Duly filled specimen pro forma for submission of application in Form MD-22 for obtaining permission for conducting Clinical Investigation of Investigational medical device

1. The name of the applicant (firm) shall be mentioned as registered under applicable law like company act, proprietorship etc.

2. The applicant may select the option as provided in the portal eg. proprietorship, LLP, Pvt. Ltd., etc.

3.(ii) Address of all the clinical study center(s) where the proposed study shall be carried out by the applicant needs to be mentioned

4. (1) Only the common name or generic name of the device shall be mentioned.

4.(3) The risk class of the devices shall be as per classification list published on the CDSCO website or clarification letter as obtained from Central Licensing Authority.
(Click here)

4. (5) Only applicable for sterile product otherwise the applicant shall mention "Not applicable"

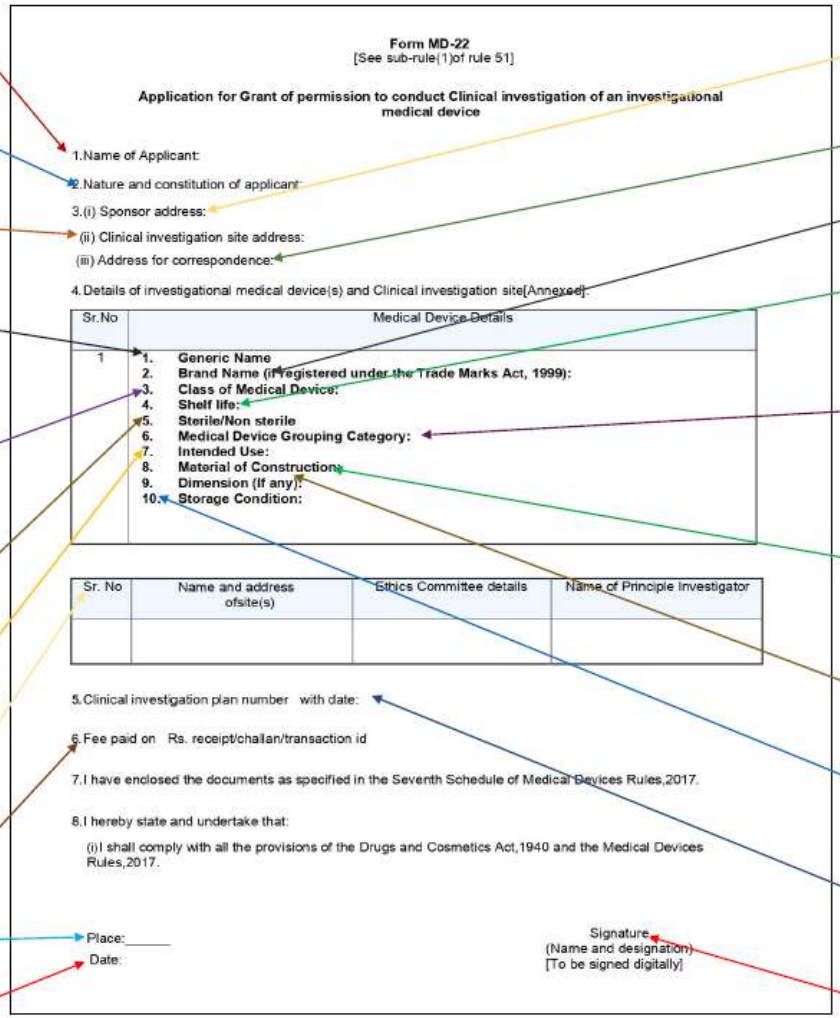
4.(7) Should be the same as mentioned in manufacturer in DMF & IFU/ UM/ PI .

Details of the Clinical Study center(s) for the proposed study shall be mentioned

6. The fee in Rupees shall be calculated to USD as on the date of application submitted

Place where the address of the applicant is located

Shall be in DD/MM/YYYY



Form MD-22
[See sub-rule(1)of rule 51]

Application for Grant of permission to conduct Clinical investigation of an investigational medical device

1.Name of Applicant:

2.Nature and constitution of applicant:

3.(i) Sponsor address:

(ii) Clinical investigation site address:

(iii) Address for correspondence:

4.Details of investigational medical device(s) and Clinical investigation site[Annexed]:

Sr.No	Medical Device Details
1	1. Generic Name 2. Brand Name (if registered under the Trade Marks Act, 1999): 3. Class of Medical Device: 4. Shelf life: 5. Sterile/Non sterile 6. Medical Device Grouping Category: 7. Intended Use: 8. Material of Construction: 9. Dimension (If any): 10. Storage Condition:

Sr. No	Name and address ofsite(s)	Ethics Committee details	Name of Principle Investigator

5.Clinical investigation plan number with date:

6.Fee paid on Rs. receipt/challan/transaction id

7.I have enclosed the documents as specified in the Seventh Schedule of Medical Devices Rules,2017.

8.I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act,1940 and the Medical Devices Rules,2017.

Place:_____
Date:

Signature
(Name and designation)
[To be signed digitally]

3. (i) The applicant shall mention name and address of the Sponsor (a person/ investigator/ company/ institution/ organization) responsible for the initiation and management of the Clinical investigation.

3.(iii) The address of the applicant shall be mentioned

4.(2) The specific brand name of the device shall be mentioned.

4.(4) It should be as per the claim made by the manufacturer.

4.(6) The grouping category (Single, System, Group, Family, etc) shall be as per guidelines published on the CDSCO website.
(Click here: Link1 ; Link2)

4.(8) The materials/composition used for the manufacturing of main devices as mentioned in DMF & IFU/ UM/ PI of the device.
In case of medical equipments, group or kits as per grouping criteria, It should be mentioned as Not applicable.

4.(9) Dimensions of the devices should be in the line of DMF & IFU/ UM/ PI , labels

4.(10) The storage condition of device should be mentioned as specified in the DMF & IFU/ UM/ PI and device labels (in metric units).

5. Applicant shall mention the Clinical Investigation Plan number with version and date of the proposed study

It should be digitally signed using digital signature certificate as per IT Act.

Abbreviations: *DMF: Device Master File* *IFU/ UM/ PI: Instructions for use/ User Manual/ Package Insert* *CLA: Central Licensing Authority*