

CHECKLIST

Form Name: Form MD-16

Category: IVD

Checklist for the grant of Licence to Import Medical Devices for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	Brief description of the medical device including intended use, material of construction, design	Yes
3.0	Justification of quantity proposed to be imported	Yes
4.0	Test protocol/Approved clinical investigation plan if any	Yes
5.0	Quality certificates like QMS etc., of the manufacturer, if any	Yes
6.0	Labels and IFU, if any	Yes
7.0	Other document, if any	No
8.0	An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial Number 7 of Form-16 and shall not be used for commercial purpose.	Yes
9.0	An undertaking from the testing laboratory, Stating that required facilities including equipment, instrument and personnel will be provided to test or evaluate medical device.	Yes
10.0	Fee Challan	Yes
11.0	Legal Form	Yes