Technical Requirements for Application for the Notification of Medical Devices under Class A

- 1. Device description consisting of the following:
 - a. Intended use
 - b. Instruction for use
 - c. List of all raw materials
 - d. Technical specification of the finished product
 - e. List of reference codes, sizes, colors, models and variance, whichever is applicable.
- 2. Certificate of Conformity (issued by government agency dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable
- 3. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable
- 4. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
- 5. Declaration of shelf life