

Meditsiinilised toiteseadmed

Medical supply units

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11197:2009 sisaldab Euroopa standardi EN ISO 11197:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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English Version

Medical supply units (ISO 11197:2004)

Gaines techniques à usage médical (ISO 11197:2004)

Medizinische Versorgungseinheiten (ISO 11197:2004)

This European Standard was approved by CEN on 21 March 2009.

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Foreword

The text of ISO 11197:2004 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11197:2009 by 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 11197:2004.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 11197:2004 has been approved by CEN as a EN ISO 11197:2009 without any modification.

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Introduction

This particular standard applies in conjunction with EN 60601-1 "Medical electrical equipment — Part 1: General requirements for safety".

As stated in EN 60601-1 the requirements of this Particular Standard take priority over those of EN 60601-1.

As in EN 60601-1 the requirements are followed by the relevant tests. The structure of this particular standard corresponds to that of EN 60601-1 and the sections, clauses and sub-clauses refer to those of EN 60601-1.

Clauses, subclauses, Tables and Figures additional to those in EN 60601-1 are numbered beginning at "101". Additional annexes are lettered beginning at "AA" except for annexes "ZA" and "ZB".

Additional items in lettered lists are lettered beginning "aa)".

Annex BB contains rationale statements for some of the requirements of EN ISO 11197. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into EN ISO 11197. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in Annex BB. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this standard, but will expedite any subsequent revision.

In any health care facility it is strongly recommended that terminal units of only one type (i.e. with the same set of specific dimensions) are used for each medical gas system, anaesthetic gas scavenging system and liquid system.

SECTION ONE - GENERAL

1 Scope

Clause 1 of EN 60601-1:1990 applies with the following addition:

This document applies to medical supply units as defined in 3.5.

This particular document applies in conjunction with EN 60601-1.

The requirements of this particular document take priority over those of EN 60601-1.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

EN 737-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements.*

EN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.*

EN 737-4, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.*

EN 739:1998, *Low-pressure hose assemblies for use with medical gases.*

EN ISO 3744, *Acoustics — Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane (ISO 3744:1994).*

EN ISO 14971, *Medical devices - Application of risk management to medical devices (ISO 14971:2000).*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

EN 60529, *Degrees of protection provided by enclosures (IP code) (IEC 60529:1989).*

EN 60598-1, *Luminaires — Part 1: General requirements and tests (IEC 60598-1:1999, modified).*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988).*

EN 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:2001).*

EN 60669-1, *Switches for household and similar fixed electrical installations — Part 1: General requirements (IEC 60669-1:1998, modified).*

EN 61386-1, *Conduit systems for electrical installations – Part 1: General requirements (IEC 61386-1:1996+A1:2000).*