

ELEKTRILISED MEDITSIINISEADMED. OSA 2-84:  
ERINÕUDED KIIRABIS KASUTATAVATE  
HINGAMISAPARAATIDE ESMASELE OHUTUSELE JA  
OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (ISO 80601-2-84:2023)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 80601-2-84:2023 sisaldab Euroopa standardi EN ISO 80601-2-84:2023 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.11.2023.</p> <p>Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 80601-2-84:2023 consists of the English text of the European standard EN ISO 80601-2-84:2023.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 15.11.2023.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
--	---

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 11.040.10

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele. Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation: Homepage [www.evs.ee](http://www.evs.ee); phone +372 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

English Version

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (ISO 80601-2-84:2023)

Appareils électromédicaux - Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence (ISO 80601-2-84:2023)

Medizinische elektrische Geräte - Teil 2-84: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Notfall- und Transportbeatmungsgeräten (ISO 80601-2-84:2023)

This European Standard was approved by CEN on 1 September 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## European foreword

This document (EN ISO 80601-2-84:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 794-3:1998+A2:2009.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

## Endorsement notice

The text of ISO 80601-2-84:2023 has been approved by CEN as EN ISO 80601-2-84:2023 without any modification.

## Contents

<b>Foreword .....</b>	<b>vi</b>
<b>Introduction.....</b>	<b>viii</b>
<b>201. 1 Scope, object and related standards.....</b>	<b>1</b>
201. 1.1 Scope.....	1
201. 1.2 Object.....	2
201. 1.3 Collateral standards.....	2
201. 1.4 Particular standards .....	3
<b>201. 2 Normative references.....</b>	<b>4</b>
<b>201. 3 Terms and definitions.....</b>	<b>5</b>
<b>201. 4 General requirements.....</b>	<b>23</b>
201. 4.3 <i>Essential performance</i> .....	23
201. 4.3.101 Additional requirements for <i>essential performance</i> .....	23
201. 4.3.102 <i>System recovery</i> .....	23
201. 4.4 Additional requirements for <i>expected service life</i> .....	24
201. 4.5 Alternative <i>risk control</i> measures or test methods for <i>ME equipment</i> or <i>ME system</i> .....	25
201. 4.6 <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i> .....	25
201. 4.11.101 Additional requirements for pressurized gas input.....	25
201. 4.11.101.1 Overpressure requirement .....	25
201. 4.11.101.2 Compatibility requirement for <i>medical gas pipeline systems</i> .....	25
201. 4.11.101.3 Compatibility requirements for pressure regulators .....	26
<b>201. 5 General requirements for testing of <i>ME equipment</i>.....</b>	<b>26</b>
201. 5.101 Additional requirements for general requirements for testing of <i>ME equipment</i> .....	27
201. 5.101.1 <i>EMS ventilator</i> test conditions .....	27
201. 5.101.2 Gas flowrate and leakage specifications.....	27
201. 5.101.3 <i>EMS ventilator</i> testing errors .....	27
<b>201. 6 Classification of <i>ME equipment</i> and <i>ME systems</i> .....</b>	<b>27</b>
<b>201. 7 <i>ME equipment</i> identification, marking and documents.....</b>	<b>28</b>
201. 7.1.101 <i>Information to be supplied by the manufacturer</i> .....	28
201. 7.2.3 Consult <i>accompanying documents</i> .....	28
201. 7.2.4.101 Additional requirements for <i>accessories</i> .....	28
201. 7.2.18 External gas source .....	28
201. 7.2.101 Additional requirements for <i>marking</i> on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts.....	29
201. 7.4.2 Control devices .....	30
201. 7.4.3 Units of measurement .....	30
201. 7.4.101 Labelling of units of measurement .....	30
201. 7.9.2.1 General .....	30
201. 7.9.2.1.101 Additional general requirements .....	30
201. 7.9.2.2.101 Additional requirements for warnings and safety notices .....	30
201. 7.9.2.8.101 Additional requirements for start-up <i>procedure</i> .....	31
201. 7.9.2.9.101 Additional requirements for operating instructions .....	32
201. 7.9.2.12 <i>Cleaning, disinfection, and sterilization</i> .....	33
201. 7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	33
201. 7.9.3.1.101 Additional general requirements .....	33
201. 7.9.3.101 Additional requirements for the <i>technical description</i> .....	34
<b>201. 8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>.....</b>	<b>34</b>
<b>201. 9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i> .....</b>	<b>34</b>

