
Medical electrical equipment —
Part 2-12:
Particular requirements for basic
safety and essential performance of
critical care ventilators

iTeh STANDARD PREVIEW

Appareils électromédicaux —

*Partie 2-12: Exigences particulières relatives à la sécurité de base
et aux performances essentielles des ventilateurs pulmonaires pour
utilisation en soins intensifs*

ISO 80601-2-12:2020

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Published in Switzerland

Contents

201. 1	Scope, object and related standards	1
201. 1.1	* Scope	1
201. 1.2	Object.....	2
201. 1.3	Collateral standards	3
201. 1.4	Particular standards.....	3
201. 2	Normative references	4
201. 3	Terms and definitions	7
201. 4	General requirements	9
201. 4.3	<i>Essential performance</i>	9
201. 4.3.101	* Additional requirements for <i>essential performance</i>	9
201. 4.4	Additional requirements for <i>expected service life</i>	9
201. 4.6	* <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	10
201. 4.11.101	* Additional requirements for pressurized gas input.....	10
201. 4.11.101.1	Overpressure requirement.....	10
201. 4.11.101.2	Compatibility requirement.....	10
201. 5	General requirements for testing of <i>ME equipment</i>	11
201. 5.101	Additional requirements for general requirements for testing of <i>ME equipment</i>	11
201. 5.101.1	<i>Ventilator</i> test conditions	11
201. 5.101.2	* Gas flowrate and leakage specifications.....	11
201. 5.101.3	* <i>Ventilator</i> testing errors.....	11
201. 6	Classification of <i>ME equipment</i> and <i>ME systems</i>	12
201. 7	<i>ME equipment</i> identification, marking and documents	12
201. 7.2.3	* Consult <i>accompanying documents</i>	12
201. 7.2.4.101	Additional requirements for <i>accessories</i>	12
201. 7.2.13.101	Additional requirements for physiological effects	12
201. 7.2.17.101	Additional requirements for protective packaging.....	12
201. 7.2.18	External gas source.....	13
201. 7.2.101	* Additional requirements for marking on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts	13
201. 7.4.3	* Units of measurement.....	14
201. 7.9.1	Additional general requirements	14
201. 7.9.2.1.101	Additional general requirements	14
201. 7.9.2.2.101	* Additional requirements for warnings and safety notices....	15
201. 7.9.2.8.101	* Additional requirements for start-up <i>procedure</i>	16
201. 7.9.2.9.101	* Additional requirements for operating instructions	16
201. 7.9.2.12	<i>Cleaning, disinfection, and sterilization</i>	17
201. 7.9.2.14.101	* Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	17

201. 7.9.2.16.101	* Additional requirements for reference to the technical description	18
201. 7.9.3.1.101	* Additional general requirements	18
201. 7.9.3.101	Additional requirements for the technical description	18
201. 8	Protection against electrical hazards from ME equipment.....	19
201. 9	Protection against mechanical hazards of ME equipment and ME systems	19
201. 9.6.2.1.101	* Additional requirements for audible acoustic energy.....	19
201. 9.101	* Additional requirements for suction procedures.....	20
201. 10	Protection against unwanted and excessive radiation hazards.....	23
201. 11	Protection against excessive temperatures and other hazards.....	23
201. 11.1.2.2	* Applied parts not intended to supply heat to a patient	23
201. 11.6.5.101	* Additional requirements for ingress of water or particulate matter into ME equipment or ME system	23
201. 11.6.6	* Cleaning and disinfection of ME equipment or ME system.....	24
201. 11.6.7	Sterilization of ME equipment or ME system	24
201. 11.7	Biocompatibility of ME equipment and ME systems	24
201. 11.8.101	* Additional requirements for interruption of the power supply/supply mains to ME equipment	25
201. 12	Accuracy of controls and instruments and protection against hazardous outputs.....	27
201. 12.1	* Accuracy of controls and instruments	27
201. 12.1.101	* Volume-control inflation-type	27
201. 12.1.102	* Pressure-control inflation-type	31
201. 12.1.103	Other inflation-types	34
201. 12.1.104	* Inspiratory volume monitoring	35
201. 12.1.105	* Response of the ventilator to an increase in set O ₂ concentration	35
201. 12.4	Protection against hazardous output.....	37
201. 12.4.101	Oxygen monitor	37
201. 12.4.102	* Measurement of airway pressure.....	38
201. 12.4.103	* Measurement of expired volume and low volume alarm conditions	39
201. 12.4.103.1	Ventilators intended to provide a tidal volume >50 ml.....	39
201. 12.4.103.2	Ventilators intended to provide a tidal volume ≤50 ml.....	40
201. 12.4.104	* Expiratory end-tidal CO ₂ monitoring equipment.....	41
201. 12.4.105	* Maximum limited pressure protection device	42
201. 12.4.106	* High airway pressure alarm condition and protection device	42
201. 12.4.107	PEEP alarm conditions	43
201. 12.4.108	* Obstruction alarm condition	44
201. 12.4.109	* Disconnection alarm condition.....	45
201. 12.4.110	Protection against inadvertent setting of high airway pressure	45
201. 12.101	* Protection against accidental or unintentional adjustments	45
201. 13	Hazardous situations and fault conditions for ME equipment	46

