TELEDYNE
ANALYTICAL INSTRUMENTS
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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
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 intended 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. This shall include: — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	• Device Compliance Matrices • ISO 21647 (ISO 7767) • EN/IEC 60601-1, 3rd Edition • EN/IEC 60601-1-2 • MDD 93/42/EEC with M5 amendments • ISO 13485:2003 • BS EN ISO 14971	Yes	Qualification Test Reports	Sections 4.1 & 6
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 measures adopted.	• Device Risk Analysis • BS EN ISO 14971	Yes	Device Risk Analysis Software Analysis Product Features	Sections 2.4, 3, 5.1 & 5.6
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.	• Device Compliance Matrices • EN/IEC 60601-1 3rd Edition • ISO 21647 (ISO 7767) • EN/IEC 60601-1-2 • Shock/Drop Test	Yes	Qualification Test Reports Compliance Matrices	Sections 4.1 & 6

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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.	• Device Compliance Matrices • EN/IEC 60601-1 3rd Edition • ISO 21647 (ISO 7767) • EN/IEC 60601-1-2	Yes	No known design/operational risks introduced that could adversely affect the user or related personnel when the devices are used in accordance with the indications of use. According to the MTBF study of similar instruments, the expected service life for AX/MX devices reach be thirty (30) years. The R17MED oxygen sensor has an expected life of 36 months in air when used at room temperature. Alkaline batteries have an estimated 2,000 hours of life on continuous use when used on non-alarm conditions.	Sections 3.2, & 6
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.	• Device Compliance Matrices • Packaging Validation • ISO 21647 (ISO 7767)	Yes	Compliance Matrices Storage Temperature Test Packaging Validation Operator's Manual	Sections 2.5, 4.1, 6.13 & 6.17
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	• Device Risk Analysis	Yes.	Risk Analysis	Section 5.6
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	• NB-MED/2.7/REC3 • MEDDEV 2.7.1 rev 3	Yes	Laboratory Tests conducted along with predicate devices. Clinical Evaluation Reports.	Section 6.16
II	**REQUIREMENTS REGARDING DESIGN & CONSTRUCTION**				
7	**Chemical, Physical and Biological properties**				

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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, — where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand	• Device Compliance Matrices • BS EN ISO 14971 • ISO 21647 (ISO 7767) • EN 60601-1, 3rd Edition • CAN/CSA22.2 No. 601.1 • Materials used are non-toxic and inert. (Sensors have a caustic substance, and Instructions for Use has requisite warnings). • Devices are not intended for contact with tissues, cells or fluids.	Yes	The choices of materials have not changed since their regulatory listings. No toxicity issues have been reported since the devices have been placed on the market. Biocompatibility & Toxicity Analyses Risk Analysis Product Labeling (Sensor Specification Sheets)	Sections 2.4, 5.6 & 6.18
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 exposure.	• Packaging Procedure • Device Risk Analysis • Devices are non-sterile	Yes	Packaging Procedure WH402 Operator's Manual Product Labeling Risk Analysis	Sections 2.4, 2.5, 3.7 & 5.6
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.	• Device Compliance Matrices • Intended Use Statement • Purpose & Objective Statement • Instructions for Use	Yes	Materials used for sensor wetted parts are compatible with the oxygen and other healthcare related gases such as common anesthesia agents. - Qualification Tests - Indications of Use statement	Sections 1.1, 1.3, 2.5, 4.1 & 6.6
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 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of	• Not Applicable – The devices do not incorporate as an integral part a device that could be a medicinal product. Nor do they incorporate as an integral part, a human blood derivative.	Not Applicable. No parts integral to the devices are medicinal products or human blood derivatives.	Not applicable	Not applicable

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	the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The				

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	notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure				
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. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	• Leak Test Procedure (in-house test procedure)	Yes	Sensor Test Procedure (TP-48785) Process Control Procedures are in place to screen for sensors that fail the leak tests.	Section 4.4
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.	• Device Compliance Matrices • EN/IEC 60601-1, 3rd Edition	Yes	Qualification Testing	Sections 4.1 & 6.1
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 Compliance Matrices • Risk Analysis • ISO 21647 (ISO 7767)	Yes	Design allows for easy handling and cleaning of devices when necessary. - Sensor Specification Sheet	Sections 2.4, 2.5, 4.1 & 5.6

