RELEVANT STANDARDS

STANDARD NUMBER/REVISION	***HARMONIZED STANDARD DESCRIPTION***
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices — Application of risk management to medical devices
EN ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
EN 1041:2008+ A1:2013	Information supplied by the manufacturer of medical devices
EN 60601-1:2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard - Safety Requirements for Medical Electrical Systems
EN 60601-1-2:2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility — Requirements and tests
EN 60601-1-4:2004	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
EN 60601-1-6:2010 + A1:2015	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN 60601-1-8:2007 +A11:2017	Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 10993-1:2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
EN 62366-1:2015	Medical devices – Application of usability engineering to medical devices
EN 60601-1-11:2015	Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 80601-2-55:2011	Medical Electrical Equipment – Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors
EN ISO 80601-2-72: 2015	Medical Electrical Equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator dependent patients.
EN ISO 5356-1:2015	Anesthetic and respiratory equipment – Conical connectors. Part 1: Cones and sockets
EN 62304:2006 + A1:2015	Medical device software – Software life-cycle process

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)

OTHER STANDARDS

STANDARD NUMBER/REVISION	*HARMONIZED STANDARD DESCRIPTION*
ISTA 2A:2011	Testing of individual packaged-products weighing 150 lb (68kg) or less when prepared for shipment.

STANDARD NUMBER/REVISION	*NON-HARMONIZED STANDARD DESCRIPTION*
IEC62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications
IEC 60601-1-9: 2007 + A1: 2013	General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design (clauses 4.1, 4.5.2 and 4.5.3).
MEDDEV 2.7.1 Rev 4	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12/2 Rev 2	Guidelines on medical devices. Post Market Clinical Follow-up Studies

Part A

Note: Part A of this document lists the Essential Requirements from Annex I of the Medical Device Directive 93/42/EEC, as amended by 2007/47/EC.

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:	Y	EN ISO 13485 EN ISO 14971 EN 60601-1	IEC 60601-1-9	ISO Certificate (Document Number: 10069298) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
• 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		IEC 60601-1 EN ISO 80601-2-72 EN 62366-1 EN 60601-1-6 IEC 60601-1-6 EN 60601-1-2		(Document Number: 10063856) PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 (Document number: RE00188741) PB560 Usability TRF (EN 60601-1-6) (Document Number: RE00188738) PB560 usability reports (Document Numbers RE00171568 & RE00171570) PB560 EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) PB560 EMC (4th Edition) Test Report for 560 Series (Document Number: RE00175424) PB560 IEC 60601-1-9 Compliance Assessment

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				(Document Number: RE00182420)
• 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).	Y	EN ISO 13485	N/A	Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856)
COMMENTS N/A				
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),	Y	EN ISO 14971 EN 60601-1 IEC 60601-1	N/A	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-2		PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
• where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	Y	EN ISO 14971 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-8		PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for alarms standards EN 60601-1-8 (Document Number: RE00188739) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)
• inform users of the residual risks due to any shortcomings of the protection measures adopted.	Y	EN ISO 14971 EN ISO 80601-2-72	N/A	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)
COMMENTS				
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.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN 60601-1 IEC 60601-1	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 Risk Management File (Document Number: 10035448)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		Power Pack Risk Management File (Document Number: 10063856) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)
		EN 60601-1-4 EN 62304		PB520/PB560 Series Ventilator Gap Analysis Report against IEC 62304:2006 + A1:2015 (RE00152400) PB560 Software TRF – EN 62304 (Document number: RE00188743)
COMMENTS				

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.	Y	EN ISO 80601-2-72	ISTA 2A	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB560 Package Validation Test Report (Document Number: 10053462) Power Packaging Validation Report (Document Number: 10076450) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Y	EN ISO 14971	N/A	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736)
6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	Y	N/A	MEDDEV 2.7.1 MEDDEV 2.12/2	Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043)
COMMENTS				
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,	Y	EN ISO 80601-2-72 EN ISO 10993-1 ISO 18562-1 EN ISO 14971	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB500 Series Biocompatibility Test Report (Document Number RE00165028) PB560 Risk Management File (Document Number: 10035448)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
• the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.	Y	EN ISO 10993-1 ISO 18562-1	N/A	PB500 Series Biocompatibility Test Report (Document Number RE00165028)
• where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	N	N/A	N/A	This essential requirement is not appropriate and does not apply to the device. The device itself does not have physical contact with the patient, therefore, there was no biophysical or modeling research that was performed.
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.	Y	EN ISO 80601-2-72 EN ISO 14971	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				(Document Number: 10063856)
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.	Y	EN ISO 10993-1 ISO 18562-1	N/A	PB500 Series Biocompatibility Test Report (Document Number RE00165028)
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 (EMEA) 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 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	N	N/A	N/A	The device does not administer medicinal products.

