CHECKLIST

Form Name: Form MD-26

Category: MD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Cover Letter	Yes
2.0	Justification for the proposed class of device along with supporting documents	Yes
3.0	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.	Yes
4.0	Design analysis data of the Investigational medical device	No
4.1	Design input, design output and design control documents, etc. along with design verification and validation report	Yes
4.2	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device	Yes
4.3	Device specification including the test parameters and its reference protocol to be carried out on the finished device along with the test report	Yes
4.4	Mechanical test, electrical tests, Reliability tests, software verification & validation, any performance test, Ex vivo tests, etc.(wherever applicable)	Yes
5.0	Stability Study data generated (if any)	Yes
6.0	Risk Management Report on the applied medical device	Yes
7.0	Biocompatibility and Animal performance study data for applied medical device (as applicable)	Yes
8.0	Proposed Labelling information	Yes
9.0	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.	Yes

10.0	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.	Yes
11.0	Clinical Investigation data including that carried out in India or other countries (if any).	Yes
12.0	Details of countries where the investigational medical device is being sold/marketed from last two year (in case of import)	Yes
13.0	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.	Yes
14.0	Details on evidence that there is no theoretical possibility of any difference in the behavior and performance in Indian population	Yes
15.7	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	Yes
16.0	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)	Yes
17.0	Constitution details of domestic manufacturer or authorized agent	Yes
18.0	Other information (if any)	Yes
19.0	Fees Challan	Yes
20.0	Application (Form MD-26)	Yes

ENDORSEMENT

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter,	Yes
2.0	Class of Medical Device(Class A or B or C or D),	Yes
3.0	Design Analysis Data,	No

3.1	Design input and design output documents,	Yes
3.2	Mechanical and electrical tests,	Yes
3.3	Reliability tests,	Yes
3.4	Validation of software relating to the function of the device,	Yes
3.5	Any performance test,	Yes
3.6	In vitro test,	Yes
4.0	Bio-compability tests data, Report of bio-compability tests along with rationale for selecting these tests. Summary report of the biocompatibility study including the conclusion of the study.,	Yes
5.0	Risk Management Data,	Yes
6.0	Animal Performance study data,	Yes
7.0	Pilot or Pivotal Clinical Investigation data, including that carried out in other countries (if any),	Yes
8.0	Regulatory status and Restriction on use in other countires (if any) where marketed or approved,	Yes
9.0	Proposed Instruction for use and labels,	Yes
10.0	Whether the drug is approved for marketing in India. If yes, then details of approval no. and company name and validity of approval etc.,	Yes
11.0	If the drug is not approved in India, the following documents are required to be submitted,	No
11.1	Data on animal toxicology,	Yes
11.2	Data on Reproduction studies,	Yes
11.3	Data on Teratogenic studies,	Yes
11.4	Data on Perinatal studies,	Yes
11.5	Data on Mutagenicity,	Yes
11.6	Data on Carcinogenicity,	Yes
11.7	Chemical and Pharmaceutical information,	Yes

12.0	Whether the medical device(which does not have predicate medical device) indicatedin life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic and medical devices indicated for conditions, diseases for which there is no therapy. If Yes, give brief details.,	Yes
13.0	Data of the investigational medical device if marketed from last two years on,	No
13.1	Safety,	Yes
13.2	Performance,	Yes
13.3	Pharmacovigilance,	Yes
14.4	Detail on evidence that there is no theoretical possibility of any difference in the behavior and performance in Indian population,	Yes
15.0	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.	Yes
16.0	Constitution details of domestic manufacturer or authorized agent require for Class B, C, and D	Yes
17.0	Fee Chalan	Yes
18.0	Legal Form	Yes

RETENTION