specified in these Rules.

(2) An application for grant of permission to conduct, clinical performance evaluation of new *in vitro* diagnostic medical device shall be made to the Central Licensing Authority in Form MD-24 by the sponsor and shall be accompanied with a fee as specified in the Second Schedule along with information specified in sub-rule (3) duly signed by the sponsor in India:

Provided that no fee shall be required to be paid by the institutes, organisation, hospitals, run by the Central Government or the State Government, involved in conduct of clinical performance evaluation of new *in vitro* diagnostic medical devices.

(3) The information required under sub-rule (2) shall contain the following, namely,-

(i) approval from an Ethics Committee, which is registered with the Central Licensing Authority, as specified in Appendix VIII of the Schedule Y of the Drugs and Cosmetics Rules, 1945 and referred to in the Seventh Schedule;

(ii) source and quantity of samples which shall be used during evaluation;

(iii) device description including specification of raw material and finished product, data allowing identification of the device in question, proposed instruction for use, labels and regulatory status in other countries, if any;

(iv) in house performance evaluation data used to establish stability, specificity, sensitivity, repeatability and reproducibility;

(v) clinical performance evaluation plan stating in particular the purpose, scientific, technical or medical grounds and scope of evaluation;

(vi) Case Report Form as specified in Table 6 of the Seventh Schedule;

(vii) undertaking by investigators as specified in Table 9 of the Seventh Schedule;

(viii) the list of laboratories or other institutions taking part in the evaluation study;

(ix) the scheduled duration for evaluation and, in case of devices for self-testing, the location and number of lay persons involved;

(x) an undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons.

(xi) performance evaluation report from a laboratory designated under sub-rule (1) of rule 19.