Brand name : _____	**Generic name: _____**	**RISK CLASS: _____**

Clause	Essential Principal	Applicable to the device?	Method of Conformity	Identity of specific Documents
1.	**GENERAL REQUIREMENTS** 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, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and 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.			
2.	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; • eliminate risks as far as reasonably practicable through inherently safe design and manufacture; • reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and • inform users of any residual risks.			

3.	Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that they are suitable for their intended purpose.			
4.	The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user 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.			
5.	Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.			
6.	Medical devices should achieve their intended performance during normal conditions of use. All known, and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance.			
	ESSENTIAL PRINCIPLES APPLICABLE TO MEDICAL DEVICES OTHER THAN IVDDS			
7.	**<u>DESIGN AND MANUFACTURING REQUIREMENTS</u>**			
7.1	<u>Chemical, physical & biological properties</u> The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in clause 6. 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 packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.			
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.			
7.4	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.			
7.5	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate 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 intended to be used.			
8. 8.1	<u>Infection & microbial contamination</u> The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: • allow easy handling, and, where necessary: • reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,			

	• prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person.			
8.2	Devices labelled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
8.3	Devices delivered in a sterile state should be designed, manufactured and packaged 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 transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.			
8.4	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
8.5	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
8.6	Packaging systems for non-sterile devices should maintain the integrity and cleanliness of the product 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.			
8.7	The labelling of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
9. 9.1	**Medical devices incorporating a substance considered to be a medicinal product/drug** 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 performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application,			

10.	**<u>Medical devices incorporating materials of biological origin</u>**			
10.1	In some jurisdictions products incorporating tissues, cells and substances of animal origin may be considered medical devices. In this case, such tissues, cells and substances 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 Regulatory Authority 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 for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
10.2	In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
10.3	In some jurisdictions products incorporating cells and substances of microbial origin may be considered medical devices. In this case, processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
11.	**<u>Manufacturing and environmental properties</u>**			
11.1	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 applying to such combinations			

	should be indicated on the labelling and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and constructed in such a way as to minimize all possible risks from incorrect connection.			
11.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: • the risk of injury to the patient, user or other persons in connection with their physical and ergonomic features, • the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration; • the risks associated with the use of the device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use; • the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; • the risks of accidental penetration of substances into the device; • the risk of incorrect identification of specimens; • 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.			
11.3	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 or use in association with flammable substances or substances which could cause combustion.			
11.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
12.	**Devices with a diagnostic or measuring function.**			

12.1	Devices with a measuring function, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device, based on appropriate scientific and technical methods. The limits of accuracy should be indicated by the manufacturer.			
12.2	Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods.			
12.3	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
12.4	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.			
13. 13.1 13.1.1	**<u>Protection against radiation</u>** General Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
13.2 13.2.1	**<u>Intended radiation</u>** Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible 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 of relevant variable parameters within an acceptable tolerance.			

13.2.2	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.			
13.3 13.3.1	**<u>Unintended radiation</u>** 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 practicable and appropriate.			
13.4 13.4.1	**<u>Instructions</u>** The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse & of eliminating the risks inherent in installation.			
13.5 13.5.1	**<u>Ionising radiation</u>** 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.			
13.5.2	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. .			
13.5.3	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.			

14. 14.1	**<u>Medical devices that incorporate software and standalone medical device software</u>** Devices incorporating electronic programmable systems, including software, or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
14.2	For devices which incorporate software or for standalone software that are devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.			
15.	**<u>Active medical devices and devices connected to them</u>**			
15.1	For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
15.2	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.			
15.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			
15.4	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			
15.5	Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
15.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			

15.7	Devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer			
16.0 16.1	**Protection against mechanical risks** 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.			
16.2	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.			
16.3	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			
16.4	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 minimize all possible risks.			
16.5	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.			
17.0 17.1	**Protection against the risks posed to the patient or user by supplied energy or substances** 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			
17.2	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 or substances from an energy and/or substance source.			
17.3	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.			
18.0 18.1	**Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons** Devices for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.			
18.2	Devices for use by lay persons should be designed and manufactured in such a way as to reduce as far as practicable the risk of error during use by the lay person in the handling of the device and also in the interpretation of results.			
18.3	Devices for use by lay persons should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.			
19.0 19.1	**Label and Instructions for Use** Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood			
20.0 20.1	**Clinical evaluation** For all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation in accordance with GHTF guidance. The clinical evaluation should review clinical data in the form of any: • clinical investigation reports, • literature reports/reviews, and • clinical experience to establish that a favourable benefit-risk			

	ratio exists for the device. **Note:** Further information is provided in GHTF/SG5/N2R8:2007 *Clinical Evaluation.*			
20.2	Clinical investigations[1] on human subjects should be carried out in accordance with 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.			
	Essential Principles applicable to IVDDs			
21.0	**Chemical, physical and biological properties**			
21.1	The IVDDs should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 6. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.			
21.2	The IVDDs should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product.			
21.3	The IVDDs should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the IVDDs. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.			
21.4	IVDDs should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the IVDDs taking into account the device and the nature of the environment in which it is intended to be used.			

[1] See GHTF/SG5/N3:2010 *Clinical Investigations*

22.0 22.1	**Infection and microbial contamination** The IVDDs and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to user, professional or lay, or, where applicable, other person . The design should: allow easy and safe handling; and, where necessary: reduce as far as reasonably practicable and appropriate any microbial leakage from the IVDDs and/or microbial exposure during use; and prevent microbial contamination of the IVDD or specimen where applicable, by the user, professional or lay, or other person.			
22.2	IVDDs labeled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.			
22.3	IVDDs labeled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
22.4	IVDDs intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
22.5	Packaging systems for non-sterile IVDD should maintain the integrity and cleanliness of the product.			
23.0 23.1	**IVDDs incorporating materials of biological origin** Where IVDD include tissues, cells and substances originating from animals, processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVDDs if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVDD or when such elimination or inactivation process would compromise the performance of the IVDD. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals.			
23.2	Where IVDDs include human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the			

	processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVDDs if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVDD or when such elimination or inactivation process would compromise the performance of the IVDD.			
23.3	Where IVDDs include cells and substances of microbial origin, processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVDDs if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVDD or when such elimination or inactivation process would compromise the performance of the IVDD.			
24.0 24.1	**Manufacturing and environmental properties** If the IVDD is intended for use in combination with other devices or equipment, the whole combination, including the connection system should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			
24.2	IVDDs should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: • the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features, • the risk of use error due to the ergonomic features, human factors and the environment in which the IVDD is intended to be used; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof; • the risks associated with the use of the IVDD when it comes			

	into contact with materials, liquids, and gases to which it is exposed during normal conditions of use; • the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; • the risks of accidental penetration of substances into the IVDD; • the risk of incorrect identification of specimens; and • the risks of reasonably foreseeable interference with other devices such as carry over between IVDDs			
24.3	IVDDs 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 IVDDs whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
24.4	IVDDs must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
25.0 25.1	**Performance characteristics** IVDDs should be designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVDD as indicated by the manufacturer.			
25.2	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through available reference measurement procedures and/or available reference materials of a higher order.			
25.3	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device. **Note:** While SG1 generally supports convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognized measurement units.			

26.0 26.1	**Protection against radiation** IVDDs should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as practicable and appropriate			
26.2	When IVDDs are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as practicable and appropriate be: designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and fitted with visual displays and/or audible warnings of such emissions			
27.0 27.1	**IVDDs that incorporate software and standalone IVDD software** For IVDDs which incorporate software or for standalone software that are IVDDs in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.			
28.0 28.1	**IVDDs connected to, or equipped with, an energy source** IVDDs where the safety of the patient depends on an internal power supply in the IVDD, should be equipped with a means of determining the state of the power supply.			
28.2	IVDDs should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
28.3	IVDDs should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
28.4	IVDDs should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVDD is installed and maintained as indicated by the manufacturer.			
29.0 29.1	**Protection against mechanical and thermal risks** IVDDs should be designed and manufactured in such a way as to			

	protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.			
29.2	IVDDs 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.			
29.3	IVDDs 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.			
29.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle should be designed and constructed in such a way as to minimize all possible risks.			
29.5	Accessible parts of the IVDDs (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.			
30.0 30.1	**Protection against the risks posed by IVDDs intended by the manufacturer for self-testing** IVDDs intended for self-testing should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.			
30.2	IVDDs intended for self-testing should be designed and manufactured in such a way as to reduce as far as practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
30.3	IVDDs intended for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.			
31.0	**Label and Instructions for Use**			

31.1	Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. Note: Further information is provided in GHTF/SG1/N43:2005 *Labelling for Medical Devices*			
32.0 32.1	**Performance evaluation including analytical performance and, where appropriate, clinical performance** For an IVDD a performance evaluation should be conducted in accordance with GHTF guidance. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any: • literature; • performance study reports; and • experience gained by routine diagnostic testing. to establish that the IVDD achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimized and acceptable when weighed against the benefits of the intended performance. The depth and extent of a performance evaluation should be appropriate to the nature, intended use and risks of the IVDD, and in accordance with GHTF guidance. **Note:** Further information is provided in GHTF/SG1/N46:2008 *Principles of Conformity Assessment for IVDDs*.			
32.2	Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study from first consideration of the need and justification of the study to publication of the results.			

I declare that the information provided in this form is accurate and correct and the device conforms to all applicable requirements stipulated above.

Name: _____

Signature: _____

Position: _____

Date: _____