Appendices

Appendix A1: The Relationship of the STED to the Work of GHTF Study Groups 2, 3 & 4

The GHTF Study Group 3 guidance on quality systems provides harmonized information and recommendations on quality systems subjects, including guidance on design control requirements. Harmonization of quality systems requirements is a building block for harmonization of documentation held by the manufacturer for conformity assessment purposes. The STED provides information related principally to the format of documentation for demonstrating conformity to the Essential Principles by Regulatory Authorities. G HTF Study Group 4 addresses auditing of manufacturer quality systems. Such audits may include the examination of the STED and source documents.

GHTF Study Group 2 work covers activities by manufacturers and regulators in response to a post-market adverse event. Such activities may include the examination of the STED and source documents.

Appendix A2: Decision Process to Determine Whether to Use the STED

A person intending to introduce a new device should first determine if documentation must be provided for regulatory conformity assessment purposes before placing on the market. If so, then the person should contact the Regulatory Authority for the country/ies in which marketing is planned, to determine first whether the globally harmonized approach described in this document may be used for the proposed device and then, if there are any country-specific device guidance or regulations that should be used as supplementary guidance to this GHTF STED document.

> **NOTE:** As an interim measure until full global harmonization of documentation requirements is achieved, a Regulatory Authority may permit use of an STED for only a few specified devices.

Even when provision to a Regulatory Authority is not required for conformity assessment purposes prior to the marketing of the device, the STED can be used for conformity assessment
post-market.

See Figure 2 below for a flow chart of this process.

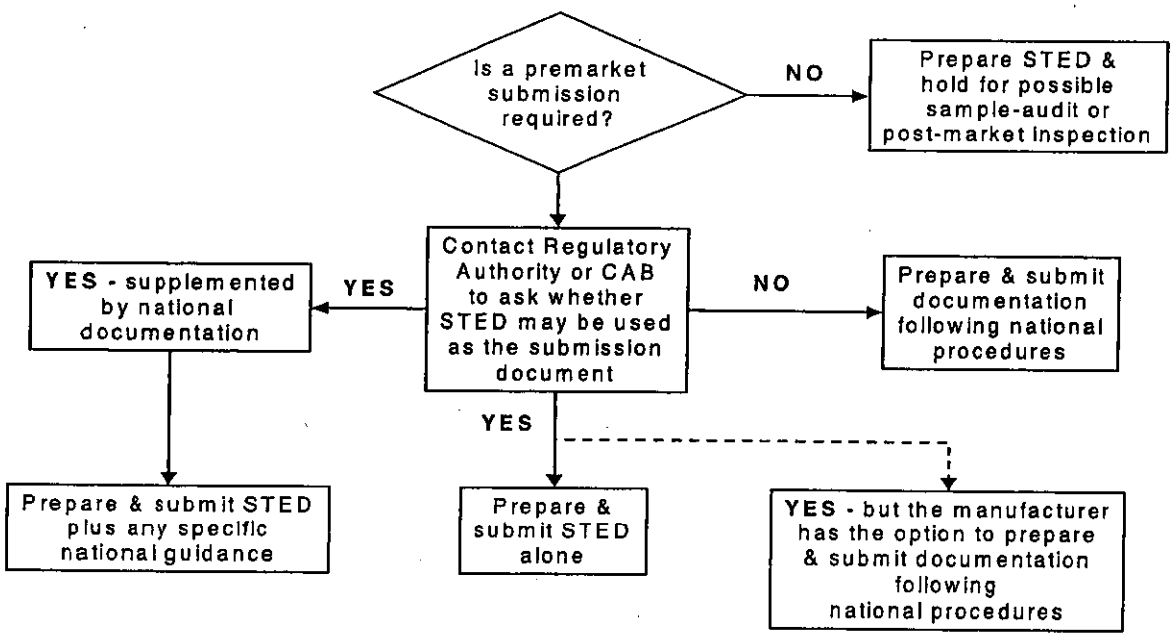

FIGURE 2: DECISION MAKING PROCESS

Appendix B: Essential Principles Conformity Checklist

Essential Principle	Applicable to the device?	Method of Conformity[14]	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: • identify hazards and the associated risks arising from the intended use and foreseeable misuse, • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	Yes		
3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	Yes		
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes		

[14] Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes		
6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.	Yes		
7.1. The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I of the 'General Requirements'. Particular attention should be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
7.2. The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.			
7.3. Etc.			
8. Etc.			
9. Etc.			

EXAMPLE 1: A Class B infusion set intended to be used with an infusion pump to deliver fluids to the body. It is a non-active, single use device that is provided sterile to the user.