201. 13.2.101	* Additional specific <i>single fault conditions</i>	46
201. 13.2.102	* Failure of one gas supply to a <i>ventilator</i>	46
201. 13.2.103	* Independence of ventilation control function and related <i>risk control</i> measures.....	47
201. 13.2.104	* Failure of <i>functional connection</i> to a <i>ventilator</i> control or monitoring means.....	47
201. 14	<i>Programmable electrical medical systems (PEMS)</i>	47
201. 14.101	Software life cycle	48
201. 15	<i>Construction of ME equipment</i>	48
201. 15.3.5.101	Additional requirements for rough handling.....	48
201. 15.3.5.101.1	* Shock and vibration (robustness)	48
201. 15.3.5.101.2	* Shock and vibration for a <i>transit-operable ventilator</i> during operation	49
201. 15.4.1	Construction of connectors	51
201. 15.101	Mode of operation.....	51
201. 15.102	Delivered oxygen concentration.....	51
201. 15.103	<i>Accessory</i> self-check.....	51
201. 16	<i>ME systems</i>	52
201. 16.1.101	Additional general requirements for <i>ME systems</i>	52
201. 16.2.101	* Additional general requirements for <i>accompanying documents</i> of an <i>ME system</i>	52
201. 17	<i>Electromagnetic compatibility of ME equipment and ME systems</i>	52
201. 101	<i>Gas connections</i>	52
201. 101.1	* Protection against reverse gas leakage	52
201. 101.2	Connection to a <i>high-pressure input port</i>	53
201. 101.2.1	Connector	53
201. 101.2.2	* Filter.....	53
201. 101.3	<i>VBS</i> connectors.....	53
201. 101.3.1	* General	53
201. 101.3.2	Other named ports.....	53
201. 101.3.2.1	<i>Patient-connection port</i>	53
201. 101.3.2.2	<i>Gas output port</i> and <i>gas return port</i>	54
201. 101.3.2.3	<i>Emergency intake port</i>	54
201. 101.3.2.4	<i>Flow-direction-sensitive components</i>	54
201. 101.3.2.5	* <i>Accessory port</i>	54
201. 101.3.2.6	<i>Gas exhaust port</i>	55
201. 101.3.2.7	Temperature sensor port.....	55
201. 102	<i>Requirements for the VBS and accessories</i>	55
201. 102.1	* General	55
201. 102.2	Labelling	55
201. 102.3	Breathing tubes.....	55
201. 102.4	* Water vapour management.....	56
201. 102.4.1	Humidification system.....	56
201. 102.4.2	<i>Heat and moisture exchanger (HME)</i>	56

201.102.6	<i>Breathing system filters</i>	56
201.102.7	<i>Ventilator breathing systems</i>	56
201.102.7.1	* Leakage from complete VBS	56
201.102.7.2	* Non-invasive ventilation	57
201.103	* Spontaneous breathing during loss of power supply	57
201.104	* Indication of duration of operation	57
201.105	<i>Functional connection</i>	58
201.105.1	General	58
201.105.2	* Connection to an electronic health record	58
201.105.3	* Connection to a <i>distributed alarm system</i>	58
201.105.4	Connection for remote control	58
201.106	Display loops	58
201.106.1	Pressure-volume loops	58
201.106.2	Flow-volume loops	59
201.107	* Timed ventilatory pause	59
201.107.1	<i>Expiratory pause</i>	59
201.107.2	<i>Inspiratory pause</i>	60
202	Electromagnetic disturbances — Requirements and tests	61
206	Usability	62
206.101	<i>Primary operating functions</i>	62
206.102	* Training	63
208	General requirements, tests and guidance for <i>alarm systems in medical electrical equipment and medical electrical systems</i>	64
<p style="text-align: center;">ISO 80601-2-12:2020 https://standards.iteh.ai/catalog/standards/sis/85865430-8789-4765-8861-80c86c2d020/iso-80601-2-12-2020</p>		
Annex C (informative) Guide to marking and labelling requirements for <i>ME equipment and ME systems</i>		
201.C.101	Marking on the outside of <i>ME equipment, ME systems</i> or their parts	66
201.C.102	<i>Accompanying documents</i> , general	67
201.C.103	<i>Accompanying documents</i> , instructions for use	67
201.C.104	<i>Accompanying documents</i> , technical description	70
Annex D (informative) Symbols on marking		
Annex AA (informative) Particular guidance and rationale		
AA.1	General guidance	75
AA.2	Rationale for particular clauses and subclauses	75
Annex BB (informative) Data interfaces		
BB.1	Background and purpose	114
BB.2	Data definition	115
Annex CC (informative) Reference to the essential principles		
Annex DD (informative) Reference to the general safety and performance requirements		
Annex EE (informative) Terminology — Alphabetized index of defined terms		
Bibliography		

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electric equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-12:2011), which has been technically revised. It also incorporates the Technical Corrigendum ISO 80601-2-12:2011/Cor 1:2011. The main changes compared to the previous edition are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-2:2014 and IEC 60601-1-6:2010+AMD1:2013.
- determination of probability of component failure during the *expected service life*;
- delivered gas maximum enthalpy requirement;
- new test protocol for *internal electrical power source* operation time;
- performance test and disclosure requirements for other *inflation-types*;
- additional protections against hazardous outputs;
- clarification of performance requirements during abnormal testing;
- consideration of input gas of Oxygen 93 %; and
- harmonization of terminology with ISO 19223, where appropriate.

ISO 80601-2-12:2020(E)

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

In this document, the following print types are used:

- Requirements and definitions: roman type;
- *Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

- “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb

- “shall” means that conformance with a requirement or a test is mandatory for conformance with this document,
- “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test),
- “can” is used to describe a possibility or capability, and
- “must” is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012.

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment*:

- intended for use in an environment that provides specialized care for *patients* whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a *professional healthcare facility*;

NOTE 1 For the purposes of this document, such an environment is referred to as a critical care environment. Ventilators for this environment are considered life-sustaining.

NOTE 2 For the purposes of this document, such a *ventilator* can provide transport within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

NOTE 3 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

- intended to be operated by a *healthcare professional operator*; and
- intended for those *patients* who need differing levels of support from artificial ventilation including for *ventilator-dependent patients*.

A critical care *ventilator* is not considered to utilize a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the ventilation therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to a *ventilator breathing system*, or to a *ventilator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

NOTE 4 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

ISO 80601-2-12:2020(E)

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document is not applicable to *ME equipment* or an *ME system* operating in a *ventilator-operational mode* solely intended for *patients* who are not dependent on artificial ventilation.

NOTE 6 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-sustaining.

This document is not applicable to *ME equipment* that is intended solely to augment the ventilation of spontaneously breathing *patients* within a *professional healthcare facility*.

This document does not specify the requirements for:

- *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13^[2];
- *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84^[3], the future replacement for ISO 10651-3^[4];
- *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72:2015^[5];
- *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in ISO 80601-2-79:2018^[6] and ISO 80601-2-80:2018^[7];
- obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70^[9];
- *continuous positive airway pressure (CPAP) ME equipment*;
- high-frequency jet ventilators (HFJVs) and high-frequency oscillatory ventilators (HFOVs), which are given in ISO 80601-2-87^[63];

NOTE 7 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-operational modes*.

- oxygen therapy constant flow *ME equipment*; and
- cuirass or “iron-lung” ventilation equipment.

201.1.2 Object

Replacement:

The object of this document is to establish *basic safety* and *essential performance* requirements for a *ventilator* and its *accessories*.

¹ ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

Accessories are included because the combination of the *ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 as indicated in Annex DD.

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3^[12], IEC 60601-1-9^[13], IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration and may add other *basic safety* or *essential performance* requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is replaced completely by the text of this document.

“Addition” means that the text of this document is additional to the requirements of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3^[12], etc.

The term “this document” is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of the general standard applies, except as follows:

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Replacement:

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — 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*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*
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ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

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ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*