

CHECKLIST

Form Name: Form MD-12

Category: MD

FRESH

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	Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices.	Yes
4.0	List of equipment, instruments	Yes
5.0	List of qualified personnel	Yes
6.0	Justification of quantity proposed to be manufactured,	Yes
7.0	Test protocol if any,	Yes
8.0	Quality certificates like QMS etc., of the manufacturer from where the raw material is procured, 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	Schematic plan of premises	Yes
13.0	Certification of site with detailed raw component	Yes
14.0	Detailed description of how the raw material will be procured so as the entire process is scrutinized	Yes
15.0	Fee Chalan	Yes

16.0	Legal Form	Yes
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ENDORSEMENT

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	Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices.	Yes
4.0	List of equipment, instruments	Yes
5.0	List of qualified personnel	Yes
6.0	Justification of quantity proposed to be manufactured,	Yes
7.0	Test protocol if any,	No
8.0	Quality certificates like QMS etc., of the manufacturer from where the raw material is procured, if any,	No
9.0	Copy of Manufacturing licence issued under these rules, if any.	No
10.0	Approval letter authorizing to undertake research and development activities issued by any government organization, if any	No
11.0	Other documents, if any,	No
12.0	Schematic plan of premises	Yes
13.0	Certification of site with detailed raw component	Yes
14.0	Detailed description of how the raw material will be procured so as the entire process is scrutinized	Yes

15.0	Fee Chalan	Yes
16.0	Legal Form	Yes

RETENTION
