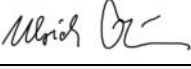


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Essential Requirements according to MDD for VM-2160 with SMARTsat technology

- Pulse Oximeter Monitor with reusable and disposable sensors -

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Valid from: 06.12.2019

Revision history:

Rev.	Effective date	Author	Change
0	06.12.2019	H. Fröhlich	Initial version only for model VM-2160 in this format. This document is based on the Master Model File "TF-04-01-0005 rev.2"

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1 Purpose

The object of this document is to verify the compliance of the medical devices listed on chapter 3 to the Essential Requirements according to MDD 93/42/EEC, Annex I as amended by 2007/47/EC.

2 Scope

This compliance verification applies to *bluepoint medical* manufactured medical devices listed on chapter 3.

3 Devices List

REF	Type	Product
12020112001E	SMARTsat® Technology	VM2160 - 0012165 complete device - Central Europe
12020112001N	SMARTsat® Technology	VM2160 - 0012166 complete device - Scandinavia
12020112001S	SMARTsat® Technology	VM2160 - 0012167 complete device - Special Europe

Used together with sensors and cables listed below:

- Reusable SMARTsat SpO₂ Sensors - Viamed labelled

REF No.	Type	Product
6020132014	0014752	SC7500VM, SoftCap SpO ₂ sensor - Large
6020132025	0014754	SCM7500VM, SoftCap SpO ₂ sensor - Medium
6020132305	0014753	SCP7500VM, SoftCap SpO ₂ sensor - Small
6020132030	0014760	SC7500-LVM, SoftCap SpO ₂ sensor - Large, 1.8m cable
6020132012	0014651	SF7500VM, SoftFlap SpO ₂ sensor
6020132016	0014851	W7500VM, SoftWrap SpO ₂ sensor
6020132264	0014850	EP7500VM, Ear Probe SpO ₂ sensor

- Disposable SMARTsat SpO₂ Sensors - Viamed labelled

REF No.	Type	Product
6020131204	0015010	10-AP-VM, Adult Plaster Disposable SpO ₂ Sensor
6020131207	0015011	10-PP-VM, Paediatric Plaster Disposable SpO ₂ Sensor
6020131209	0015012	10-IP-VM, Infant Plaster Disposable SpO ₂ Sensor
6020131211	0015013	10-NP-VM, Neonatal Plaster Disposable SpO ₂ Sensor

- Extension Cables (SpO₂) - Viamed labelled

REF	Type	Product
1020132288	0014895	XT6500VM, Viamed compatible, 1.2m
1020132296	0014896	XT6501VM, Viamed compatible, 2.4m

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4 Essential Requirements Matrix (MDD)

No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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).	yes	EN ISO 14971 Clinical evaluation DIN EN 62366-1	▪ Risk management file [1] (risk analysis of use errors); ▪ Clinical evaluation [2] (Risk-Benefit) ▪ Usability file [3] (application specification, usability specification, usability validation report)
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.	yes	EN ISO 14971 EN 1041 IEC 60601-1-8 DIN EN ISO 80601-2-61	▪ Risk management file [1] (risk control); ▪ Warnings and Cautions in User manual [14], [15], [16], [17]; ▪ Alarms Test Report [11]; ▪ SpO2 Test Report [8]
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.	yes	Clinical evaluation Performance tests	▪ Intended Use as per [14] ▪ Clinical evaluation report [2]; ▪ Verification & validation report [4], [18]; ▪ SpO2 Test Report [8]

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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.	yes	Clinical evaluation Performance tests EN ISO 14971	▪ Risk management file [1]; ▪ Clinical evaluation report [2]; ▪ Verification & validation report [4], [18]; ▪ Climatic test report [12]
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.	yes	IEC 60601-1 DIN EN ISO 80601-2-61	▪ General requirements for basic safety test report [6], [9]; ▪ SpO2 Test Report [8]; ▪ Instructions for transport and storage in User manual [14], [15], [16], [17];
6.	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	yes	EN ISO 14971	Risk management file [1] (risk management report)
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	yes	Clinical evaluation	Clinical evaluation report [2]
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, — where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	yes (only sensors)	EN ISO 14971 ISO 10993-1	▪ Risk management file [1]; ▪ Biocomp Test reports [5]
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.	yes (only sensors)	EN ISO 14971	▪ Risk management file [1]; ▪ Instructions for cleaning in User manual [14], [15], [16], [17];

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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.	yes (only sensors)	EN ISO 14971	Risk management file [1];
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 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 (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (1) 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 EMA 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 EMA, 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 EMA 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.	no	N/A	no substances are integral part of device

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
	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 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 labelling of dangerous substances ⁽¹⁾. 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 labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	no	N/A	There are no substances in the device that could leak.