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	device by the patient or vice versa during use.			- Operator's Manual - Product Labeling - Risk Analysis	
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 transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	• Not Applicable. The devices do not use any tissues of animal origin.	Not Applicable. Devices do not have any tissues of animal origin.	Not applicable.	Not applicable.
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 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.	• Not Applicable because the devices are not delivered in a sterile state and are labeled as Non-Sterile.	Not Applicable because the devices are delivered in a non-sterile state and are labeled as Non-Sterile.	Not applicable	Not applicable
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	• Not Applicable – Devices are supplied in a sterile state	Not Applicable – Devices are non-sterile.	Not applicable	Not applicable
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	• Not Applicable. Non-sterile devices.	Not Applicable – Devices are non-sterile.	Not applicable	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 sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	• Packaging Procedure • Devices are non-sterile devices	Yes	Packing Procedure Sensor Leaflet Operator's Manual Product Labeling	Sections 2.4, 2.5 & 3.7
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile	• All of our devices are sold in non-sterile condition.	Yes, as we dell devices only in non-	Not applicable. Devices are non-sterile.	Sections 2.4, 2.5 & 3.7

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	condition.		sterile state.		
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	• Operator's Manual • Device marketing brochures and specifications • EN/IEC 60601-1, 3rd Edition	Yes	Devices are designed as stand-alone devices. The sensors used in the devices, which in themselves are classified as medical devices, are designed for easy integration with the devices via signal cables. Restrictions on use are specified on the Operator's Manual and Sensor/Analyzer leaflet	Sections 2.4 & 2.5
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 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.	• Device Compliance Matrices • EN60601-1, 3rd Edition • EN60601-1-2 • ISO 21647 (ISO 7767) • Not Applicable because the devices are not implantable. Devices are expected to be calibrated before every use.	Yes	Qualification Test Reports Safety Requirements & Electromagnetic Compatibility Device Compliance Matrices	Section 3.8, 4.1, 6.1 & 6.2
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.	• Risk Analysis • IEC 60601-1, 3rd Edition	Yes	Operator's Manual Risk Analysis	Sections 2.5 & 5.6

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10	**Devices with 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.	• Device Compliance Matrices • ISO 21647 (ISO 7767)	Yes	Qualification Test Reports Product Similarity Statement Intended Use Statement Operator's Manual Relevant specification is "accuracy" in the Compliance Matrices.	Sections 1.3, 2.5, 6.4, 6.5, 6.7, 6.8, & 6.9
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.	• Device Compliance Matrices • ISO 21647 (ISO 7767)	Technical file has two user testimonials. The Devices have been built with large back-light displays, and easy to use when on its base.	Qualification Testing Device Compliance Matrices	Sections 4.1, 6.4, 6.6 & 6.7
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.	• Device Compliance Matrices • ISO 21647 (ISO 7767)	Yes	Meets ISO 7767 requirements on Section 8, Clause 50.5 Relevant specification is "Range" in the Compliance Matrices.	Sections 4.1 6
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.	• Not Applicable because the devices do not emit radiation	Not Applicable because devices do not emit radiation	Not applicable	Not applicable

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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.	• Not Applicable because devices do not emit radiation.	Not Applicable because devices do not emit radiation.	Not applicable	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 because devices do not emit radiation.	Not Applicable because devices do not emit radiation.	Not applicable	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.	• Not Applicable because devices do not emit radiation.	Not Applicable because devices do not emit radiation.	Not applicable	Not applicable
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.	• Not Applicable because devices do not emit radiation.	Not Applicable because devices do not emit radiation.	Not applicable	Not applicable
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 into account the intended use.	• Not Applicable – Devices do not emit ionizing radiation	Not Applicable – Devices do not emit ionizing radiation	Not applicable	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 minimizing radiation exposure of the patient and	• Not Applicable – Devices do not emit ionizing radiation	Not Applicable – Devices do not emit ionizing radiation	Not applicable	Not applicable

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	user.				
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 – Devices do not emit ionizing radiation	Not Applicable – Devices do not emit ionizing radiation	Not applicable	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.	• Software Specification • Risk Analysis • EN 60601-1-4	Yes	Risk Analysis Software Description & Validation The software in the devices allow minimal programming for keeping the calibration data or setting alarms, and as such, do not qualify as the commonly known programmable devices.	Section 5.6
12.1a	For devices which incorporate software or which are medical software 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.	• Software Specification • Risk Analysis • EN 60601-1-4	Yes	Risk Analysis Software Description & Validation	Section 5.6
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.	• Device Compliance Matrices • ISO 21647 (ISO 7767) • IEC/EN 60601-1, 3rd Edition	Yes	Battery Status Indictor Device Compliance Matrices	Sections 4.1, 6.14 & 6.15
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.	• Not Applicable • Unit is battery operated. No external power source required.	Not Applicable Unit is battery operated. No external power source required.	Not applicable	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	• Device Compliance Matrix (MX300 and MX300-I only) • ISO 21647 (ISO 7767) • IEC/EN 60601-1, 3rd Edition	Even though product and documentation references have	Qualification Testing Operator's Manual Oxygen Level Alarms-Audible and	Sections 2.5, 3.5, 4.1 (MX300 & MX300-I), 6.4, 6.5 & 6.10

