Annexure 11

From A **Regulation 4 (3)**

SCHEDULE I

INFORMATION REQUIRED FOR REGISTRATION OF A DEVICE.

1. Name of applicant: -……
2. Address: - ……...
3. Status of applicant : -
   Manufacturer: - ……..
   Importer: - ……..

4. Name of the device: - …….....
   Brand Name (If any): - …….
   Official or approval name: - …….

5. A certificate from the health authorities of the country in which it is produced, confirming that the device is in use there and the period of use and if not, reasons for not marketing it in the country of manufacture.

6. List of countries in which the device is approved or registered for sale.

7. Fully packed samples of the device in the form that will be offered for sale should also be sent to enable study of the product. (If requested)

LABELLING

8. The container of every device imported, manufactured, processed or packed locally or sold or exposed for sale shall have labels bearing the following information clearly indicating.

   a. The brand name ;
   b. Any special storage conditions that may be necessary ;
   c. Any warning and precautions that may be necessary ;
   d. The date of manufacturer ;
   e. The date of expiry where applicable ;
   f. The batch or lot number assigned by the manufacturer ;
   g. The name and address of the manufacturer ;
   h. Adequate directions for use of the device ;
   i. Devices sample license ;
   j. Outer pack ;

9. A sample of the label (s) used on the containers should be supplied.

10. All data should be submitted in English, in a hard file cover in duplicate.

(Applications made without these requirements will not be accepted)

Form B ***Regulation 4 (4)***

SCHEDULE – I

APPLICATION FORMS FOR CERTIFICATE OF REGISTRATION A DEVICE BY AN IMPORTER.

(TO BE FILLED IN TRIPLICATE BY APPLICANT)

I / We
…….....

Of …….

Hereby apply for a registration of the device namely.

……..

Details of which are enclosed herewith.

Date: ……..

Signed …….

Address ……

……

Designation of applicant

…….