Essential Principle	Applicable to the device?	Method of Conformity[15]	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes	Manufacturer's QA system complies with recognised and international standards. Verified through independent audit of the Manufacturer's internal systems by a Conformity Assessment Body.	ISO 9001:1994 – *Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* ISO 13485:1999 - *Specification for the application of ISO 9001 to Medical Devices* ISO 14969:1999 – *Guidance on the Application of ISO 13485 and ISO 13488 to medical devices*
		Sub-contract Assembler has a QA system that complies with recognised and international standards. Verified through independent audit by a Conformity Assessment Body. And by Manufacturer	ISO 9002:1994 - *Quality Systems. Model for Quality Assurance in Production, Installation and Servicing.* ISO 13488:1999 - *Specification for the application of ISO 9002 to the Manufacture of Medical Devices*
		Risk analysis prepared according to Manufacturer's QA system to comply with	ISO 14971 – *Application of Risk Management to Medical Devices*

[15] Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

		recognised standard.	
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: • identify hazards and the associated risks arising from the intended use and foreseeable misuse, • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	Yes	Design and manufacture complies with Manufacturer's internal documented systems since there is no recognised standard for this particular product. Risk analysis complies with recognised standard. No alarms required (Non-active device). Labelling complies with recognised standard. Labelling and instructions provide warnings.	Refer to Manufacturer's quality system documentation. ISO 14971 – *Application of Risk Management to Medical Devices* EN 1041:1998 – *Information Supplied by the Manufacturer with Medical Devices*
3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	Yes	Design and manufacture complies with Manufacturer's internal documented systems. Performance claims consistent with verification documents. Packaging meets international standard.	Refer to Manufacturer's quality system documentation. Refer to GHTF document SG1/N029 *Information Concerning the Definition of the Term "Medical Device".* Refer to Manufacturer's product brochures and specification. EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be	Yes	Manufacturer has a	Refer to GHTF document SG2/N21R8

adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.		documented post-market surveillance procedure that is verified through independent audit. Management Review provides scrutiny of any product problems.	*Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative*
5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes	Packaging complies with international standard.	EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report.
6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.	Yes	Risk analysis complies with recognised standard. Benefits identified and documented through review of clinical performance data of the product and its competition.	ISO 14971 – *Application of Risk Management to Medical Devices*
7. Chemical, physical and biological properties			
7.1. The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I of the 'General Requirements'. Particular attention should be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.	Yes	Manufacturer's QA system complies with recognised standards. Verified through independent audit of the Manufacturer's internal systems by a Conformity Assessment Body. Flammability not a hazard for this product. Mechanical wear etc. not a feature of the product	ISO 9001:1994 – *Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* ISO 13485:1999 - *Specification for the application of ISO 9001 to Medical Devices* ISO 14969:1999 – *Guidance on the Application of ISO 13485 and ISO 13488 to medical devices*

		Documented biocompatibility assessment complies with recognised standard.	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
7.2. The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.	Yes	Documented biocompatibility assessment complies with recognised standard.	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
7.3. The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Yes	Risk analysis complies with recognised standard and covers these features. Documented biocompatibility assessment complies with recognised standard	ISO 14971 – *Application of Risk Management to Medical Devices* EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.	No - Medicines not incorporated into the device.		
7.5. The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that may leach from the device.	Yes	Documented biocompatibility assessment complies with recognised standard	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference biocompatibility report.
7.6. Devices should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is	Yes	Product designed to prevent leaks etc. during normal use using Manufacturer's	Refer to Manufacturer's testing documentation and cross-reference to Test Report

intended to be used.		documented QA system. Performance verified through company testi procedure. Packaging meets international standard.	EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8 Infection and microbial contamination			
8.1. The devices and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and, where applicable, other persons. The design should allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.	Yes	Laboratory and clinical testing by independent Test House shows residual risks are acceptable in normal use. Packaging design complies with international standard and maintains the product in a sterile condition.	Cross-reference Manufacturer's Test Report EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8.2.1. Tissues of non-human origin as far as considered a medical device, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Competent/Regulatory Authority should retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods	No - no materials of this type are incorporated into the product.		

of elimination or viral inactivation in the course of the manufacturing process.			
8.2.2. In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, selection, processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	No - no materials of this type are incorporated into the product.		
8.3. Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Yes	Packaging design complies with international standard and maintains the product in a sterile condition.	EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8.4. Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	Yes	Sterilisation procedures validated and comply with recognised standard.	EN 556 – *Sterilization of Medical Devices. Requirements for Terminally-Sterilised Medical Devices to be Labelled "Sterile"* Cross-reference Manufacturer's Test Report
8.5. Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	Yes	Environmental conditions of manufacture controlled through Manufacturer's QA system by the QA system and controls at the sub-contract sterilisation company. All procedures/systems subject to validation and testing.	EN 556 – *Sterilization of Medical Devices. Requirements for Terminally-Sterilised Medical Devices to be Labelled "Sterile"* Refer to relevant aspects of manufacturing procedures and cross-reference Test Report/s.
8.6. Packaging systems for non-sterile devices should keep the product without	No – device is		

deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.	sterile.		
8.7. The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non-sterile condition.	Yes	Quality assurance procedures of the Manufacturer ensure clear identification of work-in-progress.	
9 Construction and environmental properties			
9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	Yes	Luer connectors comply with international standard.	EN 1707:1997 - *Conical Fittings with a 6% [Luer] Taper for Syringes, Needles and Certain Other Medical Equipment.*
9.2. Devices should be designed and manufactured in such a way as to remove or minimise as far as is practicable: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, • risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	No - The product is small and light. The product is manufactured from non-magnetic materials. The device is non-active. The device is not calibrated		
9.3. Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	No - The device is non-active and does not channel flammable materials		
10 Devices with a measuring function			
10.1. Devices with a measuring function should be designed and	No - The device		