201. 9.4.3.101	Additional requirements for instability from unwanted lateral movement.....	34
201. 9.4.4	Grips and other handling devices .....	35
201. 9.6.2.1.101	Additional requirements for audible acoustic energy.....	35
<b>201. 10</b>	<b>Protection against unwanted and excessive radiation hazards.....</b>	<b>36</b>
<b>201. 11</b>	<b>Protection against excessive temperatures and other hazards.....</b>	<b>36</b>
201. 11.1.2.2	Applied parts not intended to supply heat to a patient .....	37
201. 11.6.6	Cleaning and disinfection of ME equipment or ME system.....	37
201. 11.6.7	Sterilization of ME equipment or ME system.....	38
201. 11.7	Biocompatibility of ME equipment and ME systems .....	38
<b>201. 12</b>	<b>Accuracy of controls and instruments and protection against hazardous outputs .....</b>	<b>38</b>
201. 12.1.101	Volume-control inflation-type.....	38
201. 12.1.102	Pressure-control inflation-type.....	42
201. 12.1.103	Other inflation-types.....	45
201. 12.1.104	Inspiratory volume monitoring equipment.....	45
201. 12.4	Protection against hazardous output.....	45
201. 12.4.101	Oxygen monitor .....	45
201. 12.4.102	Measurement of airway pressure .....	46
201. 12.4.103	Measurement of expired volume and low volume alarm conditions .....	47
201. 12.4.104	Maximum limited pressure protection device.....	48
201. 12.4.105	High airway pressure alarm condition and protection device.....	48
201. 12.4.106	Expiratory end-tidal CO <sub>2</sub> monitoring equipment .....	50
201. 12.4.107	Protection against inadvertent setting of high airway pressure.....	50
<b>201. 13</b>	<b>Hazardous situations and fault conditions for ME equipment .....</b>	<b>50</b>
201. 13.2.101	Additional specific single fault conditions .....	50
201. 13.102	Failure of one gas supply to an EMS ventilator .....	51
201. 13.103	Independence of ventilation control function and related risk control measures .....	51
<b>201. 14</b>	<b>Programmable electrical medical systems (PEMS).....</b>	<b>52</b>
201. 14.1	General.....	52
201. 14.101	Cybersecurity capabilities of EMS ventilators.....	52
<b>201. 15</b>	<b>Construction of ME equipment .....</b>	<b>53</b>
201. 15.3.5.101	Additional requirements for rough handling.....	53
201. 15.4.1	Construction of connectors .....	53
201. 15.101	Mode of operation.....	54
201. 15.102	Delivered oxygen concentration .....	54
201. 15.103	Accessory self-check.....	54
<b>201. 16</b>	<b>ME systems .....</b>	<b>54</b>
201. 16.1.101	Additional general requirements for ME systems .....	54
201. 16.2.101	Additional requirements for power supply.....	55
<b>201. 17</b>	<b>Electromagnetic compatibility of ME equipment and ME systems .....</b>	<b>55</b>
<b>201. 101</b>	<b>Gas connections .....</b>	<b>55</b>
201. 101.1	Protection against reverse gas leakage .....	55
201. 101.2	Connection to a high-pressure inlet .....	56
201. 101.2.1	Low-pressure hose assembly.....	56
201. 101.2.2	Filter .....	56
201. 101.3	VBS connectors .....	56
201. 101.3.1	General.....	56
201. 101.3.2	Other named ports .....	56
201. 101.3.2.1	Patient-connection port.....	56
201. 101.3.2.2	Gas output port and gas return port .....	57
201. 101.3.2.3	Flow-direction-sensitive components .....	57
201. 101.3.2.4	Gas pathway connection port .....	57
201. 101.3.2.5	Gas exhaust port.....	58

