(A) Checklist for the grant of loan license for manufacturing in Form MD-10 for Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type:	**Fresh application in Form MD-8**
Section no.	Checklist Name
1.0	Covering Letter
2.0	Application (Form MD-8)
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	Agreement between the applicant and the manufacturer whose manufacturing site is to be utilized for the manufacturing of applied device(s)
7.0	Copy of manufacturing license of the manufacturer showing that the their facility is licensed for manufacturing of the same device (s)
8.0	**Plant Master File requirements:**
8.1	Undertaking from the manufacturer (parent firm) stating that there is no major changes in the Plant Master File
9.0	**Quality Management System Requirements:**
9.1	Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017 for manufacturing of applied devices
10.0	**Information on the Device Master File from the Manufacturer:**
10.1	Undertaking from the manufacturer (parent firm) stating that the Device Master File of the approved product applies for the proposed product
10.2	Executive Summary of the applied devices
10.3	Descriptive information of the applied device
10.4	Justification for the Medical Device Grouping
10.5	Product Specification, including variants and accessories of the applied devices
10.6	Labelling Details (Labels and Instruction for Use)
10.7	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
10.8	Risk analysis and control summary
10.9	Biocompatibility validation data (if applicable)
10.10	Sterilization Validation data (if applicable)
10.11	Stability study data (Real-time and Accelerated conditions)
10.12	Post Marketing Surveillance data (Vigilance reporting)
10.13	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate of the approved product
11.00	Any other additional documents

(B) Checklist for the grant of loan license for manufacturing in Form MD-10 for additional Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type:	**Endorsement application in Form MD-8**
Section no.	Checklist Name
1.0	Covering Letter
2.0	Application (Form MD-8)
3.0	Fee Challan
4.0	Agreement between the applicant and the manufacturer whose manufacturing site is to be utilized for the manufacturing of applied device(s)
5.0	Copy of manufacturing license of the manufacturer showing that the their facility is licensed for manufacturing of the same device (s)
6.0	**Plant Master File requirements:**
6.1	Undertaking from the manufacturer (parent firm) stating that there is no major changes in the Plant Master File
7.0	**Quality Management System Requirements:**
7.1	Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR, 2017 for manufacturing of applied devices
7.2	**Information on the Device Master File from the Manufacturer:**
7.3	Undertaking from the manufacturer (parent firm) stating that the Device Master File of the approved product applies for the proposed product
7.4	Executive Summary of the applied devices
7.5	Descriptive information of the applied device
7.6	Justification for the Medical Device Grouping
7.7	Product Specification, including variants and accessories of the applied devices
7.8	Labelling Details (Labels and Instruction for Use)
7.9	Essential Principles checklist for demonstrating conformity to the Safety and Performance of the Medical Device
7.10	Risk analysis and control summary
7.11	Biocompatibility validation data (if applicable)
7.12	Sterilization Validation data (if applicable)
7.13	Stability study data (Real-time and Accelerated conditions)
7.14	Post Marketing Surveillance data (Vigilance reporting)
7.15	Batch Release Certificates or Certificate of Analysis for minimum 3 consecutive batches/ Software version release certificate of the approved product
8.0	Any other additional documents

(C) Checklist for the retention of loan license granted for manufacturing in Form MD-10 for Class C & Class D Medical Devices under Medical Devices Rules, 2017

Form Type:	Retention application for Form MD-10
Sr no	**Title**
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) of the loan licensee
5.0	Copy of endorsement(s) to the existing manufacturing license
6.0	Copy of the existing manufacturing licence or its retention (if obtained) of the parent firm
7.0	List of the device(s) deleted from the existing manufacturing license along with the reason
8.0	Detailed breakup of the fees deposited in terms of site, risk class of the device and Medical device grouping etc.
9.0	Undertaking from manufacturer (loan licensee) stating that there is no change in the Constitution of the Firm.
10.0	An undertaking from the manufacturer (parent firm) stating that there is no major change(s) in the existing Device Master File (DMF) and Plant Master File (PMF)
11.0	Qualification, experience and responsibilities of current competent Technical staff.
12.0	Post marketing surveillance data (Vigilance reporting) during last 5 yrs (details of complaints, recall (if any), CAPA taken, etc), duly authenticated by the manufacturer.
13.0	Any other additional documents.
15.0	Post Approval Changes taken due to change in name and/or address of the firm, product details (if any)