

CHECKLIST

Form Name: Form MD-8

Category: IVD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
1.1	Constitution of the Firm	Yes
1.2	The Establishment /Site ownership /Tenancy Agreement	Yes
2.0	Copy of Duly notarized valid copies of Quality Certificate in respect manufacturing site(s), if any	No
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	Yes
3.0	Plant Master file from the Manufacturer as specified in Appendix 1 of Forth Schedule of Medical Devices Rules	No
3.1	Part-1 Plant Layout of premise with indication of scale	Yes
3.2	Part-2 Organization chart showing the arrangements for key personnel	Yes
3.3	Part-3 Qualification, Experience and responsibilities of key Technical Persons	Yes
3.4	Part-4 List of Equipment and Instruments	Yes
3.5	Part-5 Contract Activities if any	Yes
4.0	Quality Management System	No
4.1	Part-1 Quality Management System as per Fifth Schedule of Medical devices Rules, 2017	Yes
4.2	Part-2 Quality Manual	Yes
4.3	Part-3 Quality Policy	Yes
4.4	Part-4 Control of Documents	Yes

4.5	Part-5 Control of Records	Yes
4.6	Part-6 Management Responsibility	Yes
4.7	Part-7 Internal Audit System	Yes
4.8	Part-8 Preventive and Corrective Action	Yes
4.9	Part-9 Procedure for identifying training needs and ensure that all persons are trained to adequately perform their assigned responsibilities.	Yes
4.10	Part-10 Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of Medical devices Rules, 2017.	Yes
5.0	Device Master file from the Manufacturer as specified in Appendix II (only for Medical Devices) of Forth Schedule of Medical Device Rules. Note: In case of Class A devices, Appendix II is not required.	No
5.1	Part-1	Yes
5.2	Part- 2 Reference to predicate or previous generations of the device	Yes
5.3	Part-3 Label, Product Insert and Pack Size	Yes
5.4	Part-4 Device Design and Manufacturing process with flow chart	Yes
5.5	Part-5 Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device	Yes
5.6	Part – 6 Risk analysis and control summary	Yes
5.7	Part-7 Analytical validation data for Accuracy, Reproducibility, sensitivity and specificity	Yes
5.8	Part-8 Stability (Claimed shelf life, In use Stability and Shipping Stability study report)	Yes
5.9	Part-9 Clinical Evidence data	Yes
5.10	Part-10 Post marketing surveillance data	Yes
5.11	Part-11 Copy of three batches performance evaluation report issued by the central medical device testing	Yes

5.12	Part-12 Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in vitro diagnostic medical device (if available)	Yes
5.13	Part-13 Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits (if applicable)	Yes
5.14	Part-14 Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits (if applicable)	Yes
6.0	Performance Evaluation Report of IVDs only	Yes
7.0	Test License obtained for testing and generation of quality control data	Yes
8.0	Undertaking signed stating that the manufacturing site is in compliance with provision of Fifth schedule	Yes
9.0	Fee Challan	Yes
10.0	Legal Form	Yes

ENDORSEMENT

Section no.	Checklist Name	Mandatory or not
1.0	Covering Letter	Yes
1.1	Constitution of the Firm	Yes
1.2	The Establishment /Site ownership /Tenancy Agreement	Yes
2.0	Copy of Duly notarized valid copies of Quality Certificate in respect manufacturing site(s), if any	No
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	Yes
3.0	Plant Master file from the Manufacturer as specified in Appendix 1 of Forth Schedule of Medical Devices Rules	No
3.1	Part-1 Plant Layout of premise with indication of scale	Yes
3.2	Part-2 Organization chart showing the arrangements for key personnel	Yes
3.3	Part-3 Qualification, Experience and responsibilities of key Technical Persons	Yes
3.4	Part-4 List of Equipment and Instruments	Yes
3.5	Part-5 Contract Activities if any	Yes
4.0	Quality Management System	No

4.1	Part-1 Quality Management System as per Fifth Schedule of Medical devices Rules, 2017	Yes
4.2	Part-2 Quality Manual	Yes
4.3	Part-3 Quality Policy	Yes
4.4	Part-4 Control of Documents	Yes
4.5	Part-5 Control of Records	Yes
4.6	Part-6 Management Responsibility	Yes
4.7	Part-7 Internal Audit System	Yes
4.8	Part-8 Preventive and Corrective Action	Yes
4.9	Part-9 Procedure for identifying training needs and ensure that all persons are trained to adequately perform their assigned responsibilities.	Yes
4.10	Part-10 Table the areas showing the environmental requirement for Medical Devices as per Annexure A of Fifth Schedule of Medical devices Rules, 2017.	Yes
5.0	Device Master file from the Manufacturer as specified in Appendix II (only for Medical Devices) of Forth Schedule of Medical Device Rules. Note: In case of Class A devices, Appendix II is not required.	No
5.1	Part-1	Yes
5.2	Part-2. Reference to predicate or previous generations of the device	Yes
5.3	Part-3 Label, Product Insert and Pack Size	Yes
5.4	Part-4 Device Design and Manufacturing process with flow chart	Yes
5.5	Part-5 Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device	Yes
5.6	Part-6 Risk analysis and control summary	Yes
5.7	Part-7 Analytical validation data for Accuracy, Reproducibility, sensitivity and specificity	Yes
5.8	Part-8 Stability (Claimed shelf life, In use Stability and Shipping Stability study report)	Yes
5.9	Part-9 Clinical Evidence data	Yes
5.10	Part-10 Post marketing surveillance data	Yes
5.11	Part-11 Copy of three batches performance evaluation report issued by the central medical device testing	Yes

5.12	Part-12 Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in vitro diagnostic medical device (if available)	Yes
5.13	Part-13 Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits (if applicable)	Yes
5.14	Part-14 Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits (if applicable)	Yes
6.0	Performance Evaluation Report of IVDs only	Yes
7.0	Test License obtained for testing and generation of quality control data	Yes
8.0	Undertaking signed stating that the manufacturing site is in compliance with provision of Fifth schedule	Yes
9.0	Fee Challan	Yes
10.0	Legal Form	Yes

RETENTION

Section no.	Checklist Name	Mandatory or not
1.0	Covering letter with purpose of application	Yes
2.0	Undertaking duly signed and stamped with designation from manufacturer that there is no change in the Constitution of the Firm.	Yes
3.0	Duly signed Undertaking and stamped with designation from manufacturer stating that there is no change in Plant Master File & Device Master File.	Yes
4.0	Qualification, experience and responsibilities of current competent Technical staff.	Yes
5.0	Post Marketing Surveillance data (Details of Sales, complaints, Recall, CAPA if any).	Yes
6.0	Any other additional documents.	Yes
7.0	Copy of existing manufacturing license (MD-5/MD-6/MD-9/MD-10) for which retention is applied.	Yes
8.0	Post Approval Change Applications (If Any)	Yes
9.0	Retention Fee Challan along with late fees (if any).	Yes
10.0	Duly Signed Retention Form	Yes