CHECKLIST

Form Name: Form MD-28

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	Constitution details of authorized agent ,	Yes
4.0	Self-attested copy of valid Whole sale licence or manufacturing licence,	Yes
5.0	Regulatory Certificates,	No
5.1	Notarized and valid 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
5.2	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
5.3	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
5.4	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
5.5	copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits,	Yes
5.6	copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits,	Yes
6.0	Quality Management System certificate in respect of legal and actual manufacturing sites(s) (Wherever applicable),	No
6.1	Notarized and valid copy of Quality Management System certificate (ISO 13485) certificate issued by the competent authority,	Yes

6.2	Notarized and valid copy of Production Quality Assurance certificate or Full quality Assurance certificate issued by the competent authority.(if any),	Yes
6.3	Notarized and valid copy of CE design certificate issued by the competent authority.(if any),	Yes
7.0	Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017,	Yes
8.0	Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017.,	Yes
9.0	Device master file as specified in Appendix III of Fourth Schedule of MDR 2017,	Yes
10.0	Device data including, (whichever is applicable),	No
10.1	Design input, Design output documents, Stability data,	Yes
10.2	Device specification including specificity, Sensitivity, Reproducibility and Reputability,	Yes
10.3	Product validation and Software validation relating to the function of the Device (if any),	Yes
11.0	Risk Management Data,	Yes
12.0	Clinical Performance Evaluation data carried out in India and in other countries (if any).,	Yes
13.0	Regulatory status and Restriction on use in other countries (if any) where marketed or approved,	Yes
14.0	Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device,	Yes
15.0	Product Insert,	Yes
16.0	Labelling and Pack Size,	Yes
17.0	Fee Challan,	Yes
18.0	Legal Form,	Yes
19.0	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. ,	Yes
20.0	Stability.,	No

20.1	Claimed Shelf life - stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion,	Yes
20.2	In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion,	Yes
20.3	Shipping stability study report for 1 lot including the protocol, acceptance criteria, simulated conditions , conclusion and recommended shipping conditions,	Yes
21.0	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
22.0	Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter,	Yes
23.0	Correlation chart with respect to products list mentioned in MD-28 and FSC submitted,	Yes
24.0	Testing method preferably in Video (if available),	Yes