(1) OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).
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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
	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.			
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.	yes	DIN EN 60529 IEC 60601-1 DIN EN ISO 80601-2-61	- General requirements for basic safety test report [6], [9]; - SpO2 Test Report [8];
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.	yes (only sensors)	EN ISO 14971	- Risk management file [1]; - Instructions for cleaning in User manual [14], [15], [16], [17];
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.	no	N/A	Device does not contain any tissues of animal origin
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.	no	N/A	The device and all accessories are delivered in a non-sterile state.
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	no	N/A	The device and all accessories are delivered in a non-sterile state.

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
8.5.	Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	no	N/A	The device and all accessories are delivered in a non-sterile state.
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.	yes	EN ISO 14971	Risk management file [1];
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.	no	N/A	The device and all accessories are delivered in a non-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.	yes	EN ISO 14971 EN 1041 IEC 60601-1 DIN EN ISO 80601-2-61 Performance tests	- Risk management file [1] (risk analysis); - User manual [14], [15], [16], [17]; - Verification and validation report [4], [18]; - General requirements for basic safety test report [6], [9]; - SpO2 Test Report [8];
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.	yes	EN ISO 14971 IEC 60601-1-1	- Risk management file [1] (risk analysis); - General requirements for basic safety test report [6], [9];
		yes	IEC 60601-1-2	EMC Test Report [10]
		yes	IEC 60601-1-2	EMC Test Report [10]
		no	N/A	N/A

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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.	yes	EN ISO 14971 IEC 60601-1	- Risk management file [1] (risk analysis); - General requirements for basic safety test report [6], [9];
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.	yes	Performance tests	- Verification and validation report [4], [18]; - Accuracy specifications in User manual [14], [15], [16], [17];
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.	yes	EN ISO 14971 DIN EN ISO 80601-2-61	- Risk management file [1] (risk analysis); - SpO2 Test Report [8];
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 ⁽²⁾ .	yes	DIN EN ISO 80601-2-61	SpO2 Test Report [8];
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.	yes	IEC 62471 DIN EN ISO 80601-2-61	Radiation and SpO2 Test Report [8], [13];
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.	no	N/A	Device is not designed to emit hazardous levels of radiation

⁽²⁾ OJ No L 39, 15.2.1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ

No L 357, 7.12.1989, p. 28).

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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.	no	N/A	Device is not designed to emit hazardous levels of radiation
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.	yes	IEC 62471 DIN EN ISO 80601-2-61	Radiation and SpO2 Test Report [8], [13];
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.	yes	IEC 62471 DIN EN ISO 80601-2-61	- Radiation specifications in User manual [14], [15], [16], [17]; - Radiation and SpO2 Test Report [8], [13];
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.	no	N/A	Device is not designed to emit ionizing radiation
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 user.	no	N/A	Device is not designed to emit ionizing radiation
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.	no	N/A	Device is not designed to emit ionizing radiation
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.	yes	EN ISO 14971 IEC 60601-1	- Risk management file [1] (risk analysis) - General requirements for basic safety test report [6], [9];

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
12.1.a	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.	yes	EN ISO 14971 EN ISO 62304 SW Verification and Validation IEC 60601-1	▪ Risk management file [1]; ▪ General requirements for basic safety test report [6], [9]; ▪ SW Verification and validation report [4];
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.	yes	EN ISO 14971 DIN EN ISO 80601-2-61	▪ Risk management file [1] (risk analysis) ▪ SpO2 Test Report [8]
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.	no	N/A	Battery powered
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.	yes	IEC 60601-1-8	▪ Alarms Test Report [8]
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.	yes	IEC 60601-1-2	▪ EMC Test Report [10]
12.6.	Protection against electrical risks			
12.6.	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.	yes	IEC 60601-1 DIN EN ISO 80601-2-61	▪ General requirements for basic safety test report [6], [9] ▪ SpO2 Test Report [8]
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.	no	N/A	No moving parts
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.	no	N/A	No vibrating parts

