

**Checklist for the grant of Test license to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training under Medical Devices Rules, 2017**

<b>Form Type</b>	<b>Application in Form MD-16 (Medical Devices)</b>
Section no.	Checklist Name
1.0	Covering Letter mentioning the objective of test license
2.0	Brief description of applied medical device
3.0	Justification of quantity proposed to be imported along with its utilization break-up
4.0	Test specification and protocol along with applicable standards
5.0	Quality certificates like QMS etc., of the manufacturer, if any
6.0	Labels and IFU, as per Rule 48
7.0	Other document, if any
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.
9.0	An undertaking stating that required facilities including equipment, instruments, and personnel will be provided to test or evaluate medical devices.
10.0	Fee Challan
11.0	Legal Form