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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 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 (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 labeled on the device	N	N/A	N/A	The device does not incorporate medicinal substances.

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.				
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
COMMENTS				
8. Infection and microbial contamination	Y		N/A	PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.		EN ISO 80601-2-72		72 Document Number: RE00188741) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)
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.	N	N/A	N/A	Device does not incorporate 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.	N	N/A	N/A	Device is not delivered in a sterile condition
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	N	N/A	N/A	Device is not delivered in a sterile condition
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	N	N/A	N/A	Device is not delivered in a sterile condition
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.	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714)
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.	Y	N/A	N/A	Device is not delivered in a sterile condition

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
COMMENTS				
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.	Y	EN ISO 80601-2-72 EN1041	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 (Document Number: RE00188741) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) Test Report EN1041:2008+A1:2013 (Document number RE00146714)
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,	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-2		72 Document Number: RE00188741) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
• risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	Y	EN 60601-1-2 EN ISO 80601-2-72	N/A	EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
• the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	Y	EN 60601-1-2 EN ISO 80601-2-72	N/A	EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				72 Document Number: RE00188741)
• 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.	Y	EN 1041 EN ISO 14971	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856)
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.	Y	EN 60601-1 IEC 60601-1	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736)
COMMENTS				

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN 62366-1 EN 60601-1-6 EN ISO 80601-2-72	N/A	PB560 Usability TRF (EN 60601-1-6) (Document Number: RE00188738) PB560 Usability reports (Document Numbers RE00171568 & RE00171570) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72 EN1041	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) Test Report EN1041:2008+A1:2013 (Document number RE00146714)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
COMMENTS				
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.	N	N/A	N/A	This device does not emit radiation
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.	N	N/A	N/A	This device does not emit radiation
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.	N	N/A	N/A	This device does not emit 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.	N	N/A	N/A	This device does not emit radiation
11.4. Instructions	N	N/A	N/A	This device does not emit radiation

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.				
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.	N	N/A	N/A	This device does not 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.	N	N/A	N/A	This device does not 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.	N	N/A	N/A	This device does not emit ionizing radiation
COMMENTS				
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.	Y	EN 60601-1-4 EN 60601-1 EN 62304	N/A	PB520/PB560 Series Ventilator Gap Analysis Report against IEC 62304:2006 + A1:2015 (RE00152400)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		PB560 Software TRF – EN 62304 (Document number: RE00188743) PB560 Risk Management File (Document Number: 10035448) PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN ISO 80601-2-72 EN 62304	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB520/PB560 Series Ventilator Gap Analysis Report against IEC

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				62304:2006 + A1:2015 (RE00152400) PB560 Software TRF – EN 62304 (Document number: RE00188743) Design Verification Test Summary Report, PB560 (Document Number: RE00181291) Design Verification Test Summary Report, PB560 (Document Number: RE00213912)
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	IEC62133	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN ISO 80601-2-72 EN 60601-1-8 IEC 60601-1-8	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 TRF for alarms standards EN 60601-1-8 (Document Number: RE00188739)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if 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.	Y	EN ISO 80601-2-72 EN 60601-1-8 IEC 60601-1-8	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 TRF for alarms standards EN 60601-1-8 (Document Number: RE00188739)
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.	Y	EN 60601-1-2	N/A	EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856)
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-2		72 Document Number: RE00188741) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
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.	Y	EN 60601-1 IEC 60601-1 EN 60601-1-2	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if 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.	Y	EN 60601-1 IEC 60601-1	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736)
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72 EN 60601-1-2	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
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.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	N/A	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-2		72 Document Number: RE00188741) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
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.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN ISO 80601-2-72 EN 60601-1-2	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for 560 Series (Document Number: RE00175424)
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.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if 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.	Y	EN ISO 80601-2-72 EN 62366-1 EN 60601-1-6	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Software TRF – EN 62304 (Document number: RE00188743) PB560 Usability reports (Document Numbers RE00171568 & RE00171570) PB560 Usability TRF (EN 60601-1-6) (Document Number: RE00188738)
COMMENTS				
13. Information supplied by the manufacturer 13.1. Each device must be accompanied by the information needed to use it safely and 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.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 User manual, Clinician's Manual and