201. 101.3.2.6	<i>Gas intake port</i> .....	58
<b>201. 102</b>	<b>Requirements for the VBS and accessories</b> .....	<b>58</b>
201. 102.1	General .....	58
201. 102.2	Labelling .....	58
201. 102.3	Breathing sets.....	59
201. 102.4	Water vapour management .....	59
201. 102.4.1	Humidification system .....	59
201. 102.4.2	<i>Heat and moisture exchanger (HME)</i> .....	59
201. 102.5	<i>Breathing system filters</i> .....	59
201. 102.6	Leakage from complete VBS.....	59
<b>201. 103</b>	<b>Spontaneous breathing during loss of ventilation</b> .....	<b>60</b>
<b>201. 104</b>	<b>Indication of duration of operation</b> .....	<b>60</b>
<b>201. 105</b>	<b>Functional connection</b> .....	<b>60</b>
201. 105.1	General .....	60
201. 105.2	Connection to an electronic health record .....	61
201. 105.3	Connection to a <i>distributed alarm system</i> .....	61
<b>201. 106</b>	<b>Display loops</b> .....	<b>61</b>
201. 106.1	Pressure-volume loops .....	61
201. 106.2	Flow-volume loops.....	61
<b>201. 107</b>	<b>Timed ventilatory pause</b> .....	<b>61</b>
201. 107.1	<i>Expiratory pause</i> .....	62
201. 107.2	<i>Inspiratory pause</i> .....	62
<b>202</b>	<b>Electromagnetic disturbances — Requirements and tests</b> .....	<b>63</b>
<b>206</b>	<b>Usability</b> .....	<b>64</b>
206.101	<i>Primary operating functions</i> .....	64
206.102	Training.....	66
<b>208</b>	<b>General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</b> .....	<b>66</b>
<b>212</b>	<b>Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment</b> .....	<b>68</b>
<b>Annex C (informative)</b>	<b>Guide to marking and labelling requirements for ME equipment and ME systems</b> .....	<b>71</b>
201.C.1	<i>Marking on the outside of ME equipment, ME systems or their parts</i> .....	71
201.C.2	<i>Accompanying documents, general</i> .....	72
201.C.3	<i>Accompanying documents, instructions for use</i> .....	72
201.C.4	<i>Accompanying documents, technical description</i> .....	74
<b>Annex D (informative)</b>	<b>Symbols on marking</b> .....	<b>76</b>
<b>Annex AA (informative)</b>	<b>Particular guidance and rationale</b> .....	<b>78</b>
AA.1	General guidance .....	78
AA.2	Rationale for particular clauses and subclauses.....	78
<b>Annex BB (informative)</b>	<b>Data interfaces</b> .....	<b>114</b>
BB.1	Background and purpose.....	114
BB.2	Data definition .....	115
<b>Annex CC (informative)</b>	<b>Reference to the IMDRF essential principles and labelling guidances</b> .....	<b>122</b>
<b>Annex DD (informative)</b>	<b>Reference to the essential principles</b> .....	<b>126</b>
<b>Bibliography</b> .....		<b>129</b>
<b>Terminology — Alphabetized index of defined terms</b> .....		<b>133</b>

## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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](http://www.iso.org/directives) or [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC 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](http://www.iso.org/patents)) or the IEC list of patent declarations received (see <https://patents.iec.ch>).

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](http://www.iso.org/iso/foreword.html). In the IEC, see [www.iec.ch/understanding-standards](http://www.iec.ch/understanding-standards).

