manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.	does not have a measuring function.		
10.2. The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.	No - The device does not have a measuring function.		
10.3. The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold	No - The device does not have a measuring function.		
11 Protection against radiation			
11.1. General 11.1.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	No - The device does not emit radiation.		
11.2. Intended radiation 11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	No - The device does not emit radiation.		
11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	No - The device does not emit radiation.		
11.3. Unintended radiation 11.3.1. Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	No - The device does not emit radiation.		
11.4. Instructions for use 11.4.1. The operating instructions for devices emitting radiation should give detailed	No - The device does not emit		

information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	radiation.		
11.5. Ionizing radiation 11.5.1 Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	No - The device does not emit radiation.		
11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	No - The device does not emit radiation.		
11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	No - The device does not emit radiation.		
12. Requirements for medical devices connected to or equipped with an energy source			
12.1. Devices incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	No - The device is non-active.		
12.2. Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	No - The device is non-active.		
12.3. Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.	No - The device is non-active.		
12.4. Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	No - The device is non-active.		
12.5. Devices should be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	No - The device is non-active.		
12.6. Protection against electrical risks 12.6.1 Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	No - The device is non-active.		

12.7 Protection against mechanical and thermal risks 12.7.1. Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	No – There are no hazards of this type.		
12.7.2. Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	No - The device does not vibrate.		
12.7.3 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	No - The device does not emit noise.		
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimise all possible risks.	No - The device is not connected to such energy supplies.		
12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.	No - The device does not generate heat.		
12.8. Protection against the risks posed to the patient by energy supplies or substances. 12.8.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	No - The device does not supply energy.		
12.8.2. Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	No - The device does not supply energy.		
12.8.3. The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.	No - The device does not incorporate indicators and controls.		
13 Information supplied by the manufacturer			
13.1. Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure the intended performance, taking account of the training and	Yes	Labelling complies with recognised standard and with the GHTF guidance.	EN 1041:1998 – *Information Supplied by the Manufacturer with Medical Devices* Refer to GHTF guidance SG1/N009

knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understood. (NOTE: Detailed information on labelling requirements is the subject of a separate document)			*Labelling for Medical Devices.*
14 Clinical Evaluation			
14.1. Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction. Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.	Yes	Clinical bibliography and a summary of clinical performance of the product, its predecessors and competitor devices has been documented and is available to the Regulatory Authority/CAB if required. It is sufficient in itself a further testing of the medical device is not required.	Cross-reference Manufacturer's clinical bibliography and summary of clinical experience.

Appendix C: Additional Recommendations for STEDs provided to regulatory authorities for review/approval

C.1 General

If a manufacturer must provide a STED for review/approval by a Regulatory Authority, the STED must address the Authority's country-specific requirements, which – as an interim measure until full global harmonization of documentation requirements is achieved - may be in addition to the recommendations given in this guidance document.

For example, if national regulations require specific forms or legal statements, then these must be included in the STED

When conformity assessment by a Regulatory Authority to the Essential Principles is required before a device is marketed ("pre-market"), then the manufacturer should provide the STED in the format described in Section 6.0 (see also Annex A2 for deciding when to use the STED).

Even when conformity assessment by a Regulatory Authority to the Essential Principles is not required before a device is marketed, the Regulatory Authority may still request that the manufacturer demonstrate conformity after it is marketed ("post-market"). Post-market assessment may be carried out by means of providing the STED to the Regulatory Authority or by audit of the STED by a Regulatory Authority at the manufacturer's facilities. Special circumstances may necessitate the examination of documentation supporting the STED.

> **EXAMPLE:** For a Class I device in Europe and Canada, and a Class I nonexempt device in the United States, as currently defined by country-specific classification regulations, the Regulatory Authority may request that the manufacturer provide documentation demonstrating conformity to the Essential Principles after the device is marketed. The manufacturer may provide documentation in any one of the four forms described as Options 1 – 4 in Section 6.0 unless the Regulatory Authority stipulates the need for a specific form or documents.

C.2 Cover Page

A covering letter should be at the beginning of a STED provided to Regulatory Authorities for review/approval. The covering letter will explain the purpose of the STED. Country-specific requirements may detail information to include in the Cover Page.

C.3 The Executive Summary

An executive summary provides an overview of the medical device and helps to orient the reviewer. Where the STED is provided to regulatory authorities for review/approval, the

executive summary may be included in a cover page or it may be a separate section of the STED. Country-specific requirements or guidance may indicate what the complete summary should include.

The GHTF recommends that the executive summary include at least the following information:

- an overview of the STED, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the STED; and
- a commercial marketing history of the device including, for example, the countries in which the device is sold, the intended uses and indications in labelling, status of any pending requests for market clearance, important safety or performance related information such as recalls and adverse effects encountered.

C.4 Recommended Test Report Format

A test report should include, as applicable:

i) Report title and other identifying information.
ii) Name and address of facility performing the test.
iii) Name of the responsible person involved.
iv) Dates that testing was initiated and completed.
v) Study plan, results, and conclusions, including, for example:

- the study objective and test hypothesis;
- a description of the test system used including relevant specifications (a diagram may be helpful);
- a description of the differences between the test samples and final specifications, if any;
- deviations from test plan, if any;
- a comprehensive summary of the data in the form and manner specified by the Regulatory Authorities which will allow an independent assessment;
- statistical evaluation of the test results, where appropriate;
- bibliography of all references pertinent to the report.