

CHECKLIST

Form Name: Form MD-22

Category: MD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter,	Yes
2.0	Details on Phase of the study (pilot/pivotal/postmarketing clinical investigation),	Yes
3.0	Whether this study is a global clinical investigation if yes, Number of sites and patients as well as justification for undertaking such clinical investigation in India,	Yes
4.0	Design analysis data as per Table 1 of schedule VII,	No
4.1	Design input and design output documents,	Yes
4.2	Mechanical and electrical tests,	Yes
4.3	Reliability tests,	Yes
4.4	Validation of software relating to the function of the device,	Yes
4.5	Any performance test,	Yes
4.6	Ex vivo tests,	Yes
5.0	Biocompatibility and Animal performance study for Investigational medical device as per Table 2 of schedule VII,	Yes
6.0	The agreement between the Sponsor and Principal and coordinating investigator,	Yes
7.0	Appropriate Insurance certificate, if any,	No
8.0	Forms for reporting any adverse event and serious adverse event,	Yes
9.0	Report of biocompatibility tests along with rationale for selecting these tests including a summary report and conclusion of the study,	Yes

10.0	Results of the risk analysis,	Yes
11.0	Animal Performance study data,	Yes
12.0	Investigators Brochure as per Table 4 of schedule VII,	Yes
13.0	Clinical Investigational Plan as per Table 5 of schedule VII,	Yes
14.0	Case Report Form as per Table 6 of schedule VII,	Yes
15.0	Informed Consent Form as per Table 8 of schedule VII,	Yes
16.0	Undertaking by the Investigator as per Table 9 of schedule VII,	Yes
17.0	Pilot or Pivotal Clinical Investigation data, including that carried out in other countries (if any),	No
18.0	Regulatory status and Restriction on use in other countries (if any) where marketed or approved,	No
19.0	Proposed Instruction for use and labels,	Yes
20.0	Ethics Committee Approval letter as per format prescribed in APPENDIX VIII of Schedule Y of Drugs and Cosmetics Act 1945,	Yes
21.0	Other information, if any,	No
22.0	Fees Challan,	Yes
23.0	Legal Form,	Yes

ENDORSEMENT

RETENTION