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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.	no	N/A	No noise emitting parts (except alarms according to IEC 60601-1-8)
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.	yes	IEC 60601-1 DIN EN ISO 80601-2-61	- General requirements for basic safety test report [6], [9] (SpO2 connector) - SpO2 Test Report [8] (SpO2 connector)
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.	yes	IEC 60601-1 DIN EN ISO 80601-2-61	- General requirements for basic safety test report [6], [9], [7] (temperature at SpO2 sensor applied part) - SpO2 Test Report [8], [7] (temperature at SpO2 sensor applied part)
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.	no	N/A	no flow-rate
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.	yes	IEC 62471 DIN EN ISO 80601-2-61	- Radiation specifications in User manual [14], [15], [16], [17]; - Radiation and SpO2 Test Report [8], [13];
12.9.	The function of the controls and indicators must be clearly specified on the devices.			
12.9.	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.	yes	EN 1041 DIN EN ISO 15223-1 EN 62366 EN ISO 14971 IEC 60601-1	- User manual [14], [15], [16], [17]; - Usability file [3] (usability validation report) - Risk management file [1]; - General requirements for basic safety test report [6], [9];

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
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. 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. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	yes	EN 1041 DIN EN ISO 15223-1 IEC 60601-1 DIN EN ISO 80601-2-61	- User manual [14], [15], [16], [17]; - General requirements for basic safety test report [6], [9]; - SpO2 Test Report [8];
13.2.	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	yes	EN 1041 DIN EN ISO 15223-1 IEC 60601-1	- User manual [14], [15], [16], [17]; - General requirements for basic safety test report [6], [9];
13.3.	The label must bear the following particulars:			
13.3.	(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 authorised representative where the manufacturer does not have a registered place of business in the Community;	yes	EN 1041 DIN EN ISO 15223-1 IEC 60601-1	- User manual [14], [15], [16], [17]; - General requirements for basic safety test report [6], [9];
	(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	yes	EN 1041 DIN EN ISO 15223-1 IEC 60601-1	- User manual [14], [15], [16], [17]; - General requirements for basic safety test report [6], [9]; (label test)
	(c) where appropriate, the word 'STERILE';	no	N/A	No sterile device
	(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	yes	EN 1041 DIN EN ISO 15223-1	User manual [14], [15], [16], [17];

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	yes (only disposable sensors)	IEC 60601-1	- User manual [16], - General requirements for basic safety test report [6], [9]; (label test)
	(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;	yes (only disposable sensors)	IEC 60601-1	- User manual [16], - General requirements for basic safety test report [6], [9]; (label test)
	(g) if the device is custom-made, the words 'custom-made device';	no	N/A	No custom-made device
	(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	no	N/A	Not for clinical investigations
	(i) any special storage and/or handling conditions;	no	N/A	No special storage and/or handling conditions
	(j) any special operating instructions;	no	N/A	no special operating instructions
	(k) any warnings and/or precautions to take;	yes	EN 1041 / DIN EN ISO 15223-1 EN ISO 14971 IEC 60601-1 DIN EN ISO 80601-2-61	- Warnings and precautions in User manual [14], [15], [16], [17]; - Risk Management File [1]; - General requirements for basic safety test report [6], [9]; (mandatory warnings) - SpO2 Test Report [8]; (mandatory warnings)
	(l) year of manufacture for active devices other than those covered by (e) . This indication may be included in the batch or serial number;	yes	EN 1041 / DIN EN ISO 15223-1	User manual [14], [15], [16], [17]
	(m) where applicable, method of sterilization.	no	N/A	No sterile device
	(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	no	N/A	Standalone Software
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.	no	N/A	obvious intended purpose
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	yes	EN 1041 / DIN EN ISO 15223-1 IEC 60601-1 DIN EN ISO 80601-2-61	Serial number for each device, SMARTsat module and sensor:

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	and detachable components.			- General requirements for basic safety test report [6], [9]; (labels) - SpO2 Test Report [8]; (labels)
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);	yes	EN 1041 / DIN EN ISO 15223-1 IEC 60601-1	User manual [14], [15], [16], [17]
	(b) the performances referred to in Section 3 and any undesirable side effects;	yes	EN 1041, DIN EN ISO 80601-2-61	User manual [14], [15], [16], [17]
	(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;	yes	EN 1041	User manual [14], [15], [16], [17]
	(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;	yes	EN 1041	User manual [14], [15], [16], [17];
13.6.	(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	no	N/A	No implantable device
	(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	yes	IEC 60601-1-2	EMC Test Report [10]
	(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	no	N/A	No sterile device
	(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 resterilized, 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.	yes	EN ISO 14971 EN 1041,	- Risk Management File [1] - Cleaning instructions in User manual [14], [15], [16], [17]

