

CHECKLIST

Form Name: Form MD-7

Category: IVD

FRESH

| Section no. | Checklist Name | Is Mandatory |
|-------------|---|--------------|
| 1.0 | Covering Letter | Yes |
| 2.0 | Constitution Details of Manufacturer, | No |
| 2.1 | Part 1, | Yes |
| 2.2 | Part 2, | Yes |
| 3.0 | Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017. | 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 |

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| 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 | Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017 | Yes |
| 6.0 | Regulatory certificates | No |
| 6.1 | 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 |
| 6.2 | copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits (if available) | Yes |
| 6.3 | copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits (if available) | Yes |
| 6.4 | valid copy of Quality Management System certificate (ISO:13485) certificate issued by the competent authority .(if any) | Yes |
| 6.5 | Copy of Test licence obtained for testing and generation of quality control data, if any | Yes |
| 6.6 | Self-attested copy of valid Whole sale licence or manufacturing licence if any | 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 | 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 Description and specification, including variants and accessories of the in vitro diagnostic medical device | Yes |
| 7.4 | Part – 4 Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device | Yes |
| 7.5 | Part – 5 Risk analysis and control summary | Yes |

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| 7.6 | Part – 6 Device Design and Manufacturing Information | Yes |
| 7.7 | Part-7 Product validation and verification | Yes |
| 7.8 | Part-8 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 |
| 7.9 | Part – 9 Claimed Shelf life - stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion. | Yes |
| 7.10 | Part-10 In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion for | Yes |
| 7.11 | Part-11 Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion for Part-11 Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion for | Yes |
| 7.12 | Part-12 Clinical Evidence | Yes |
| 7.13 | Part-13 Product Insert, Pack size, Label | Yes |
| 7.14 | Part-14 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter | Yes |
| 7.15 | Part-15 Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in vitro diagnostic medical device | Yes |
| 7.16 | Part-16 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 |
| 7.17 | Part-17 Post Market Surveillance Data | Yes |
| 7.18 | Part-18-Others | Yes |
| 8.0 | Fee Challan | Yes |
| 9.0 | Legal Form | Yes |

ENDORSEMENT

| Section no. | Checklist Name | Mandatory or not |
|-------------|-----------------|------------------|
| 1.0 | Covering Letter | Yes |

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| 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 | Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017 | Yes |
| 6.0 | Regulatory certificates | No |

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| 7.17 | Part-17 Post Market Surveillance Data | Yes |
| 7.18 | Part-18-Others | Yes |
| 8.0 | Fee Challan | Yes |
| 9.0 | 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 |