Irish Standard
I.S. EN ISO 11197:2016

Medical supply units (ISO 11197:2016)

I.S. EN ISO 11197:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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National Foreword

I.S. EN ISO 11197:2016 is the adopted Irish version of the European Document EN ISO 11197:2016, Medical supply units (ISO 11197:2016)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11197

March 2016

ICS 11.040.10

Supersedes EN ISO 11197:2009

English Version

Medical supply units (ISO 11197:2016)

Gaines techniques à usage médical (ISO 11197:2016)

Medizinische Versorgungseinheiten (ISO 11197:2016)

This European Standard was approved by CEN on 25 December 2015.

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 11197:2016 E

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European foreword

This document (EN ISO 11197:2016) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment”.

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 September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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 11197:2009.

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 11197:2016 has been approved by CEN as EN ISO 11197:2016 without any modification.

Annex ZA
(informative)

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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC.

Once this standard 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 normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

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

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
201.4 201.5 201.6 201.8 201.9 201.11.7 201.12 201.13 201.15	7.1 (first and second indents)	
201.13 201.15.4.101 201.15.4.102 201.15.4.103 201.11	7.3 (up to semicolon)	
201.7.2.1 201.8 201.9.1 201.16 201.15	9.1 (first sentence)	
201.5.9.2.3 201.6 201.8 201.9 201.10 201.17 202	9.2 (first and second indents)	Adds specific requirements Mandates 60601-2

201.8 201.11 201.11.2 201.12 201.13 201.15 201.16 201.15.101	9.3	
201.10	11	
201.14	12.1	
201.14	12.1 a)	
201.17 202	12.5	
201.6.2 201.8 201.13 201.16	12.6	
201.9 201.15	12.7.1	
201.9.6 201.9.8	12.7.2	
201.9.6	12.7.3	
201.7 201.7.2.8 201.15.4.101	12.7.4	Only covered for gas connectors
201.4 201.11.1	12.7.5	
201.7	12.9	
201.7	13.1	
201.7.2	13.3 a)	
201.7.9.2	13.6 a)	Covers item in 13.3 a) only
201.7.9.2	13.6 d)	
201.7.9.2.16	13.6 i)	
201.7.9.2.1	13.6 q)	

NOTE Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with the Medical Devices Directive 93/42/EEC. This means that RISKS have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 11197:2016

INTERNATIONAL STANDARD

ISO 11197

Third edition
2016-02-15

Medical supply units

Gaines techniques à usage médical

Reference number
ISO 11197:2016(E)

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Contents

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. 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. 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121.

ISO 11197 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with ISO Technical Committee TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11197:2004), which has been technically revised.

Introduction

Many healthcare facilities use surface-mounted or recessed containment systems and ENCLOSURES for accommodating and displaying essential PATIENT care services. These are known as MEDICAL SUPPLY UNITS.

This International Standard specifies requirements for MEDICAL SUPPLY UNITS manufactured in factories or assembled from components on site.

It is intended for use by those persons involved in the design, construction, inspection, testing, maintenance and operation of healthcare facilities as well as those manufacturing, assembling and installing MEDICAL SUPPLY UNITS.

Persons involved in the design, manufacture, installation, maintenance and testing of equipment intended to be connected to MEDICAL GAS, vacuum, ANAESTHETIC GAS SCAVENGING and/or PLUME EXTRACTION SYSTEMS should be aware of the contents of this document.

This International Standard is a particular standard, based on IEC 60601-1:2005+A1:2012. IEC 60601-1:2005+A1:2012 is the basic standard for the safety of all MEDICAL ELECTRICAL EQUIPMENT used by or under the supervision of qualified personnel in the general medical and PATIENT environment; it also contains certain requirements for reliable operation to ensure safety.

IEC 60601-1:2005+A1:2012 has associated collateral standards and particular standards. The collateral standards include requirements for specific technologies and/or HAZARDS and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The particular standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of collateral standard and particular standard can be found in IEC 60601:2005+A1:2012.

For an explanation of the special numbering in this document and more on the terms “collateral”, “particular” and “general” standards, see 201.1.3, 201.1.4, and 201.1.5.

Annex AA contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. The clauses and subclauses marked with (*) after their number have a corresponding rationale contained in Annex AA.

Medical supply units

201.1 Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies except as follows:

201.1.1 Scope

IEC 60601-1:2005+A1:2012, 1.1 is replaced by:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL SUPPLY UNITS, hereafter also referred to as ME EQUIPMENT.

This International Standard applies to MEDICAL SUPPLY UNITS manufactured within a factory or assembled on site, including cabinetry and other ENCLOSURES, which incorporate PATIENT care services.

NOTE 1 A party that assembles on site various components intended for PATIENT care services into an ENCLOSURE is considered the MANUFACTURER of the MEDICAL SUPPLY UNIT.

HAZARDS inherent in the intended function of ME EQUIPMENT or ME SYSTEMS within the scope of this International Standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1:2005+A1:2012 (see 201.1.4).

NOTE 2 See also IEC 60601-1:2005+A1:2012, 4.2.

201.1.2 Object

IEC 60601-1:2005+A1:2012, 1.2 is replaced by:

The object of this International Standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL SUPPLY UNITS as defined in 201.3.103.

201.1.3 Related standards

201.1.3.1 Collateral standards

IEC 60601-1:2005+A1:2012, 1.3 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 606011:2005+A1:2012, Clause 2 as well as 201.2 of this particular standard.