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Infusion equipment for medical use — Part 8: Infusion equipment for use with pressure infusion apparatus

Infusion equipment for medical use — Part 8:
Infusion equipment for use with pressure infusion
apparatus

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 8536-8:2004 sisaldab Euroopa standardi EN ISO 8536-8:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 26.10.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 8536-8:2004 consists of the English text of the European standard EN ISO 8536-8:2004.</p> <p>This document is endorsed on 26.10.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This part of ISO 8536 gives users information on sterilized infusion sets for single use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).</p>	<p>Scope: This part of ISO 8536 gives users information on sterilized infusion sets for single use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).</p>
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ICS 11.040.20

Võtmesõnad:

ICS 11.040.20

English version

Infusion equipment for medical use

Part 8: Infusion equipment for use with pressure infusion apparatus
(ISO 8536-8 : 2004)

Matériel de perfusion à usage médical – Partie 8: Matériel de perfusion pour utilisation avec des appareils de perfusion sous pression (ISO 8536-8 : 2004)

Infusionsgeräte zur medizinischen Verwendung – Teil 8: Infusionsgeräte zur Verwendung mit Druckinfusionsapparaten (ISO 8536-8 : 2004)

This European Standard was approved by CEN on 2004-07-29.

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 Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 8536-8 : 2004 Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus,

which was prepared by ISO/TC 76 'Transfusion, infusion and injection equipment for medical and pharmaceutical use' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by February 2005 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8536-8 : 2004 was approved by CEN as a European Standard without any modification.

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1 Scope

This part of ISO 8536 gives users information on sterilized infusion sets for single use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

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.

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 8536-4:2004, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

IEC 60601-2-24, *Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers*

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1 shall be used for rigid containers.