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				Powerpack User's Manual (Manual BOM:RE00207625) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
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.	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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.	Y	EN ISO 80601-2-72 EN 1041	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
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.	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician's Manual and

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		Powerpack User's Manual (Manual BOM:RE00207625) PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
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;	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(b) the details strictly necessary for the user to identify the device and the contents of the packaging, especially for the users;	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(c) where appropriate, the word 'STERILE';	N	N/A	N/A	Not sterile device.
(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	N	N/A	N/A	Device does not have a defined shelf life.
(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;	N	N/A	N/A	Device is not for single use.
(g) if the device is custom-made, the words 'custom-made device';	N	N/A	N/A	This device is not custom-made.
(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	N	N/A	N/A	This device is not intended exclusively for clinical investigations.
(i) any special storage and/or handling conditions;	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 15223-1 EN ISO 80601-2-72		PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(j) any special operating instructions;	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(k) any warnings and/or precautions to take;	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 Risk Management File (Document Number: 10035448) TEST REPORT ISO 15223-1:2016 (RE00144411) Power Pack Risk Management File (Document Number: 10063856) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Labeling Validation Report (Document Number: RE00207887)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	Y	EN 1041 EN ISO 15223-1	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Labeling Validation Report (Document Number: RE00207887)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN 60601-1-2		PB560 EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for PB560 (Document Number: RE00175424) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(m) where applicable, method of sterilization.	N	N/A	N/A	This device is not intended to be sterilized
(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	N	N/A	N/A	The device does not contain 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.	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 810601-2-72		PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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.	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Labeling Validation Report (Document Number: RE00207887)
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);	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				72 Document Number: RE00188741)
(b) the performances referred to in Section 3 and any undesirable side-effects;	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
(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;	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72		Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
(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;	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	N	N/A	N/A	This device is not implantable.
(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	Y	EN 1041	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				Powerpack User's Manual (Manual BOM:RE00207625) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	N	N/A	N/A	Device is not sterile.
(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.	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
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;	N	N/A	N/A	Device is not sterile.

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
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;	N	N/A	N/A	Device is reusable.
(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
(j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	N	N/A	N/A	This device does not emit 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: (k) precautions to be taken in the event of changes in the performance of the device;	Y	EN ISO 14971 EN 1041	N/A	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(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.;	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
(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;	N	N/A	N/A	This device does not administer medicinal products.
(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	Y	EN 1041	IEC 60601-1-9	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 IEC 60601-1-9 Compliance Assessment (Document Number: RE00182420) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(o) medicinal substances or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	N	N/A	N/A	This device does not incorporate medicinal substances or human blood derivatives.
(p) degree of accuracy claimed for devices with a measuring function.	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 TRF for homecare particular - EN ISO 80601-2-

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				72 Document Number: RE00188741) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)
(q) date of issue or the latest revision of the instructions for use	Y	EN 1041 EN ISO 80601-2-72	N/A	Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741) PB560 Risk Management File (Document Number: 10035448) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

COMMENTS

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)

Part B

Notes:

1) Part B of this document lists the Australian Essential Principles as per the *Therapeutic Goods (Medical Devices) Regulations 2002* that do not have a comparable European Essential Requirement as per Annex I of the *Medical Device Directive 93/42/EEC*.
2) This section is prepared in accordance with the Australian Regulatory Guidelines for Medical Devices Version 1.0 dated April 2010.

2. Design and construction of medical devices to conform with safety principles (1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art. (2) Without limiting sub-clause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimize any risks associated with the use of the device, the manufacturer must: (a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and (c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted	Y	EN ISO 14971 EN 1041 EN 60601-1 IEC 60601-1	IEC62133	PB560 Risk Management File (Document Number: 10035448) Power Pack Risk Management File (Document Number: 10063856) Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 TRF for homecare particular -

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
		EN ISO 80601-2-72 EN 60601-1-2		EN ISO 80601-2-72 Document Number: RE00188741) PB560 EMC 4th Edition TRF (EN 60601-1-2) (Document Number RE00188737) 4th Edition EMC Test Report for PB560 (Document Number: RE00175424)
COMMENTS				
7.5 Minimization of risks associated with leaching substances A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimized.	N	N/A	N/A	The ventilator is itself non patient contacting and thus requirement is not considered.