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	the patient's state of health.		been made in the requirement, this Essential Requirement itself is not applicable because of the non-clinical nature of the Devices.	Visual Compliance Matrix, relevant spec is alarms.	
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.	• IEC/EN 60601-1-2 • ISO 21647 (ISO 7767)	Yes	Qualification Test Reports, EMC Test.	Section 6.2
12.6	*Protection against electrical risks*				
12.6.1	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.	• Not Applicable - Devices cannot administer a shock because there is no circuit in the design that would produce sufficient voltage to produce shock.	Based on the study of EN 60601-1, this requirement is deemed not applicable.	Based on the study of EN 60601-1, this requirement is deemed not applicable.	Not applicable
12.7	*Protection against mechanical and thermal risks*				
12.7.1	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.	• IEC/EN 60601-1, 3rd Edition • Shock Test	Yes	Qualification Test Reports	Sections 6.1 & 6.3
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.	• Not Applicable because the devices do not vibrate.	Not Applicable because the devices do not vibrate.	Not applicable	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.	• Not Applicable because the devices do not emit noise during normal operation. MX300 & MX300l devices have audible alarms.	Not Applicable because the devices do not emit noise.	Not applicable	Not applicable

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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.	• Not Applicable because the devices are battery powered devices.	Not Applicable because the devices are a battery powered device.	Not applicable	Not applicable
12.7.5	Accessible parts of the 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.	• Not Applicable because the devices generate no heat.	Not Applicable because the devices generate no heat.	Not applicable	Not applicable
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.	• Not Applicable - Devices do not deliver any energy or substances.	Not Applicable - Devices do not deliver a substance or energy.	Not applicable	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.	• Not Applicable- Product is flow insensitive.	Not Applicable- Product is flow insensitive.	Not applicable	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.	• Operator's Manual • IEC/EN 60601-1, 3rd Edition	Yes	Front panel indicators & control areas clearly labeled and determined by inspection. -Product Labeling -Operator's Manual	Sections 2.4, 2.5 & 3.1
13	**Information supplied by the manufacturer**				
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	• Operator's Manual • Sensor Specification Sheet	Yes	Operator's Manual contains information needed to use the device safely and effectively. -Product Labeling	Sections 2.4, 2.5 & 6.1

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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
	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 IIa if they can be used safely without any such instructions.	• EN/IEC 60601-1, 3rd Edition		-Sensor Leaflet -Qualification Test Report, General Requirements for Safety	
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	• Operator's Manual • EN/IEC 60601-1, 3rd Edition • EN 980	Yes	Operator's Manual Product Labeling Qualification Test Report, General Requirements for Safety	Sections 2.4, 2.5 & 6.1
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 the authorized representative where the manufacturer does not have a registered place of business in the Community;	• Operator's Manual • MDD93/42/EEC, with M5 amendments • Sensor Specification Sheet • Sensor/Analyzer Warning Information (sheet or IFU) • EN 980	Yes	Product & Packaging Labels Sensor Leaflet Operator's Manual Medical Oxygen Sensor/Analyzer Warning Information Form	Sections 2.4 & 2.5
	(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	• Sensor/Analyzer Specification Sheet and Label/Labeling	Yes	Label identifies device and leaflets the content.	Section 2.4
	(c) where appropriate, the word 'STERILE';	• Not Applicable-Devices are marked as non-sterile.	Not Applicable-Devices are marked as non-sterile.	Not applicable	Not applicable
	(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	• Devices are identified by their Serial Numbers.	Yes	Information on the Labels	Device History Record and Customer Order files.

