ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Február 2015

STN	**Zdravotnícke elektrické prístroje. Časť 2-69: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti koncentrátorov kyslíka (ISO 80601-2-69: 2014).**	**STN EN ISO 80601-2-69** 85 2753

Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/15

Obsahuje: EN ISO 80601-2-69:2014, ISO 80601-2-69:2014

Oznámením tejto normy sa ruší
STN EN ISO 8359 (85 2753) zo septembra 2009

119976

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-69

July 2014

ICS 11.040.10

Supersedes EN ISO 8359:2009

English Version

Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2014)

Appareils électromédicaux - Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO 80601-2-69:2014)

Medizinische elektrische Geräte - Teil 2-69: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO 80601-2-69:2014)

This European Standard was approved by CEN on 28 May 2014.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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Ref. No. EN ISO 80601-2-69:2014 E

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Foreword

This document (EN ISO 80601-2-69:2014) 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 January 2015, and conflicting national standards shall be withdrawn at the latest by July 2017.

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

This document supersedes EN ISO 8359:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-69:2014 has been approved by CEN as EN ISO 80601-2-69:2014 without any modification.

Annex ZA
(informative)

Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.11.6.4, 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the PATIENT are addressed.
201.11.6.4, 201.11.6.6	7.3	Only the part of the first sentence of ER 7.3 relating to design is addressed.
201.11.6.4	7.5	
201.11	7.6	
201.11.6.6, 201.11.6.7	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11135-1, ISO 11137-1 and ISO 17665-1.
201.4.6, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.14.101, 201.12.1.101, 201.12.1.102, 201.12.1.103, 201.16, 201.101, 201.102	9.1	
201.9, 202, 206, 211	9.2	The 4th indent of ER 9.2 is not addressed.
201.11	9.3	
201.12.1, 201.102	10.1	The part of ER 10.1 relating to stability is not addressed.

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7, 201.12.1, 206, 208	10.2	
201.7.4.3	10.3	
201.14	12.1	
201.14	12.1 a)	
202	12.5	
201.8	12.6	
201.9, 211	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.101, 201.15, 201.103	12.7.4	
201.11	12.7.5	
201.12.1	12.8.1	Only the protection of the PATIENT is covered.
201.12.4	12.8.2	Only the first sentence of ER 12.8.2 is covered.
201.7, 206	12.9	
201.7, 201.11.6.4	13.1	
201.7.2.1, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.8, 201.9, 201.11.6.4	13.2	
201.7.9.1	13.3 a)	
201.7.2.17.101	13.3 b)	
201.7, 201.7.2.17.101 a)	13.3 c)	
201.7.2.17.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT.
201.7.2.17.101	13.3 f)	
201.7.2.101 a), 211	13.3 i)	
201.7.2.101 b), 201.7.2.101 d), 211	13.3 j)	
201.7.2.101 b)	13.3 k)	
201.7, 201.7.2.17.101 a)	13.3 m)	Presumption of conformity is only provided if one of the symbols 5.21 to 5.24 from ISO 15223-1:2012 are utilized, as applicable.
201.7.9.1, 201.7.9.2, 201.16	13.6 a)	
201.7.9.2.5.101	13.6 b)	
201.7.9.2.14.101, 201.16, 201.102	13.6 c)	
201.7, 201.7.9.2.8.101, 201.7.9.2.13.101, 201.16	13.6 d)	

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.16	13.6 f)	
201.7.9.2.1.101, 201.7.9.2.12, 201.16, 211	13.6 h)	
201.7	13.6 i)	
211	13.6 k)	
211	13.6 k)	
211	13.6 l)	
211	13.6 n)	
201.12.1.103, 211	13.6 p)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
—	1.1.4	This relevant EHSR is not covered by this European Standard.
201.12.1, 201.12.101	1.2.2	
201.7.2.101 c), 201.7.2.101 d), 201.101	1.5.4	
—	1.6.2	This relevant EHSR is not covered by this European Standard.
201.8	1.6.3	

INTERNATIONAL STANDARD

ISO 80601-2-69

First edition
2014-07-15

Medical electrical equipment —

Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

Reference number
ISO 80601-2-69:2014(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO/IEC 80601-2-69 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment.*

This first edition of ISO 80601-2-69 cancels and replaces the first edition of ISO 8359:1996. This edition of ISO 80601-2-69 constitutes a major technical revision of ISO 8359:1996 and includes an alignment with the third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

– extending the scope to include not only the OXYGEN CONCENTRATOR but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR;
– identification of ESSENTIAL PERFORMANCE for an OXYGEN CONCENTRATOR and its ACCESSORIES;
– and the following additions:
  — tests for oxygen delivery performance;
  — new symbols;
  — new requirement for a means to prevent the propagation of fire into the OXYGEN CONCENTRATOR and its ACCESSORIES;
  — tests for cleaning and disinfection PROCEDURES; and
  — consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: 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.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

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

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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 A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Oxygen supplementation can be part of management of PATIENTS with chronic, acute–on-chronic and acute respiratory disorders. The amount of supplemental oxygen depends on the individual PATIENT'S needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate.