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
	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;			
	(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	no	N/A	no such treatment required
	(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:	yes	DIN EN ISO 80601-2-61	Radiation specifications in sensor User manual [15], [16], [17]
	(k) precautions to be taken in the event of changes in the performance of the device;	yes	EN ISO 14971 EN 1041, DIN EN ISO 80601-2-61	- Risk Management File [1] - instructions regarding interpretation of signal adequacy (signal quality indicator) and interpretation of measurement results in User manual [14] - SpO2 Test Report [8];
	(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.;	yes	IEC 60601-1-2	EMC Test Report [10]
	(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;	no	N/A	no substances to be delivered
	(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	yes (only disposable sensors)	EN ISO 14971	- Risk Management File [1] - Instructions in sensor User manual to not dispose used disposable sensors in normal waste [14], [15], [16], [17]
	(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	no	N/A	no such substances

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No.	Essential Requirement	Applicable (yes/no)	Method to demonstrate compliance (e.g. Applied Standard)	Reference to objective evidence / Comments
	(p) degree of accuracy claimed for devices with a measuring function;	yes	DIN EN ISO 80601-2-61	- Clinical accuracy study according to DIN EN ISO 80601-2-61 [18]; - Accuracy specifications in User manual [14], [15], [16], [17];
	(q) date of issue or the latest revision of the instructions for use.	yes	EN 1041	User manual [14], [15], [16], [17]

5 Conclusion

This document verifies that the manufactured medical devices as listed on chapter 3 comply with the Essential Requirements according to MDD 93/42/EEC, Annex I as amended by 2007/47/EC.

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6 Annex

6.1 Applicable and relevant documents

The following documents are relevant for the Essential Requirements Matrix:

No.	Document ID	Rev.	Description
[1]	RM-04-01-0001	7	Risk management file: Consists of the risk management plan, risk analysis (table) and risk management report
[2]	TF-04-01-001	2	Clinical Evaluation Report: Describes the results of the clinical evaluation
[3]	TR-04-01-0004	1	Usability Report: Consists of the application specification, usability specification, usability verification & validation plan and report
[4]	TR-04-01-0005	0	System Verification and Validation Report
[5]	TR-01-02-0001	4	Biocompatibility Test Report Summary
[6]	TR-04-01-0001	0	Test Report for Electrical safety according to IEC_60601-1
[7]	414.328.1	0	Test Report clause201.11 of IEC 80601-2-61 by CeCert Test lab
[8]	TR-04-01-0002	0	Test Report for SpO2 measurement function according to ISO_80601-2-61
[9]	414.280.2	0	Test Report for Electrical safety acc. to IEC 60601-1 by CeCert Test lab
[10]	418.316.2	0	Test Report for EMC acc. to IEC 60601-1-2 by CeCert Test lab
[11]	TR-04-01-0003	0	Test Report verifying the Alarm System according to IEC_60601-1-8
[12]	CT-OTA-SM-001	0	Environmental Test report to verify requirements for emergency transport
[13]	416.281.1	0	Test Report for Photobiological safety acc. to IEC 62471:2006 by CeCert Test lab
[14]	IFU-04-01-0101	3.7	Instructions for Use for VM2160 with SMARTsat OEM III - EN
[15]	IFU-01-02-0004	0	Instructions for Use for reusable Viamed SMARTsat Sensors
[16]	IFU-01-02-0005	0	Instructions for Use for disposable Viamed SMARTsat Sensors
[17]	IFU-01-02-0006	0	Instructions for Use for Viamed SMARTsat Ear Sensors
[18]	BLUE20150807	1	Clinical Accuracy Study according to ISO 80601-2-61

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6.2 Applied Standards

Standard	No.	Date / Edition	Title
EN	1041	2008+A1:2013	Information supplied by the manufacturer of medical devices.
EN ISO	14971	2012	Application of risk management to medical devices
DIN EN	60529	2014-09	Degrees of protection provided by enclosures (IP Code)
DIN EN	62304	2016-10	Medical device software - Software life-cycle processes
IEC	62471	2006	Photobiological safety of lamps and lamp systems
ISO	10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
DIN EN ISO	15223-1	2017	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement
IEC	60601-1	2005+CORR.1:2006+CORR.2:2007+A1:2012 (Ed.3.1)	Medical electric equipment - Part 1: General requirements for basic safety and essential performance
IEC	60601-1-2	2014 (4th Ed)	Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
DIN EN	60601-1-6	2016-02	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC	60601-1-8	2006(2nd Ed.) +Am.1. 2012 in conjunction with IEC 60601-1:2005+Am. 1:2012	Medical electrical equipment - General requirements for safety. Collateral standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
DIN EN	62366-1	2017-07	Medical devices - Application of usability engineering to medical devices
DIN EN ISO	80601-2-61	2019-09	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

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