

ANNEX B

Technical Requirements for Application for the Notification of IVD under Class A

1. Device description consisting of the following:
 - 1.2 Intended use
 - 1.3 Instruction for use
 - 1.4 List of all raw materials
 - 1.5 Technical specification of the finished product
 - 1.6 List of references 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