

CHECKLIST

Form Name: Form MD-24

Category: IVD

FRESH

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter,	Yes
2.0	Constitution of the Firm,	Yes
3.0	Device description including specification of raw material and finished product, data allowing identification of the device in question, proposed instruction for use, labels and regulatory status in other countries, if any,	Yes
4.0	In house performance evaluation data used to establish stability, specificity, sensitivity, repeatability and reproducibility,	Yes
5.0	Approval from an Ethics Committee,	Yes
6.0	Clinical performance evaluation plan,	Yes
7.0	Case Report Form,	Yes
8.0	Undertaking by investigators,	Yes
9.0	An undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons,	Yes
10.0	Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19,	Yes
11.0	Fee Challan	Yes
12.0	Legal Form	Yes