CHECKLIST

Form Name: Form MD-14

Category: IVD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter,	Yes
2.0	Power of Attorney (Original) 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 along with under taking from the authorized agent as specified in Part I of Forth Schedule,	Yes
3.0	Self-attested copy of valid Whole sale licence or manufacturing licence if any,	Yes
4.0	Regulatory Certificates along with previous import license.(if any)	No
4.1	Notarized copy of overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority,	Yes
4.2	Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin.(if any)	Yes
4.3	Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan, and European Union Countries.	Yes
4.4	copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.	Yes
4.5	copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits,	Yes
4.6	copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits,	Yes
5.0	Quality Management System certificate in respect of legal and actual manufacturing sites(s) (Wherever applicable),	No
5.1	Notarized and valid copy of Quality Management System certificate (ISO 13485) certificate issued by the competent authority,	Yes
5.2	Notarized and valid copy of Production Quality Assurance certificate or Full quality Assurance certificate issued by the competent authority.(if any)	Yes

5.3	Notarized and valid copy of CE design certificate issued by the competent authority.(if any),	Yes
6.0	Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017.,	No
6.1	Part 1,	Yes
6.2	Part 2,	Yes
6.3	Part 3,	Yes
6.4	Part 4,	Yes
7.0	Device Master File for In Vitro Diagnostic Medical Devices as per Appendix – III of Part III of Fourth Schedule of Medical devices Rules, 2017	No
7.1	Part-1 Executive Summary, Description and specification, including variants and accessories and Design & manufacturing information of the in vitro diagnostic medical device	Yes
7.2	Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device).	Yes
7.3	Part – 3 Essential principles checklist	Yes
7.4	Part – 4 Risk analysis and control summary, Product validation and verification and Clinical Evidences	Yes
7.5	Part-5 Analytical studies, Specimen type, Analytical performance characteristics, Analytical sensitivity, Analytical Specificity, Metrological traceability of calibrator and control material values, Measuring range of assay, Definition of assay	Yes
7.6	Part – 6 Claimed Shelf life – stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion, In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion & Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion.	Yes
7.7	Part-7 Product Insert, Pack size, Label	Yes
7.8	Part-8 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter	Yes

7.9	Part-9 Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches/ Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in-vitro diagnostic medical device	Yes
7.10	Part-10 Post Market Surveillance Data and any other information of the product	Yes
8.0	Correlation chart with respect to products list mentioned in MD-14 and FSC submitted,	Yes
9.0	Testing method preferably in Video (if available),	Yes
10.0	Fee Challan	Yes
11.0	Legal Form	Yes

ENDORSEMENT

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter,	Yes
2.0	Power of Attorney (Original) 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 along with under taking from the authorized agent as specified in Part I of Forth Schedule,	Yes
3.0	Self-attested copy of valid Whole sale licence or manufacturing licence if any,	Yes
4.0	Regulatory Certificates along with previous import license.	No
4.1	Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin.(if any)	Yes
4.2	Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan, and European Union Countries.	Yes
4.3	copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.	Yes
4.4	copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits,	Yes
4.5	copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits,	Yes

5.0	Quality Management System certificate in respect of legal and actual manufacturing sites(s) (Wherever applicable),	No
5.1	Notarized and valid copy of Quality Management System certificate (ISO 13485) certificate issued by the competent authority,	Yes
5.2	Notarized and valid copy of Production Quality Assurance certificate or Full quality Assurance certificate issued by the competent authority.(if any)	Yes
5.3	Notarized and valid copy of CE design certificate issued by the competent authority. (if any),	Yes
6.0	Device Master File for In Vitro Diagnostic Medical Devices as per Appendix – III of Part III of Fourth Schedule of Medical devices Rules, 2017	No
6.1	Part-1 Executive Summary, Description and specification, including variants and accessories and Design & manufacturing information of the in vitro diagnostic medical device	Yes
6.2	Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device).	Yes
6.3	Part – 3 Essential principles checklist	Yes
6.4	Part-4 Risk analysis and control summary, Product validation and verification and Clinical Evidences	Yes
6.5	Part-6 Claimed Shelf life – stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion, In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion & Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion.	Yes
6.6	Part-5 Analytical studies, Specimen type, Analytical performance characteristics, Analytical sensitivity, Analytical Specificity, Metrological traceability of calibrator and control material values, Measuring range of assay, Definition of assay	Yes
6.7	Part-7 Product Insert, Pack size, Label	Yes
6.8	Part-8 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter	Yes
6.9	Part-9 Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches/ Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in-vitro diagnostic medical device	Yes
6.10	Part-10 Post Market Surveillance Data and any other information of the product	Yes
7.0	Correlation chart with respect to products list mentioned in MD-14 and FSC submitted,	Yes
8.0	Testing method preferably in Video (if available),	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	Base licence no., issue date	Yes
3.0	End. No.1,2,3,4,5,6...	Yes
4.0	Copy of earlier licences and endorsements.	Yes
5.0	If applicant intends to remove any of the medical device which are approved under the said license/endorsement, then the reason thereof shall be given.	Yes
6.0	Fees breakup as per the class and no. of products including manufacturing site & late fees if any.	Yes
7.0	An undertaking duly signed and stamped by the manufacturer, that there is no change in Device master file (DMF) and Plant master file (PMF).	Yes
8.0	Post marketing surveillance data (Vigilance reporting) during last 5 yrs. including the details of complaints received, recall if any and CAPA, if initiated, duly signed and stamped by authorized agent or manufacturer.	Yes
9.0	Valid Free Sale Certificate/Marketing Authorization of the product from National Regulatory Authority of country of origin (if any) and Free Sale Certificate/Marketing Authorization of the product from National Regulatory Authority of any of the following countries viz USA, EU, UK, Canada, Japan, Australia.	Yes
10.0	Sales data of each device in India during last 5 yrs.	Yes
11.0	Valid copies of Quality Certificate ISO 13485 and CE design certificate, if applicable.	Yes
12.0	An undertaking duly signed and stamped with designation by the manufacturer and authorized agent, stating that they are agreed for further retention of the Import License No, if applicable.	Yes
13.0	Undertaking duly signed and stamped by the manufacturer and authorized Indian agent stating that there is no change in the Power of Attorney (POA). In case any change in a copy of fresh Power of Attorney (Original) as specified in Part I of Forth Schedule may be submitted.	Yes
14.0	Undertaking from the foreign manufacturer that there is no change in the Certificate of Incorporation.	Yes

15.0	Undertaking stating that they shall submit the requisite fees for all the products endorsed in the base license before completion of the five years from the date of issue of the base license. For this purpose, the portal may have option for the applicant	Yes
16.0	Post Approval Change Application (If Any)	Yes
17.0	Bharat kosh receipt	Yes
18.0	Duly Signed Retention Form	Yes