Document Checklist – Medical Devices Import License – MD 14 - MD

Section No.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	Power of Attorney (Original) authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille along with under taking from the authorized agent as specified in Part I of Forth Schedule, - Format Available	Yes
3.0	Self-attested copy of valid whole sale licence or manufacturing licence	Yes
4.0	Regulatory Certificate	
4.1	Duly apostilled/notarized copy of Free Sale Certificate/ Marketing Authorization of the product from National Regulatory Authority of country of origin (if any)	Yes
4.2	Duly apostilled/notarized copy of Free Sale Certificate Marketing Authorization of the product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan, Australia.	Yes
4.3	Copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.	Yes
5.0	Notarized copy of Duly notarized valid copies of Quality Certificate in respect of the legal and actual manufacturing site (s) (wherever applicable)	
5.1	Notarized copy of Certificate supporting quality management system (ISO: 13485)	Yes
5.2	Notarized Full quality Assurance Certificate/ CE type examination Certificate/CE product quality asurance	Yes
5.3	Notarized CE design Certificate	Yes
5.4	Notarized Declaration of conformity	Yes
6.0	Plant Master file from the Manufacturer as per Medical devices Rules, 2017	Yes
7.0	Device Master file from the Manufacturer for Medical Devices as per Medical devices Rules, 2017	
7.1	Part 1. Device Master File for Medical Devices as per Medical devices Rules, 2017	Yes
7.2	Part 2. Reference to predicate or previous generations of the device	Yes
7.3	Part 3. Label and IFU	Yes
7.4	Part 4. Device Design and Manufacturing process with flow chart	Yes
7.5	Part 5. Essential Principles Checklist	Yes

7.6	Part 6. Risk analysis and control summary	Yes
7.7	Part 7. Design Verification and validation of the medical device	Yes
7.8	Part 8 .Biocompatibility validation data	Yes
7.9	Part 9. Medicinal substances data if device contains Drug	Yes
7.10	Part 10. Biological Safety (TSE/BSE)	Yes
7.11	Part 11. Sterilization Validation data	Yes
7.12	Part 12. Software verification and validation if software used	Yes
7.13	Part 13. Animal studies Preclinical data	Yes
7.14	Part 14. Stability validation data	Yes
7.15	Part 15. Clinical evidence	Yes
7.16	Part 16. Post Marketing Surveillance data	Yes
7.17	Part 17. Batch Release Certificates or Certificate of Analysis of finished product for minimum 3 consecutive batches	Yes
8.0	Notarized copy of overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority	Yes
9.0	Constitution details of domestic manufacturer or authorized agent require for Class B, C and D	Yes
10.0	Fee Challan	Yes
11.0	Legal Form	Yes