**Statement of Compliance**

Manufacturer:

Medical device under investigation:

Clinical investigation plan title:

Clinical investigation reference no. / ID no.:

The manufacturer of the above investigational device(s) hereby confirms that the device(s) under investigation conforms to the essential requirements of the

Choose the appropriate legislation

Medical Device Directive 93/42/EEC OR Active Implantable Medical Device Directive 90/385/EEC

apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient

Date:

Signature

Name

Title (Representative from manufacturer’s management)