Labels ; Essential Requirements : Master

13.1 This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out 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 must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device.
By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.
13.2. Where appropriate, this 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.

Requirement	**Yes**	**N/A**
the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;		
the details strictly necessary to identify the device and the contents of the packaging especially for the users;		
where appropriate, the word ‘STERILE’;		
where appropriate, the batch code, preceded by the word ‘LOT’,or the serial number;		
where appropriate, an indication of the date by which the devices hould be used, in safety, expressed as the year and month;		
where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent acrossthe Community;		
if the device is custom-made, the words ‘custom-made device’;		
if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;		
any special storage and/or handling conditions;		
any special operating instructions;		
any warnings and/or precautions to take;		
year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;		
where applicable, method of sterilization;		

Labels ; Essential Requirements : Master

13.1 This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out 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 must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions. **13.2.** Where appropriate, this 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.		
indication that the device contains a human blood derivative.		
If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.		
Comments		
Checked & Signed By ; **Date**		

Table 1: