APPENDIX A

Essential Requirements BILIBAND™

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I. GENERAL REQUIREMENTS 1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, 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.	Requirements 1 and 2 require the device to be safe and effective. In practice, this is likely to involve a different approach for new (or recently introduced) products and established products. In the case of new products, a manufacturer would typically (i) review the design brief and the design solutions represented in the product specifications. This will include a risk assessment in line with the harmonised standards. (ii) review published literature and his own experience of similar devices. (iii) assess compliance of the product and its packaging to his own specifications and to published standards. (iv) review labelling and (where appropriate) instructions for use. (v) review final release procedures for commercial distribution for the product.	This is a product that has been manufactured in such a way that, when used under the conditions and for the purposes intended will not compromise the clinical condition or the safety of patients, or the safety and health of users.	Performance of units in use in the clinical environment under trial and normal clinical use for over 1½ years	Technical File

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2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: -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 methods adopted	. Risk analysis and Essential Requirements checklist play a key role in documenting evidence for compliance with this requirement. In case of established products, the manufacturer is likely to rest on a documented review of his complaint history	The design and construction of the devices conforms to safety principles, taking account of the generally acknowledged state of the art.	Performance of units in use in the clinical environment. Risk Assessment	Technical File Technical File
3. The devices must achieve the performances 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 referred to in Article 1(2) (a), as specified by the manufacturer.	This is a performance requirement. The manufacturer will need to have evidence that the device complies with his specified requirements. Any test protocols should reflect this. Where the manufacturer is operating a quality system to Annexes II, V or VI of the Directive, this essential requirement will be addressed at least in part by certification of the quality system (Annexes II, V and VI strive in effect for a certification against EN ISO 9001/EN46001, EN ISO 9002/EN46002 and EN ISO 9003).	The NASCOR Oxygen hoods meet the required specification.	Performance of units in use in the clinical environment.	Technical File

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4. The characteristics and performances referred to in sections 1, 2 and 3 must 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.	The manufacturer should be able to demonstrate that he has identified the stresses which occur during the normal conditions of use intended by the manufacturer during the lifetime of the device as expected or indicated by the manufacturer. The manufacturer must then consider any adverse effects and assess whether these are acceptable. The lifetime of the device can be considered to include the period prior to first use, and the period or number of uses expected or recommended by the manufacturer. In practice, such assessments will normally be done by appropriate bench testing, simulated shelf life testing and clinical evaluation if applicable. For established products, the manufacturer would normally rely on a documented review of complaint history.	The characteristics and performances referred to in sections 1, 2 and 3 is not 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.	Performance of units in use in the clinical environment. Risk Analysis	Technical File Technical File
5. The devices must 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.	The manufacturer should be able to demonstrate that he has identified the stresses that can occur during transport and storage in accordance with any instructions and information provided by the manufacturer (see 13.3 i), and adequately addressed these in the design and testing of the device and its packaging. Again for established products, the manufacturer will normally rely on a documented review of complaint history.	The devices is designed, manufactured and packed in such a way that their characteristics and performances during their intended use is not adversely affected during transport and storage.	Performance of units in use in the clinical environment.	Technical File

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6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	This requires identification of undesirable side effects. For new or significantly modified products, the manufacturer will be expected to perform and act upon a risk analysis. For well established products, the manufacturer will be expected to have acted upon experience in use. The manufacturer must ensure that the side effects are not out of proportion to the performances intended by the manufacturer. The documentation of sufficient clinical data is important in this matter. However the analysis which the manufacturer is expected to make must not be confused with the judgement that each user must make as to whether the use of a particular device is justified in the particular clinical circumstances.	The NASCOR BILIBAND™ Have been shown to have no undesirable side-effects.	Documented design control history as the result of feedback from clinical use.	Technical File Design File
II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION 7. Chemical, physical and biological properties 7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the "General requirements". Particular attention must 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 manufacturer should be able to demonstrate that it has chosen materials which are appropriate, given the intended purpose of the device. The risk of toxicity, flammability and bio-compatibility should be examined and may call for particular labelling or instructions for use. Examination of these should have been included in the risk analysis. The manufacturer will often have historic data on materials used in similar products, and this should be reviewed. A biological safety evaluation should be made in accordance with relevant standards, though here again it may well be possible to limit testing by considering past tests on the same or similar materials used for the same or similar applications.	The material used to manufacture the BILIBAND™ is a fully tested clinical bandage material (Kimberley Clark's SBL) which contains no Latex and has been tested and declared safe by the FDA over open skin	Performance of units in use in the clinical environment.	Technical File Part A Section 4

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7.2 The devices must be designed, manufactured and packed 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 the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of the exposure.	Any contaminants and residues in or on the device which could cause significant adverse effects should be identified. This would include solvents; process residues (including sterilisation EtO, chemical); mould release agents; particulate contamination; fluid spillage in the case of medical electrical devices, etc. Once identified, the potential risk to patients or others should be considered and reduced as far as practicable. Particular labelling or instructions may be necessary.	Nil hazard	Risk Assessment : Acceptable risk.	Technical File
7.3 The devices must 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 must 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.	Evidence will be needed that reasonably foreseeable interactions with materials, substances and gases in normal use have been examined. If it is probable that under the intended conditions of use the device may come into contact with materials with which it is incompatible, appropriate warnings must be included in the labelling or instructions for use. Where the device is intended by the manufacturer to be cleaned or disinfected or sterilised, suitable materials should be specified. The effect of ingress of liquids and gases during these procedures will need to be considered. This may call for particular instructions in the documentation supplied with the product.	Clear instructions supplied with each unit	Risk analysis User Instruction	Technical File Part A Section 3 Technical File Part A Section 13
7.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC 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 must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.	See MEDDEV 2.1/3 Guidelines to the demarcation between directive 93/42/EEC on Medical Devices and directive 65/65/EEC relating to Medicinal Products and related directives Example: Heparinised catheter. A consultation process needs to be initiated by the Notified Body at a drug agency (e.g. MCA, BfArM, etc.) A separate file according to MEDDEV 2.1/3 has to be submitted.	Not applicable		
7.5 The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	"Leaking" includes leaching. Risks include those to patients and other persons. Example: EtO-residues after sterilisation, resorption of the device, etc.	Not applicable		

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7.6 Devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	This is the counterpart of 7.5. It should include, for example, reduction of the risk of air leaking into infusion apparatus. Both this and the previous Essential Requirement will normally be addressed by appropriate bench testing and biological safety testing and (if applicable) by clinical evaluation.	Not applicable		
8. Infection and microbial contamination 8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	.Of particular relevance will be sterilisation validation reports and bioburden data, as well as the control of tissue of animal origin.	"One use" disposable product	Risk Assessment User Instructions	Technical File Technical File
8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	MEDDEV 2.5/5 „guidelines on assessment of Medical Devices incorporating materials of animal origin with respect to viruses and transmissible agents has to be considered to comply with this requirement. PrEN 12442 parts 1, 2, 3 outline what is required and how compliance can be demonstrated (risk management, sourcing, inactivation)	Not applicable		

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8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure 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.	Single use sterile products or implants should be presented as far as practicable in a form which facilitates aseptic presentation for use.	Not applicable		
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.	The European sterilisation standards series EN 550 applies~~y~~. ISO and AAMI standards may be used, especially for existing products. A review of sterilisation validation should be made to ensure there are no conflicts with the EN standard and there should be a justification if not used. A brief description of the equipment utilised for sterilisation should form part of the documentation as well as the certification status of the sterilisation subcontractor that might have been used. It needs to be ensured that at least an SAL of 10^{-6} is achieved.	The BILIBAND™ is not delivered or required to be delivered in a sterile state		
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.	It is important to interpret this E.R. in the context of each particular manufacturer's product range and manufacturing process. The extent to which it is necessary or practicable to control the manufacturing environment will vary, and the manufacturer should be allowed flexibility in the choice of method to achieve bioburden and/or particulate levels appropriate to the particular products in question.	Not applicable		
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimize the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.	Packaging validation data and an adequate environmental monitoring system should be sufficient to comply with this requirement.	The packaging meets this requirement	Clinical Performance Packing Method	Technical File Part A Section4 Technical File Part A Section 5

