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 Name**
1.0	Cover Letter mentioning whether the Study is Pilot/ Pivotal/ Postmarketing clinical study along with its objective
2.0	Application (Form MD-22)
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 (if any) along with the 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 Investigational medical device
9.0	Biocompatibility and Animal performance study data for Investigational medical device (as applicable)
10.0	Proposed Labelling information
11.0	The agreement between the Sponsor and Principal investigator
12.0	Appropriate Insurance certificate, if any,
13.0	Forms for reporting any adverse event and serious adverse event,
14.0	Investigators Brochure as per Seventh Schedule of MDR-2017
15.0	Clinical Investigational Plan as per Seventh Schedule of MDR-2017
16.0	Case Report Form as per Seventh Schedule of MDR-2017
17.0	Informed Consent Form as per Seventh Schedule of MDR-2017
18.0	Undertaking by the Investigator as per Seventh Schedule of MDR-2017
19.0	Published technical documents/literature (if any)
20.0	Clinical Investigation data generated on the applied device (if any)
21.0	Ethics Committee Approval letter
22.0	Other information (if any)