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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	• Devices have no expiration dates. Manufactured Date is encoded on the label.	Devices have no expiration dates. Manufactured Date is encoded on the label.	Information on the Labels	Device History Record.
	(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;	• Not Applicable -Devices are not designed as single-use devices.	Not Applicable - Devices are not designed as a single use device.	Not applicable	Not applicable
	(g) if the device is custom-made, the words 'custom-made device';	• Not Applicable -Devices are not custom made.	Not Applicable - Devices are not custom made.	Not applicable	Not applicable
	(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	• Not Applicable-Devices are placed in the market for commercial sales.	Not Applicable-Devices are not designed exclusively for clinical investigations.	Not applicable	Not applicable
	(i) any special storage and/or handling conditions;	• Instructions for Use	Yes	Storage/handling requirements are disseminated via the IFU	Section 2.5
	(j) any special operating instructions;	• Sensor Specification Sheets & Operator's Manual	Yes	Operating instructions are disseminated through the IFU	Sections 2.4, 2.5, 3.4 & 3.5
	(k) any warnings and/or precautions to take;	• Sensor Specification Sheet • IEC/EN 60601-1, 3rd Edition	Yes	Product Label, Operator's Manual, Qualification Report, Sensor Leaflet	Sections 2.4, 2.5 & 6.1
	(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	• EN 980 • Sensor's Label	Yes	Product Label Operator's Manual	Sections 2.4 & 2.5
	(m) where applicable, method of sterilization;	• Not Applicable-Devices are shipped marked non-sterile.	Not Applicable-Devices are shipped marked non-sterile.	Not applicable	Not applicable
	(n) in the case of a device within the meaning of Article 1(4a), an	• Not Applicable-The devices do not incorporate any human	Not Applicable-The devices do not	Not applicable	Not applicable

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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
	indication that the device contains a human blood derivative.	blood derivatives.	incorporate a human blood derivative.		
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.	• The scope and purpose of the devices are clearly defined in Operator's Manual.	Yes	Operator's Manual	Sections 1.3 & 2.4
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.	• There is no appreciable risk from detachable components.	Yes	Only detachable component in the devices is the battery compartment door.	Not applicable
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);	• Operator's Manual • Sensor Specification Sheet	Yes	Operator's Manual Sensor Specification Sheet	Sections 2.4 & 2.5
	(b) the performances referred to in Section 3 and any undesirable side-effects;	• Operator's Manual • Sensor Specification Sheet • There are no side effects.	Yes	Operator's Manual Sensor Specification Sheet	Sections 2.4 & 2.5
	(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;	• Oxygen Analyzers and Monitors do not have to be connected to other medical equipment to satisfy their intended uses.	Devices do not have to be connected to other medical equipment.	Not applicable	Not applicable
	(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;	• Operator's Manual	Yes	Operator's Manual	Sections 2.5 & 3
	(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	• Not Applicable • Devices are non-implantable devices.	Non-implantable devices.	Not applicable	Not applicable
	(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	• Devices are CE marked and have undergone EMC compatibility tests. • EN 60601-1-2	Devices have undergone the EMC tests. No known risks of reciprocal interference have been reported since	Qualification Test Report EMC	Section 6.2

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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
			they have been put into service.		
	(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	• Not applicable. Devices are not designed to be sterilized.	Not applicable as the devices are non-sterile devices.	Not applicable	Not applicable
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I. If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;	• Operator's Manual • Sensor Specification Sheet • Devices are non-sterile devices, and do not need to be sterilized. • Devices are not designed as single use devices.	Yes, where applicable	Operator's Manual Sensor Specification Sheet The sterilization and single-use statements in the "Description" column are not applicable.	Sections 2.4, 2.5 & 3.7
	(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	• Operator's Manual	Yes	Units must be calibrated periodically and before every use as indicated in the IFU.	Sections 2.4, 2.5 & 3.4
	(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:	• Not Applicable-The devices do not emit any radiation.	Not Applicable-The devices emit no radiation.	Not applicable	Not applicable
	(k) precautions to be taken in the event of changes in the performance of the device;	• Operator's Manual and Sensor Specification Sheet.	Yes	Precautions to be taken are indicated on relevant documents.	Sections 2.4 & 2.5
	(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	• Sensor Specification Sheet.	Yes	Precautions to be taken are indicated on relevant device documents.	Section 2.4

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Essential Requirements (MDD Annex I)	Description	Harmonized Standards, Codes & Regulations, and References & Comments	Do we comply?	Method of Compliance & Comments	Technical File Location
	(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	• Not Applicable-Devices do not deliver any medicinal products.	Not Applicable-Devices deliver no medicinal product.	Not applicable	Not applicable
	(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	• Sensor Specification Sheet • Operator's Manual	Yes	Proper disposal of the sensor is described on the Sensor Specification Sheet and Operator's Manual.	Sections 2.4 & 2.5
	(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	• Not Applicable-There are no medicinal substances or human blood derivatives incorporated.	Not Applicable	Not applicable	Not applicable
	(p) degree of accuracy claimed for devices with a measuring function;	• Sensor Specification Sheet • Operator's Manual	Yes	Degree of Accuracy is stated on the device specification sheets and in the IFU -Performance Spec -Qualification Tests	Sections 2.5, 4.1 & 6
	(q) date of issue or the latest revision of the instructions for use.	• Operator's Manual	Yes	Information on the IFU	Section 2.5

Prepared by			Approved by		
Signature		7-17-13 Date	Signature		July 17, 2013 Date
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