Appendix C

Medical Devices / Equipment

C.1 will the medical device/item of medical equipment be:

- **Prototype/currently unmarketed product?** **Yes** ☐ **No** ☐
- **New application of an existing product?** **Yes** ☐ **No** ☐

C.2 Details of Medical Devices/Equipment

Please attach any details of manufacturer's recommended usage for existing products.

Approved name

Intended study usage

C.3 Safety data relevant to the protocol usage.

Yes ☐ **No** ☐

If No, please indicate the classification of a company manufactured device under the EC Directive. It relates to the level of risk attached to the product and can be obtained from the manufacturer.

a) Please give details of relevant safety data, including references where appropriate.

C.5 Who will fit the device /use the equipment?

C.6 who is the supplier and how do they ensure appropriate manufacturing quality?

Please supply certification or registration numbers.