Form MD-25

[See sub-rule (5) of rule 59]

Permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device

Permission No. _____

1. M/s _____(Name and full address of manufacturer with telephone and e-mail) is hereby granted permission to conduct clinical performance evaluation of following new *in vitro* diagnostic device as per clinical performance evaluation plan_____ dated:_____on the below mentioned laboratory(s) or institution(s) involved.

2. Details of new *in vitro* diagnostic medical device and laboratory(s) or institution(s) [Annexed].

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.

Place:_____ Central Licensing Authority

Date:_____ [To be signed digitally]

Annexure:

Details of new *in vitro* diagnostic medical device:

S. N.	Generic name	Intended use	Class of medical device

Details of laboratory(s)/institution(s) involved.

S. N.	Name and address of laboratory(s)/ institution(s)	Ethics Committee details	Name of Principle Investigator