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8.7 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Sterile devices are required by E.R. 13.3 (c) to be labelled "STERILE". Products not so labelled will therefore be considered to be non-sterile. A manufacturer need only label a device "non-sterile" if it produces both sterile and non-sterile versions of the same device such that there might otherwise be confusion. Products made by competitors will have a different trademark and will therefore not be confused with their own products. In any event, it is impracticable for a manufacturer to be expected to know if other manufacturers have on the market or introduce a "sterile" product similar to their own "non-sterile" product.	Not applicable		
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 must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	Through the reviews of the labelling and the compatibility with other products or materials indicated above. Data (e.g. test reports about the compatibility must be available. Example: Extracorporeal Circuit and Heart-Lung-Machine	The unit is complete as supplied. Clear instruction for use is supplied with each device	Technical File User Instruction	Technical File Part A

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9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate the 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.	The first and second indents are, for medical electrical equipment, covered by the EN60601 series. The third indent will be covered by the EN 60601 collateral standard on EMC. The fourth indent only applies where maintenance or calibration are impossible i.e. an implanted device.	Not applicable	Risk Assessment	Technical File
9.3 Devices must 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 must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	EN 60601-1 covers medical electrical equipment for use in flammable atmospheres, however it does not cover oxygen enriched atmospheres. Any special requirements should be covered by the relevant subparts.	Not applicable		

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10. Devices with a measuring function. 10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	This requirement means that the device must perform according to the manufacturer's specification, and that the choice of that specification of accuracy and stability will be justified in the technical documentation, or as required by the relevant subparts of EN 60601.	Not applicable		
10.2 The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	The choice of units is covered by EN 60601 series for medical electrical equipment. Consideration of the ergonomics of the display will need to be demonstrated in the design documentation.	Not applicable		
10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC, as last amended by Directive 89/617/EEC.		Not applicable		
11. Protection against radiation 11.1 General 11.1.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall 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.	Note that this covers all forms of radiation e.g. light, radio frequency and heat. Active medical devices are covered by the EN 60601 series.	Not applicable		Technical File Part A Section 22 and Technical File Part B (full report Technical File Part A Section 22 and Technical File Part B (full report

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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 must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	This requirement should be covered by EN 60601-1, the collateral standard on radiation protection and the relevant subparts.	Not applicable		
11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.		Not applicable		
11.3 Unintended radiation 11.3.1 Devices shall 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.	Note that this requirement is addressed to all forms of radiation. This requirement should be covered by EN60601-1 and the relevant subparts.	Not applicable		Technical File Part A Section 22 and Technical File Part B (full report Technical File Part A Section 22 and Technical File Part B (full report
11.4 Instructions 11.4.1 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 and of eliminating the risks inherent in installation.	This requirement should be covered by EN 60601-1 and the relevant subparts.	Not applicable		

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11.5 Ionizing radiation 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking account the intended use.	This requirement should be covered by EN 60601-1 and the relevant subparts.	Not applicable		
11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.		Not applicable		
11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology shall 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 quality of radiation.		Not applicable		
12. Requirements for medical devices connected to or equipped with an energy source 12.1 Devices incorporating electronic programmable systems must 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.	A collateral standard to EN 60601-1 is under preparation addressing this issue.	Not applicable		
12.2 Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Will be covered by the relevant EN 60601 subparts.	Not applicable		

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12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Will be covered by the relevant EN 60601 subparts.	Not applicable		
12.4	Devices intended to monitor one or more clinical parameters of a patient must 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.	Will be covered by the relevant EN 60601 subparts.	Not applicable		
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Will be covered by completion of Clause 36 of EN 60601-1 by reference to collateral EMC standard and any changes required in the relevant subparts.	Not applicable		
12.6	Protection against electrical risks Devices must 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.	Covered by EN 60601-1 and any relevant subparts.	Not applicable		
12.7 12.7.1	Protection against mechanical and thermal risks Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	"Resistance" in this context means resistance to breakage e.g. "Strength". Covered by EN 60601-1 and any relevant subparts.	Not Applicable.		

