(A) Checklist for the grant of manufacturing license in Form MD-9 for Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type:	**Fresh application in Form MD-7**
Section no.	Checklist Name
1.0	Covering Letter
2.0	Application (Form MD-7)
3.0	Fee Challan
4.0	Details of the constitution of the firm along with the relevant documents
5.0	The Establishment /Site ownership /Tenacy Agreement
6.0	**Plant Master file as per Appedix I of Fourth Schedule of MDR, 2017**
6.1	General Information of the facility
6.2	Personnel- Organisation chart
6.3	Personnel -Qualification, Experience and responsibilities
6.4	Premises and Facilities
6.5	Plant Layout of premise with indication of scale
6.6	List of equipments and instruments used for manufacturing and testing
6.7	Sanitation
6.8	Production
6.9	Quality Assurance
6.10.	Storage
6.11	Documentation
7.0	**Quality Management System Requirements**
7.1	Undertaking from the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017
7.2	Quality Manual
7.3	Control of Documents
7.4	Control of Records
7.5	Management Responsibility
7.6	Resource management
7.7	Control of production and service provision
7.8	Internal Audit System
7.9	Control of nonconfomting product
7.10	Corrective Action and Preventive Action
7.11	Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of MDR, 2017.
8.0	**Device Master file in the line of Appendix II of Fourth Schedule of MDR, 2017**
8.1	Executive Summary
8.2	Descriptive information of the device
8.3	Justification for the Medical Device Grouping
8.4	Product Specification, including variants and accessories
8.5	Substantial equivalence with reference to the predicate device or previous generations of the device
8.6	Labelling information (Labels, Instruction for Use, etc)
8.7	Device Design and Manufacturing Information

8.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
8.9	Risk analysis and control summary
8.1	Verification and validation of the medical device
8.11	Biocompatibility validation data (if applicable)
8.12	Medicinal substances data (if device contains Drug)
8.13	Biological Safety (if applicable)
8.14	Sterilization Validation data (if applicable)
8.15	Software verification and validation (if software used)
8.16	Animal studies – Preclinical data (if any)
8.17	Stability study data (Real-time and Accelerated conditions)
8.18	Clinical evidence (if any)
8.19	Post Marketing Surveillance data (Vigilance reporting)
8.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate
9.0	Any other additional documents
10.0	Test License obtained in Form MD-13 (if any)
11.0	Copy of Permission in Form MD-27 (incase of Medical device which does not have Predicate medical device)

(B) Checklist for the grant of manufacturing license in Form MD-9 for additional Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type	**Endorsement application in Form MD-7**
Section no.	**Checklist Name**
1.0	Covering Letter
2.0	Application (Form MD-7)
3.0	Fee Challan
4	Copy of manufacturing license obtained under MDR-2017
5.0	**Plant Master file as per Appendix I of Fourth Schedule of Medical Devices Rules, 2017**
5.1	Undertaking from the manufacturer stating that there is no major change in the Plant master file
6.0	**Quality Management System Requirements**
6.1	Undertaking from the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of Medical Devices Rules, 2017 for manufacturing of applied product
6.2	Table the areas showing the environmental requirement for applied product as per Annexure A of Fifth Schedule of Medical Devices Rules, 2017.
7.0	**Device Master file in the line of Appendix II of Forth Schedule of Medical Devices Rules, 2017**
7.1	Executive Summary
7.2	Descriptive information of the device
7.3	Justification for the Medical Device Grouping
7.4	Product Specification, including variants and accessories
7.5	Substantial equivalence with reference to the predicate device or previous generations of the device
7.6	Labelling information (Labels, Instruction for Use, etc)
7.7	Device Design and Manufacturing Information
7.8	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
7.9	Risk analysis and control summary
7.10	Verification and validation of the medical device
7.11	Biocompatibility validation data (if applicable)
7.12	Medicinal substances data (if device contains Drug)
7.13	Biological Safety (if applicable)
7.14	Sterilization Validation data (if applicable)
7.15	Software verification and validation (if software used)
7.16	Animal studies – Preclinical data (if any)
7.17	Stability study data (Real-time and Accelerated conditions)
7.18	Clinical evidence (if any)
7.19	Post Marketing Surveillance data (Vigilance reporting)
7.20	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate
8.0	Any other additional documents
9.0	Test License obtained in Form MD-13 (if any)
10	Copy of Permission in Form MD-27 (incase of Medical device which does not have Predicate medical device)

(C) Checklist for the retention of manufacturing license granted in Form MD-9 for Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type:	**Retention application for Form MD-9**
Section no.	**Checklist Name**
1.0	Covering letter
2.0	Duly Signed Retention Form
3.0	Fee Challan
4.0	Copy of the existing manufacturing licence or its retention (if obtained)
5.0	Copy of endorsement(s) to the existing manufacturing license
6.0	List of the device(s) deleted from the existing manufacturing license along with the reason
7.0	Detailed breakup of the fees deposited in terms of site, risk class of the device and Medical device grouping etc.
8.0	Undertaking from manufacturer stating that there is no change in the Constitution of the Firm.
9.0	An undertaking from the manufacturer stating that there is no major change(s) in the existing Device Master File (DMF) and Plant Master File (PMF)
10.0	Qualification, experience and responsibilities of current competent Technical staff.
11.0	Post marketing surveillance data (Vigilance reporting) during last 5 yrs (details of complaints, recall (if any), CAPA taken, etc), duly authenticated by the manufacturer.
12.0	Any other additional documents.
13.0	Copy of the manufacturing license obtained under MDR-2017 or its retention (if obtained)
14.0	Post Approval Changes taken due to change in name and/or address of the firm, product details (if any)