CHECKLIST

Form Name: Form MD-14
Category: MD

FRESH

Section no.	Checklist Name
1.0	Covering Letter
2.0	Fee Challan
3.0	Application (Form MD-14)
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)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)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)
5.0	Copy of Whole Sale licence / Manufacturing licence / Registration Certificate in Form MD-42 of the Authorized agent
6.0	Constitution details of the authorized agent
7.0	Regulatory Certificate
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)Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any) (duly notarized)Copy of Free Sale Certificate/Marketing Authorization of the product issued by the National Regulatory Authority of country of origin (if any) (duly notarized)

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)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)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)
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)Copy of overseas manufacturing site / establishment / plant registration, by whatever name called, in the country of origin issued by the competent authority (duly notarized)Copy of overseas manufacturing site / establishment / plant registration, by whatever name called, in the country of origin issued by the competent authority (duly notarized)
7.4	Copy of latest inspection or audit report carried out by the Competent Authority within last 3 years, if any.
8.0	Quality Certificate in respect of the actual manufacturing site, as applicable
8.1	Copy of Certificate supporting Quality Management System (duly notarized)
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)Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable (duly notarized)Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable (duly notarized)
8.3	Declaration of conformity issued by the manufacturer
9.0	Plant Master file from the Manufacturer as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017
10.0	Device Master file from the Manufacturer as per Appendix II of Fourth Schedule of Medical Devices Rules, 2017
10.1	Executive Summary
10.2	Descriptive information of the device

10.3	Justification for the Medical Device Grouping
10.4	Product Specification, including variants, accessories, etc
10.5	Substantial equivalence with reference to the predicate device or previous generations of the device
10.6	Labelling information (Labels, Instruction for Use, etc)
10.7	Device Design and Manufacturing Information
10.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
10.9	Risk analysis and control summary
10.10	Verification and validation of the medical device
10.11	Biocompatibility validation data (if applicable)
10.12	Medicinal substances data (if device contains Drug)
10.13	Biological Safety (TSE/BSE), if applicable
10.14	Sterilization Validation data (if applicable)
10.15	Software verification and validation (if software used)
10.16	Animal studies – Preclinical data (if any)
10.17	Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable)
10.18	Clinical evidence (if any)
10.19	Post Marketing Surveillance data (Vigilance reporting)
10.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate
11.0	Any other additional documents
12.0	Copy of Permission in Form MD-27 (incase of Investigational Medical Device)

ENDORSEMENT

Section no.	Checklist Name
1.0	Covering letter
2.0	Application (Form MD-14)
3.0	Fee Challan
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)
5.0	Copy of Import License obtained for which the endorsement is applied
6.0	Regulatory Certificate
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)
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)
7.0	Quality Certificate in respect of the actual manufacturing site, as applicable (duly notarized)
7.1	Copy of Certificate supporting Quality Management System
7.2	Copy of Full Quality Assurance Certificate/ CE type examination Certificate/ CE product quality asurance certificate, CE design Certificate, etc as applicable
7.3	Declaration of conformity issued by the manufacturer
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
9.0	Device Master file from the Manufacturer as per Appendix II of Fourth Schedule of Medical Devices Rules, 2017
9.1	Executive Summary
9.2	Descriptive information of the device
9.3	Justification for the Medical Device Grouping

9.4	Product Specification, including variants, accessories, etc.
9.5	Substantial equivalence with reference to the predicate device or previous generations of the device
9.6	Labelling information (Labels, Instruction for Use, etc)
9.7	Device Design and Manufacturing Information
9.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
9.9	Risk analysis and control summary
9.10	Verification and validation of the medical device
9.11	Biocompatibility validation data (if applicable)
9.12	Medicinal substances data (if device contains Drug)
9.13	Biological Safety (TSE/BSE), if applicable
9.14	Sterilization Validation data (if applicable)
9.15	Software verification and validation (if software used)
9.16	Animal studies – Preclinical data (if any)
9.17	Stability study data (Real-time and Accelerated conditions) for the claimed shelf life (if applicable)
9.18	Clinical evidence (if any)
9.19	Post Marketing Surveillance data (Vigilance reporting)
9.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate.
10.0	Any other additional documents
11.0	Copy of Permission in Form MD-27 (incase of Investigational Medical Device)

RETENTION