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12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible 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.	This requirement should be interpreted in the context of particular products. IEC decided not to address vibration when preparing the second edition of IEC 601-1. In many devices, vibration is unlikely to adversely affect the patient and in other cases it may be precisely intended that the device vibrates. In other cases (e.g. an operating table) it may be critical to minimize vibration. It may also be necessary to avoid vibration which could adversely affect the user.	Not Applicable		
12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible 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.	Hazardous levels of noise are defined in ISO standards, however it is extremely unlikely that any medical devices would approach such levels. Certain equipment will for medical reasons require limits for low noise e.g. baby incubators. If necessary these limits will be defined in the appropriate EN 60601 part 2. Where alarms are fitted, the EN for Audible Alarms will specify minimum sound levels.	Not Applicable		
12.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Covered generally by EN 60601-1 and specifically by the relevant subparts.	Not Applicable		
12.7.5 Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	This requirement should be interpreted in the context of particular devices and for some devices may be impossible to satisfy, e.g. cauter, radiant heat lamps. This E. R. obviously excludes devices or parts of them intended to supply heat. Any hazards to the environment, unless specifically covered by EN 60601 should be covered by labelling and warnings.	Not Applicable		

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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 must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	This ER only applies to devices intended to supply the patient with energy or substances the rate of which can be adjusted. Even if absolute accuracy were assumed this would not guarantee the safety of the patient and user. EN 60601-1 and the relevant subparts apply.	Not Applicable		
12.8.2 Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	This is covered generally by EN 60601-1 and specifically by any relevant subparts.	Not Applicable		
12.9 The function of the controls and indicators must 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 must be understandable to the user and, as appropriate, the patient.	The requirement only applies to adjustable controls (i.e. not internal control mechanisms). Covered generally by EN 60601-1 and specifically by any relevant subparts.	Not Applicable		

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13. Information supplied by the manufacturer. 13.1 Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or Class IIa if they can be used safely without any such instructions.	Guidance as to interpretation of the Essential Requirements relating to labelling and instructions for use is to be found in the EUCOMED document entitled "Guidance on interpretation of requirements relating to labelling and instructions for use". This should be read alongside the harmonised labelling and instructions for use standards EN 980 (c and pr EN 1041+. The EUCOMED document also includes illustrative examples of labelling which would comply with the Directive. In case product specific standards require particular label requirements, those have to be followed, too.	Detailed insert in each sealed package	User Instructions Printed instructions on device	Technical File
13.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.		Graphics and pictures are used in the Instruction to make such instruction as clear as possible	User Instructions	

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13.3 The label must bear the following particulars: a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14. (2) or of the authorised representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; b) the details strictly necessary for the user to identify the device and the contents of the packaging; c) where appropriate, the word "STERILE"; d) where appropriate, the batch code, preceded by the word "LOT", or the serial number. e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; f) where appropriate, an indication that the device is for single use; g) if the device is custom-made, the words "custom made device"; h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; i) any special storage and/or handling conditions; j) any special operating instructions; k) any warnings and/or precautions to take; l)year of manufacture for active devices other than those covered by e). This indication	EN 980 (graphical symbols) can be used for terminally sterilised products. The labelling of a Medical Device needs to be very clear and should avoid any kind of confusion (e.g. between manufacturer, manufacturing facility, manufactured by, etc.). The responsible MANUFACTURER of the device needs to be identified in prominent form on the label. „Where appropriate" means „where applicable"		User Instructions Labels	Technical File

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13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.			User Instructions Stickers on each device	Technical File
13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.			User Instructions	Technical File

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13.6 Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in section 13.3, with the exception of d) and e); b) the performances referred to in section 3 and any undesirable side effects; c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; e) where appropriate, information to avoid certain risks in connection with implantation of the device; f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation; h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfecting, packaging and, where appropriate, the method of sterilisation of the device to be re-sterilised, and any			User Instructions	Technical File

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14 Where conformity with the essential requirements must be based on clinical data, as in section I (6), such data must be established in accordance with Annex X.	See Notified Body Recommendation NB-MED/2.7/Rec1 Guidance on clinicals This should not be taken to imply that clinical investigation of the device on human subjects will necessarily be required, nor that clinical data are only needed for class IIb or class III products.		Not applicable	