This document was prepared jointly 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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, 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 80601-2-84:2020), which has been technically revised. The main changes are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, and IEC 60601-1-12:2014+AMD1:2020;
- added requirements for a *responsible organization* log
- added requirements for the display legibility for *operators* wearing personal protective equipment;
- added requirements for display during calibration of gas monitors;
- clarified *maximum limited pressure* requirements;
- added requirements for *ventilator system recovery*;
- added requirements and definitions for *cybersecurity*; and



— harmonization with ISO 20417, where appropriate.

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

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](http://www.iso.org/members.html) and [www.iec.ch/national-committees](http://www.iec.ch/national-committees).

## Introduction

In referring to the structure of this document, the term

- “clause” means one of the five 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 201.9 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 particular 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.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” is used to describe a possibility or capability; and
- “must” is used to indicate 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.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

# Medical electrical equipment —

## Part 2-84:

# Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

## 201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

### 201.1.1 Scope

*Replacement:*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

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

- intended for *patients* who need differing levels of support from *artificial ventilation* including *ventilator-dependent patients*;
- intended to be operated by a *healthcare professional operator*;
- intended for use in the *EMS environment*; and
- intended for *invasive or non-invasive ventilation*.

NOTE 2 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

An *EMS ventilator* is not considered to use a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the *artificial ventilation* therapy settings.

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

NOTE 3 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.

*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+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 4 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for the following:

NOTE 5 See ISO/TR 21954 for guidance on the selection of the appropriate *ventilator* for a given *patient*.

- *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications, which are given in ISO 80601-2-12.

- *ventilators or accessories intended for ventilator-dependent patients in the home healthcare environment*, which are given in ISO 80601-2-72.
- *ventilators or accessories intended for anaesthetic applications*, which are given in ISO 80601-2-13.
- *ventilators or accessories intended for ventilatory support equipment (intended only to augment the ventilation of spontaneously breathing patients)*, which are given in ISO 80601-2-79 and ISO 80601-2-80.
- *obstructive sleep apnoea therapy ME equipment*, which are given in ISO 80601-2-70.
- *user-powered resuscitators*, which are given in ISO 10651-4.
- *gas-powered emergency resuscitators*, which are given in ISO 10651-5.
- *continuous positive airway pressure (CPAP) ME equipment*.
- *high-frequency jet ventilators (HFJVs)*, which are given in ISO 80601-2-87.
- *high-frequency oscillatory ventilators (HFOVs)*<sup>[44]</sup>, which are given in ISO 80601-2-87.

NOTE 6 An EMS ventilator can incorporate high-frequency jet or high-frequency oscillatory ventilation-modes.

- *respiratory high-flow therapy equipment*, which are given in ISO 80601-2-90.

NOTE 7 An EMS ventilator can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing patients.

- *oxygen therapy constant flow ME equipment*.
- *cuirass or “iron-lung” ventilators*.

### 201.1.2 Object

*Replacement:*

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an EMS ventilator, as defined in 201.3.228, and its *accessories*.

*Accessories* are included because the combination of the EMS ventilator and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an EMS ventilator.

NOTE 1 This document has been prepared to address the relevant *essential principles*<sup>[38]</sup> and labelling<sup>[39]</sup> guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745<sup>[40]</sup>.

### 201.1.3 Collateral standards

*Amendment (add at the end of the subclause):*

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.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-12:2014+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 212 respectively.

IEC 60601-1-3, IEC 60601-1-9, and IEC 60601-1-11 do not apply.

All other published collateral standards in the IEC 60601-1 series apply as published.

## 201.1.4 Particular standards

### *Replacement:*

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+AMD1:2012+AMD2:2020 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular 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+AMD2:2020 or the applicable collateral standard is replaced completely by the text of this particular document.

“Addition” means that the text of this document is additional to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard.

“Amendment” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 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 3.154, 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, 208 for IEC 60601-1-8, 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+AMD2:2020 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+AMD2:2020 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.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

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+AMD1:2017, *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+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

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*

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 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3:2019, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRS)*

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 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2023, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration aspects*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-12:2014+AMD1:2020, *Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

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

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformance assessment activities in the electrotechnical sector*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 201.3.201

#### accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]