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Irish Standard
I.S. EN ISO 11197:2019

Medical supply units (ISO 11197:2019)

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1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
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National Foreword

I.S. EN ISO 11197:2019 is the adopted Irish version of the European Document EN ISO 11197:2019, Medical supply units (ISO 11197:2019)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11197

November 2019

ICS 11.040.10

Supersedes EN ISO 11197:2016

English Version

Medical supply units (ISO 11197:2019)

Gaines techniques à usage médical (ISO 11197:2019)

Medizinische Versorgungseinheiten (ISO 11197:2019)

This European Standard was approved by CEN on 15 September 2019.

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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.

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Ref. No. EN ISO 11197:2019 E

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European foreword

This document (EN ISO 11197:2019) 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of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

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 ISO 11197:2016.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11197:2019 has been approved by CEN as EN ISO 11197:2019 without any modification.

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I.S. EN ISO 11197:2019

INTERNATIONAL STANDARD

ISO 11197

Fourth edition
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Medical supply units

Gaines techniques à usage médical

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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.

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).

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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 6, *Medical gas supply systems*.

This fourth edition cancels and replaces the third edition (ISO 11197:2016), which has been technically revised. The main changes compared to the previous edition are as follows:

— editorial revision;

— change in the requirements defining the inclusion of USB outlets within medical supply units;

— addition of methods of internal cabling connections and specific tests including but not limited to impact resistance.

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

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 document 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 *gas for medicinal use*, *medical device gas*, *vacuum*, *anaesthetic gas scavenging* and/or *plume extraction systems* should be aware of the contents of this document.

This document 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, *electromagnetic compatibility* (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, 201.1.3.1, 201.1.3.2.

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

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller roman type. Normative text of tables is also in a smaller roman type;

— *test methods: italic type;*

— *terms defined in clause 3 of the general standard, in this document or as noted: italic type.*

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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 document applies to the *basic safety* and *essential performance* of *medical supply units*, hereafter also referred to as *ME equipment*.

This document 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 document are not covered by specific requirements in this standard, except in of IEC 60601-1:2005+A1:2012, 7.2.13 and 8.4.1 (see 201.1.4).

NOTE 2 Refer to 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 document is to establish particular *basic safety* and *essential performance* requirements for *medical supply units* as defined in 201.3.201.

201.1.3 Related standards

201.1.3.1 General and Collateral standards

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

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012, Clause 2 as well as 201.2 of this particular standard.

IEC 60601-1-3:2008+A1:2013, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-9:2007, IEC 60601-1-10:2007+A1:2013 and IEC 60601-1-11 and IEC 60601-1-12 do not apply.

NOTE Collateral standards are referred to by their document numbers.

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