its specifications, indication for use, performance and stability of the medical device;
2. in the manufacturing process, equipment, or testing which shall not affect quality of the device;
3. packaging specifications excluding primary packaging material.

Seventh Schedule

[See rules 51(1), 51(2), 53(ii), 53(v), 59(3)]

Requirements for permission to import or manufacture investigational medical device for conducting clinical investigation**1. Application for permission.-**

- (1) an application in Form MD-22 shall be made to the Central Licensing Authority along with following data in accordance with tables, namely:-
 - (i) Design analysis data as per Table 1.
 - (ii) Biocompatibility and Animal Performance Study as per Table 2.
 - (iii) Information specified in Table 3 shall be submitted along with Investigator's Brochure as prescribed in Table 4, Clinical Investigational Plan as prescribed in Table 5, Case Report Form as prescribed in Table 6, Serious adverse event reported, if any, as prescribed in Table 7, Informed Consent Form as prescribed in Table 8, investigator's undertaking as prescribed in Table 9, of this schedule and Ethics Committee approval, if available, as prescribed in Appendix VIII of Schedule Y of the Drugs and Cosmetics Rules, 1945.
 - (iv) Regulatory status in other countries, including information in respect of restrictions imposed, if any, on use of investigational medical device in other countries, prescription based device, exclusion of certain age groups, warning about adverse device effect. Likewise, if the investigational medical device has been withdrawn in any country by the manufacturer or by regulatory authority, such information shall also be furnished along with reasons and its relevance, if any. This information must continue to be submitted by the sponsor to the Central Licensing Authority during the entire duration of marketing of the said medical device in the Country;
 - (v) Proposed Instruction for use or direction for use and labels shall be submitted as part of the application. The drafts of label shall comply with provisions of labeling rules specified in Medical Devices Rules, 2017:

Provided that after submission and approval by the Central Licensing Authority, no change in the Instructions for Use shall be effected without such changes having been approved by the Central Licensing Authority;
 - (vi) Report of clinical investigation should be in consonance with the format as prescribed in Table 10, such reports shall be certified by Principal Investigator.
- (2) For investigational medical device developed in India, clinical investigation is required to be carried out in India right from Pilot clinical investigation or first in human study and data generated should be submitted.
- (3) For investigational medical devices developed and studied in country other than India, Pilot Clinical Investigation or relevant clinical study data should be submitted along with the application. After submission of such data generated outside India to the Central Licensing Authority, permission may be granted to repeat pilot study or to conduct Pivotal Clinical Investigation. Pivotal Clinical Investigation is required to be conducted in India before permission to market the medical device in India except investigational medical device classified under class A, in exceptional cases, the Central Licensing Authority, may, for reasons to be recorded in writing, if consider it necessary, mandate conduct of clinical investigation, depending on the nature of the medical device.
- (4) The number of study subjects and sites to be involved in the conduct of clinical investigation shall depend on the nature and objective of the clinical investigation.

2. CLINICAL INVESTIGATION:**(1) Approval for clinical investigation**

- (i) Clinical investigation on an investigational medical device shall be initiated only after approval has been obtained from the Ethics Committee(s), registered under rule 122DD of Drugs and Cosmetics Rules, 1945, and