CHECKLIST

Form Name: Form MD-3

Category: MD

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 /Tenacy Agreement	Yes
2.0	Copy of Duly notarized valid copies of Quality Certificate in respect manufcturing 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 Appedix 1 of Forth Schedule of Medical Devices Rules	No
3.1	Part 1	Yes
3.2	Part 2	No
3.3	Part 3	No
3.4	Part 4	No
3.5	Part 5	No
3.6	Part 6	No
3.7	Part 7	No
3.8	Part 8	No
3.9	Part 9	No
3.10	Part 10	No

4.0	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. For Class A devices upload information as specified in Part II of Forth Schedule for Medical Devices or IVDs, as the case may be.	No
4.1	Part 1	Yes
4.2	Part 2	No
4.3	Part 3	No
4.4	Part 4	No
4.5	Part 5	No
4.6	Part 6	No
4.7	Part 7	No
4.8	Part 8	No
4.9	Part 9	No
4.10	Part 10	No
4.11	Part 11	No
4.12	Part 12	No
4.13	Part 13	No
4.14	Part 14	No
4.15	Part 15	No
4.16	Part 16	No
4.17	Part 17	No
4.18	Part 18	No
4.19	Part 19	No
4.20	Part 20	No
5.0	Performance Evaluation Report of IVDs only	Yes

6.0	Test License obtained for testing and generation of quality control data	Yes
7.0	Undertaking signed stating that the manufacturing site is in compliance with provison of Fifth schedule	Yes
8.0	Fee Chalan	Yes
9.0	Legal Form	Yes

ENDORSEMENT

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
1.1	Constitution of the Firm	Yes
1.2	The Establishment /Site ownership /Tenacy Agreement	Yes
2.0	Copy of Duly notarized valid copies of Quality Certificate in respect manufcturing site(s), if any	No
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	Yes
4.0	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. For Class A devices upload information as specified in Part II of Forth Schedule for Medical Devices or IVDs, as the case may be.	No
4.1	Part 1	Yes
4.2	Part 2	No
4.3	Part 3	No
4.4	Part 4	No
4.5	Part 5	No
4.6	Part 6	No
4.7	Part 7	No

4.8	Part 8	No
4.9	Part 9	No
4.10	Part 10	No
4.11	Part 11	No
4.12	Part 12	No
4.13	Part 13	No
4.14	Part 14	No
4.15	Part 15	No
4.16	Part 16	No
4.17	Part 17	No
4.18	Part 18	No
4.19	Part 19	No
4.20	Part 20	No
5.0	Performance Evaluation Report of IVDs only	Yes
6.0	Test License obtained for testing and generation of quality control data	Yes
7.0	Undertaking signed stating that the manufacturing site is in compliance with provison of Fifth schedule	Yes
8.0	Fee Chalan	Yes
9.0	Legal Form	Yes

RETENTION

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes

1.0	Covering letter with purpose of application	Yes
1.1	Constitution of the Firm	Yes
1.2	The Establishment /Site ownership /Tenacy Agreement	Yes
2.0	Copy of Duly notarized valid copies of Quality Certificate in respect manufcturing site(s), if any	No
2.0	Undertaking duly signed and stamped with designation from manufacturer that there is no change in the Constitution of the Firm.	Yes
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	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
3.0	Plant Master file from the Manufacturer as specified in Appedix 1 of Forth Schedule of Medical Devices Rules	No
3.1	Part 1	Yes
3.2	Part 2	No
3.3	Part 3	No
3.4	Part 4	No
3.5	Part 5	No
3.6	Part 6	No
3.7	Part 7	No
3.8	Part 8	No
3.9	Part 9	No
3.10	Part 10	No
4.0	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. For Class A devices upload information as specified in Part II of Forth Schedule for Medical Devices or IVDs, as the case may be.	No
4.0	Qualification, experience and responsibilities of current competent Technical staff.	Yes

4.1	Part 1	Yes
4.2	Part 2	No
4.3	Part 3	No
4.4	Part 4	No
4.5	Part 5	No
4.6	Part 6	No
4.7	Part 7	No
4.8	Part 8	No
4.9	Part 9	No
4.10	Part 10	No
4.11	Part 11	No
4.12	Part 12	No
4.13	Part 13	No
4.14	Part 14	No
4.15	Part 15	No
4.16	Part 16	No
4.17	Part 17	No
4.18	Part 18	No
4.19	Part 19	No
4.20	Part 20	No
5.0	Performance Evaluation Report of IVDs only	Yes
5.0	Post Marketing Surveillance data (Details of Sales, complaints,Recall, CAPA if any).	Yes
6.0	Any other additional documents.	Yes
6.0	Test License obtained for testing and generation of quality control data	Yes

7.0	Copy of existing manufacturing license (MD-5/MD-6/MD-9/MD-10) for which retention is applied.	Yes
7.0	Undertaking signed stating that the manufacturing site is in compliance with provison of Fifth schedule	Yes
8.0	Copy of ml along with product list	Yes
8.0	Post Approval Change Applications (If Any)	No
9.0	Retention Fee Challan along with late fees (if any).	Yes
9.0	Total Qty of product mfg during last 3 years Processing of Class C and Class D Products wise domestic and non export purpose manual(Qty wise and value wise)	Yes
10.0	Duly Signed Retention Form	Yes
10.0	Fee Chalan	Yes
11.0	Legal Form	Yes