

**Checklist for the grant of Test license to manufacture Medical devices for the purposes of Clinical investigations or test or evaluation or demonstration or training in Form MD-13 under Medical Devices Rules, 2017**

<b>Form Type</b>	<b>Application in Form MD-12 (Medical Devices)</b>
<b>Section no.</b>	<b>Checklist Name</b>
1.0	Covering Letter mentioning the objective of the test license
2.0	Brief description of applied medical device
3.0	Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices.
4.0	List of equipment, instruments for manufacturing and testing of applied medical devices
5.0	List of qualified personnel for manufacturing and testing of applied medical devices
6.0	Justification of quantity proposed to be manufactured along with its utilization breakup
7.0	Test specification and protocol along with applicable standards
8.0	Brief description on the manufacturing and testing process and flowchart
9.0	Copy of Manufacturing license of the premises where the development/testing activity is to be carried out, under these rules, if any
10.0	Approval letter authorizing to undertake research and development activities issued by any government organization, if any
11.0	Other documents, if any,
12.0	Fee Chalan
13.0	Legal Form.