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
7.6 Minimization of risks associated with ingress or egress of substances A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress of substances out of, the device are minimized, having regard to the nature of the environment in which the device is intended to be used.	Y	EN 60601-1 IEC 60601-1 EN ISO 80601-2-72	IEC62133	PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)
COMMENTS				
8.2 Control of animal, microbial or recombinant tissues, cells and other substances (1) This clause applies in relation to a medical device that contains: (a) tissues, cells or substances or animal origin that have been rendered non-viable; and (b) tissues, cells or substances of microbial or recombinant origin (2) If the tissues, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, cells or substances. (3) If the medical device contains tissues, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, cells or substances originated.	N	N/A	N/A	This device does not contain animal, microbial, or recombinant tissues, cells, or other substances

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
(4) The processing, preservation, testing and handling of tissues, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person. (5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.				
COMMENTS				
10 – Medical devices with a measuring function. (1) A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device. (2) The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device. (3) The measurements made by the device must be expressed: (a) in Australian legal units of measurement or be compared to at least one point of reference indicated in Australian legal units of measurement; or (b) if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the National Measurement Act 1960, in units approved in writing by the Secretary for the particular device.	Y	EN ISO 80601-2-72	N/A	PB560 TRF for homecare particular - EN ISO 80601-2-72 Document Number: RE00188741)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
13. Information supplied by the manufacturer **13.1 Information to be provided with medical devices – general** (3) The information: (a) must be provided in English; and (b) may also be provided in any other language (5) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimeter high.	Y	EN ISO 13485 EN 1041	N/A	Compliance Review PB 560 Post Launch Gap Analysis (Document Number: 10101297) Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043) Test Report EN1041:2008+A1:2013 (Document number RE00146714) PB560 User manual, Clinician's Manual and Powerpack User's Manual (Manual BOM:RE00207625) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
13.3 Information to be provided with medical devices – particular requirements The information mentioned below must be provided with a medical device. (11) The batch code, lot number or serial number of the device. (12) If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used (13) If the information provided with the device does not include the information mentioned in item 12 – a statement of the date of manufacture of the device(this may be included in the batch code, lot number or serial number of the device provided the date is clearly identifiable) (14) If applicable, the words “for export only” Note: In addition to the information mentioned above, regulation 10.2 requires certain information to be provided with a medical device.	Y	EN 1041 EN ISO 15223-1	IEC62133	Test Report EN1041:2008+A1:2013 (Document number RE00146714) TEST REPORT ISO 15223-1:2016 (RE00144411) PB560 User manual, Clinician’s Manual and Powerpack User’s Manual (Manual BOM:RE00207625) PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively) Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
13.4 Instructions for use (3) Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance images) (5) Any contraindications, warnings, restrictions on use, or precautions that may apply in relation to use of the device	Y	EN ISO 14971 EN ISO 13485 EN 1041	IEC62133	PB560 Risk Management File (Document Number: 10035448) Test Report EN1041:2008+A1:2013 (Document number RE00146714) Power Pack Risk Management File (Document Number: 10063856) Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043) PB560 Labeling Validation Report (Document Number: RE00207887) PB560 TRF for general standard - EN ISO 60601-1 (Document Number: RE00188736) PB560 Ventilator Product/Package label (Label BOM: RE00207340 Bubble # 8 & 12 respectively)

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
				Powerpack Product/Package label (Label BOM: RE00207340 Bubble # 17 & 16 respectively)

COMMENTS

Essential Requirement/Principle	Apply (Y/N)	Harmonized Medical Device Standards Applied	Other non-Harmonized Standards or Local/Corporate Procedures Applied	Evidence of compliance or reason for non-applicability (and document location, if applicable)
14. Clinical evidence Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles. Note: See regulation 3.11 and the clinical evaluation procedures.	Y	EN ISO 13485	MEDDEV 2.7.1 MEDDEV 2.12/2	PB560 Risk Management File (Document Number: 10035448) Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043 Clinical evaluation for Puritan Bennett 560/520 (Document Number: 10054043)

COMMENTS