

CHECKLIST

Form Name: Form MD-12

Category: IVD

Checklist for the grant of licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, 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	Quality certificates like QMS etc., of the manufacturer from where the raw material is procured, if any,	Yes
4.0	Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to Manufacture such medical devices	No
5.0	List of equipment, instruments	Yes
6.0	List of qualified personnel	Yes
7.0	Justification of quantity proposed to be manufactured,	Yes
8.0	Test protocol if any,	Yes
9.0	Copy of Manufacturing licence issued under these rules, if any.	Yes
10.0	Approval letter authorizing to undertake research and development activities issued by any government organization, if any	Yes
11.0	Other documents, if any,	No
12.0	Fee Challan	Yes
13.0	Legal Form	Yes