Checklist for the grant of permission to conduct Clinical Investigation in Form MD-23 under Medical Devices Rules, 2017

Form Type	Application in Form MD-22 (Investigational Medical Devices)
Section no.	**Checklist**
1.0	Cover Letter
2.0	Application (Form MD-26)
3.0	Fees Challan
4.0	Justification for the proposed class of device along with supporting documents
5.0	Regulatory status of the device if approved by any National regulatory authority of the countries viz. United Kingdom, United States of America, Australia, Canada, Japan, etc. along with the notarized copy of approval letter.
6.0	Design analysis data of the Investigational medical device
6.1	Design input, design output and design control documents, etc. along with design verification and validation report
6.2	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
6.3	Device specification including the test parameters and its reference protocol to be carried out on the finished device along with the test report
6.4	Mechanical test, electrical tests, Reliability tests, software verification & validation, any performance test, Ex vivo tests, etc.(wherever applicable)
7.0	Stability Study data generated (if any)
8.0	Risk Management Report on the applied medical device
9.0	Biocompatibility and Animal performance study data for applied medical device (as applicable)
10.0	Proposed Labelling information
11.0	In case if the device contains drug, whether the drug is approved in India, If yes, then details of approval no. and company name and validity of approval etc.,
12.0	If the drug is not approved in India, the following documents are required to be submitted: Data on animal toxicology, Reproduction studies, Teratogenic studies, Perinatal studies, Mutagenicity, Carcinogenicity, Chemical and Pharmaceutical information, etc.
13.0	Clinical Investigation data including that carried out in India or other countries (if any),
14.0	Details of countries where the investigational medical device is being sold/marketed from last two year (in case of import)
15.0	Post marketing surveillance data of the investigational medical device if marketed in the countries viz. United Kingdom, United States of America, Australia, Canada, Japan, etc, from last two years.
16.0	Details on evidence that there is no theoretical possibility of any difference in the behavior and performance in Indian population
17.0	Undertaking in writing to conduct post marketing clinical investigation with the objective of safety and performance of such investigational medical device as per protocol approved by the Central Licensing Authority
18.0	Notarized copy of overseas manufacturing site or establishment or plant registration, in the country of origin issued by the competent authority (in case of import)
19.0	Constitution details of domestic manufacturer or authorized agent
20.0	Other information (if any)