LABELLING CHECKLIST
REQUIREMENTS FOR MEDICAL DEVICES

A. Information mandatory to be marked on the 'Unit pack for sale' of Device.

1. Name / Trade Name of the device.
2. The Name & Address of manufacturer
3. Lot / Batch No.
4. Date of Expiry
5. Indication for single use (if applicable)
6. The word "STERILE" (For Sterile Devices)
7. Caution in event of damage to sterile pack
8. Max. Retail Price

B. If space constraint "unit pack for sale", the following information is also mandatory on secondary pack of Device, user/ consumer can be cautioned by use of caution symbol on the unit pack.

1. Device description
2. Mfg. Lic. No. (if applicable)
3. Date of Mfg.
4. Storage / handling instruction
5. Operating instruction / Instruction for use, where appropriate
6. Method of sterilization (For Sterile Devices)
7. Warning / Precautions & Symbols (if applicable)
8. Customer care –Contact Detail.

Note 1. As far as it is practicable and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and/or on the packaging for each unit, and/or on the packaging of multiples devices.

Note 2. As far as practicable and appropriate, the information needed to use the Device safely to be given on the Device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information to be given in the leaflet/ Information to Use supplied with one or more Devices.

Note 3. Each Device to be accompanied by the information needed to use it safely and

properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

Note 4. **Where appropriate, the information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized Standards. In areas for which no Standards exist, the symbols and colours must be described in the documentation supplied with the Device".** Graphical symbol as per ISO 15223 can be used as appropriate for all of above. Any additional labeling requirement specified in related product standard to be included appropriately.

Note 5. The unit pack can be containing more than one number or type of medical devices.