CHECKLIST

Form Name: Form MD-14

Category: MD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	Fee Challan	Yes
3.0	Application (Form MD-14)	Yes
4.0	Power of Attorney along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly 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)	Yes
5.0	Copy of Whole Sale licence / Manufacturing licence / Registration Certificate in Form MD-42 of the Authorized agent	Yes
6.0	Constitution details of the authorized agent	Yes
7.0	Regulatory Certificate	No
7.1	Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any) (duly notarized)	Yes
7.2	Copy of Free Sale Certificate Marketing Authorization of the product isued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia (duly notarized)	Yes
7.3	Copy of overseas manufacturing site / establishment / plant registration, by whatever name called, in the country of origin issued by the competent authority (duly notarized)	Yes
7.4	Copy of latest inspection or audit report carried out by the Competent Authority within last 3 years, if any.	Yes
8.0	Quality Certificate in respect of the actual manufacturing site, as applicable	No
8.1	Copy of Certificate supporting Quality Management System (duly notarized)	Yes

8.2	Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable (duly notarized)	Yes
8.3	Declaration of conformity issued by the manufacturer	Yes
9.0	Plant Master file from the Manufacturer as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017	Yes
10.0	Device Master file from the Manufacturer as per Appendix II of Fourth Schedule of Medical Devices Rules, 2017	No
10.1	Executive Summary	Yes
10.2	Descriptive information of the device	Yes
10.3	Justification for the Medical Device Grouping	Yes
10.4	Product Specification, including variants, accessories, etc	Yes
10.5	Substantial equivalence with reference to the predicate device or previous generations of the device	Yes
10.6	Labelling information (Labels, Instruction for Use, etc)	Yes
10.7	Device Design and Manufacturing Information	Yes
10.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device	Yes
10.9	Risk analysis and control summary	Yes
10.10	Verification and validation of the medical device	Yes
10.11	Biocompatibility validation data (if applicable)	Yes
10.12	Medicinal substances data (if device contains Drug)	Yes
10.13	Biological Safety (TSE/BSE), if applicable	Yes
10.14	Sterilization Validation data (if applicable)	Yes
10.15	Software verification and validation (if software used)	Yes
10.16	Animal studies – Preclinical data (if any)	Yes
10.17	Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable)	Yes
10.18	Clinical evidence (if any)	Yes
10.19	Post Marketing Surveillance data (Vigilance reporting)	Yes

10.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate	Yes
11.0	Any other additional documents	Yes
12.0	Copy of Permission in Form MD-27 (incase of Investigational Medical Device)	Yes

ENDORSEMENT

Section no.	Checklist Name	Is Mandatory
1.0	Covering letter	Yes
2.0	Application (Form MD-14)	Yes
3.0	Fee Challan	Yes
4.0	Power of Attorney along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly 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)	Yes
5.0	Copy of Import License obtained for which the endorsement is applied	Yes
6.0	Regulatory Certificate	Yes
6.1	Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any) (duly notarized)	Yes
6.2	Copy of Free Sale Certificate Marketing Authorization of the product isued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia (duly notarized)	Yes
7.0	Quality Certificate in respect of the actual manufacturing site, as applicable (duly notarized)	Yes
7.1	Copy of Certificate supporting Quality Management System	Yes
7.2	Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable	Yes
7.3	Declaration of conformity issued by the manufacturer	Yes

8.0	Undertaking from the overseas manufacturer stating that there is no major change(s) in the existing Plant Master File (PMF). Otherwise, information as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017 needs to be submitted	Yes
9.0	Device Master file from the Manufacturer as per Appendix II of Fourth Schedule of Medical Devices Rules, 2017	Yes
9.1	Executive Summary	Yes
9.2	Descriptive information of the device	Yes
9.3	Justification for the Medical Device Grouping	Yes
9.4	Product Specification, including variants, accessories, etc.	Yes
9.5	Substantial equivalence with reference to the predicate device or previous generations of the device	Yes
9.6	Labelling information (Labels, Instruction for Use, etc)	Yes
9.7	Device Design and Manufacturing Information	Yes
9.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device	Yes
9.9	Risk analysis and control summary	Yes
9.10	Verification and validation of the medical device	Yes
9.11	Biocompatibility validation data (if applicable)	Yes
9.12	Medicinal substances data (if device contains Drug)	Yes
9.13	Biological Safety (TSE/BSE), if applicable	Yes
9.14	Sterilization Validation data (if applicable)	Yes
9.15	Software verification and validation (if software used)	Yes
9.16	Animal studies – Preclinical data (if any)	Yes
9.17	Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable)	Yes
9.18	Clinical evidence (if any)	Yes
9.19	Post Marketing Surveillance data (Vigilance reporting)	Yes

9.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate.	Yes
10.0	Any other additional documents	Yes
11.0	Copy of Permission in Form MD-27 (incase of Investigational Medical Device)	Yes

RETENTION

Section no.	Checklist Name	Is Mandatory
1.0	An undertaking from the manufacturer stating that there is no change(s) in the existing Device Master File (DMF), Plant Master File (PMF) and Constitution of the firm	Yes
2.0	Post marketing surveillance data (Vigilance reporting) during last 5 yrs. (details of complaints, recall from any country (if any), CAPA taken, etc), duly authenticated by the manufacturer or authorized agent.	No
3.0	Duly notarized valid Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any)	No
4.0	Duly notarized valid Free Sale Certificate Marketing Authorization of the product issued from National Regulatory Authority of any of the following countries viz USA, UK, EU, Canada, Japan or Australia)	Yes
5.0	Copy of Certificate supporting Quality Management System, Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality assurance certificate, CE design Certificate, DOC etc.,	Yes
6.0	POA along with undertaking from the authorized agent as per Part I of Fourth Schedule of MDR, 2017 (duly 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) shall be submitted.	Yes
7.0	Duly Signed Retention Application	Yes
8.0	Fee Challan	Yes