

CHECKLIST

Form Name: Form MD-39

Category: IVD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	constitution details of testing laboratory	Yes
3.0	Plant Layout of premise with indication of scale	Yes
4.0	Organization chart showing the arrangements for key personnel	Yes
5.0	Qualification, experience of technical staff employed for testing and the person incharge of testing	Yes
6.0	List of equipment's/apparatus/instruments along with manufacturer details	Yes
7.0	Contract Activities (if any)	Yes
8.0	Requirements of Laboratory Quality Management System	Yes
9.0	Procedure for identifying training needs and ensure that all persons are trained to adequately perform their assigned responsibilities	Yes
10.0	List of standard/test method for performing the test	Yes
11.0	List of SOPs.	Yes
12.0	Valid accreditation certificate issued by the National Accreditation Body for Testing and calibration Laboratories or any other similar body as may be notified by the Central Government along with Scope of test for which is accredited Valid accreditation certificate issued by the National Accreditation Body for Testing and calibration Laboratories or any other similar body as may be notified by the Central Government along with Scope of test for which is accredited	Yes
13.0	ISO/IEC Accreditation certificate from Registered Certification body (if any)	Yes

14.0	Fee Challan	Yes
15.0	Legal Form	Yes

ENDORSEMENT

Section no.	Checklist Name	Mandatory or not
1.0	Covering Letter	Yes
2.0	List of qualification, experience of technical staff employed for testing and the person incharge of testing (in case any change in technical staff)	Yes
3.0	List of equipment's/apparatus/instruments along with manufacturer details	Yes
4.0	List of standard/test method for performing the test	Yes
5.0	Valid accreditation certificate issued by the National Accreditation Body for Testing and calibration Laboratories or any other similar body as may be notified by the Central Government along with Scope of test for which is accredited	Yes
6.0	ISO/IEC Accreditation certificate from Registered Certification body (if any)	Yes
7.0	Copy of existing registration certificate in Form MD-40	Yes
8.0	Any other document	Yes
9.0	Application Form in MD-39	Yes