The goal of long term oxygen therapy is to keep the oxygen saturation above 90 % in PATIENTS that require supplemental oxygen. The flowrate should be adjusted for rest, exertion, and sleep to meet the individual PATIENT'S needs under these various conditions. Ideally, the resting flowrate is adjusted to maintain SpO_2 > 90 % as indicated by pulse oximetry.

Supplemental oxygen is supplied by various sources: MEDICAL GAS PIPELINE SYSTEMS, OXYGEN CONCENTRATORS, compressed gas cylinders, and liquid oxygen reservoirs. This standard covers the particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of OXYGEN CONCENTRATORS. OXYGEN CONCENTRATORS produce oxygen enriched air from room air for delivery to a PATIENT requiring oxygen therapy. The most common OXYGEN CONCENTRATOR uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air, generating oxygen concentrations of typically 82 % to 96 %. The main component of this type of OXYGEN CONCENTRATOR is the molecular sieve, which adsorbs nitrogen from air to produce a product gas which is a mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption process.

INTERNATIONAL STANDARD **ISO 80601-2-69:2014(E)**

Medical electrical equipment —

Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

201.1 Scope, object and related standards

IEC 60601-1:2005+Amendment 1:2012, Clause 1 applies, except as follows:

201.1.1 Scope

IEC 60601-1:2005+Amendment 1:2012, 1.1 is replaced by:

This particular standard specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of an OXYGEN CONCENTRATOR in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT, intended to increase the oxygen concentration of gas intended to be delivered to a single PATIENT. Such OXYGEN CONCENTRATORS are typically intended for use in the HOME HEALTHCARE ENVIRONMENT, including TRANSIT-OPERABLE use by a single PATIENT in various environments including any private and public transportation as well as in commercial aircraft.

NOTE 1 Such an OXYGEN CONCENTRATOR can also be used in professional healthcare facilities.

This particular standard is applicable to a TRANSIT-OPERABLE and non-TRANSIT-OPERABLE OXYGEN CONCENTRATOR. This particular standard is applicable to an OXYGEN CONCENTRATOR integrated into or used with other medical devices, ME EQUIPMENT or ME SYSTEMS.

EXAMPLE 1 An OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT [10] or humidifier [4].

EXAMPLE 2 An OXYGEN CONCENTRATOR used with a flowmeter stand.

EXAMPLE 3 An OXYGEN CONCENTRATOR as part of an anaesthetic system for use in areas with limited logistical supplies of electricity and anaesthetic gases. [3]

EXAMPLE 4 An OXYGEN CONCENTRATOR with an integrated liquid reservoir or gas cylinder filling system.

This particular standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to an OXYGEN CONCENTRATOR, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR.

This particular standard does not specify the requirements for OXYGEN CONCENTRATORS for use with a MEDICAL GAS PIPELINE SYSTEM which are given in ISO 10083.

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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 2 See also 4.2 of the General Standard.

This International Standard is a particular standard in the IEC 60601-1 series of standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by:

The object of this International Standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an OXYGEN CONCENTRATOR [as defined in 201.3.203] and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the OXYGEN CONCENTRATOR and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of an OXYGEN CONCENTRATOR.

201.1.3 Collateral standards

IEC 60601-1:2005+Amendment 1:2012, 1.3 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+Amendment 1:2012, Clause 2 of the general standard and 201.2 of this particular standard.

IEC 60601-1-3:2008+Amendment 1:2013 does not apply.

201.1.4 Particular standards

IEC 60601-1:2005+Amendment 1:2012, 1.4 is replaced by:

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 the general standard or the collateral standards.

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

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard 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 the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, 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 2xx, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

Where there is no corresponding clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography beginning on page 37.

IEC 60601-1:2005+Amendment 1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*

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

IEC 60601-1-8:2006, *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*
+Amendment 1:2012

IEC 60601-1-11:2010, *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*

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 7000:2012, *Graphical symbols for use on equipment -- Registered symbols*

ISO 7010:2011, *Graphical symbols -- Safety colours and safety signs -- Registered safety signs*
+Amendment 1:2012
+Amendment 2:2012

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO/DIS 14644-1:2010, *Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration*

ISO 17664:2004, *Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-67:2014, *Medical Electrical Equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
+Amendment 1:2014

EN 15986:2011, *Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates*