# SLOVENSKI STANDARD
# SIST EN ISO 11197:2016

**01-maj-2016**

**Nadomešča:**
**SIST EN ISO 11197:2009**

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**Enote za oskrbo v medicini (ISO 11197:2016)**

Medical supply units (ISO 11197:2016)

Medizinische Versorgungseinheiten (ISO 11197:2016)



Gaines techniques à usage médical (ISO 11197:2016)

**Ta slovenski standard je istoveten z:** **EN ISO 11197:2016**



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**ICS:**

| | | |
|---|---|---|
| 11.040.01 | Medicinska oprema na splošno | Medical equipment in general |

**SIST EN ISO 11197:2016** **en**

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**



Ref. No. EN ISO 11197:2016 E

## Contents

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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<br>201.5<br>201.6<br>201.8<br>201.9<br>201.11.7<br>201.12<br>201.13<br>201.15 | 7.1 (first and second indents) | |
| 201.13<br>201.15.4.101<br>201.15.4.102<br>201.15.4.103<br>201.11 | 7.3 (up to semicolon) | |
| 201.7.2.1<br>201.8<br>201.9.1<br>201.16<br>201.15 | 9.1 (first sentence) | |
| 201.5.9.2.3<br>201.6<br>201.8<br>201.9<br>201.10<br>201.17<br>202 | 9.2 (first and second indents) | Adds specific requirements<br>Mandates 60601-2 |

| | | |
|---|---|---|
| 201.8<br>201.11<br>201.11.2<br>201.12<br>201.13<br>201.15<br>201.16<br>201.15.101 | 9.3 | |
| 201.10 | 11 | |
| 201.14 | 12.1 | |
| 201.14 | 12.1 a) | |
| 201.17<br>202 | 12.5 | |
| 201.6.2<br>201.8<br>201.13<br>201.16 | 12.6 | |
| 201.9<br>201.15 | 12.7.1 | |
| 201.9.6<br>201.9.8 | 12.7.2 | |
| 201.9.6 | 12.7.3 | |
| 201.7<br>201.7.2.8<br>201.15.4.101 | 12.7.4 | Only covered for gas connectors |
| 201.4<br>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.

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.