

SVENSK STANDARD

SS-EN ISO 8536-1:2011

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Infusionsutrustning för medicinskt bruk – Del 1: Glasflaskor för infusionsvätskor (ISO 8536-1:2011)

Infusion equipment for medical use – Part 1: Infusion glass bottles (ISO 8536-1:2011)

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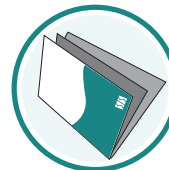
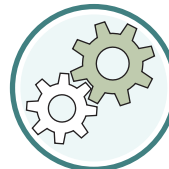
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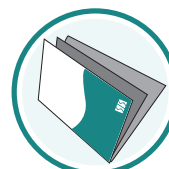
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Europastandarden EN ISO 8536-1:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8536-1:2011.

Denna standard ersätter SS-EN ISO 8536-1:2008, utgåva 2.

The European Standard EN ISO 8536-1:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 8536-1:2011.

This standard supersedes the Swedish Standard SS-EN ISO 8536-1:2008, edition 2.

**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 8536-1:2011/
Relations to other parts under the same general title - Extract from the Foreword of
ISO 8536-1:2011**

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- Part 1: *Infusion glass bottles*
- Part 2: *Closures for infusion bottles*
- Part 3: *Aluminium caps for infusion bottles*
- Part 4: *Infusion sets for single use, gravity feed*
- Part 5: *Burette infusion sets for single use, gravity feed*
- Part 6: *Freeze drying closures for infusion bottles*
- Part 7: *Caps made of aluminium-plastics combinations for infusion bottles*
- Part 8: *Infusion equipment for use with pressure infusion apparatus*
- Part 9: *Fluid lines for use with pressure infusion equipment*
- Part 10: *Accessories for fluid lines for use with pressure infusion equipment*
- Part 11: *Infusion filters for use with pressure infusion equipment*
- Part 12: *Check valves*

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Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 8536-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2011

ICS 11.040.20

Supersedes EN ISO 8536-1:2008

English Version

Infusion equipment for medical use - Part 1: Infusion glass bottles (ISO 8536-1:2011)

Matériel de perfusion à usage médical - Partie 1: Flacons en verre pour perfusion (ISO 8536-1:2011)

Infusionsgeräte zur medizinischen Verwendung - Teil 1: Infusionsflaschen aus Glas (ISO 8536-1:2011)

This European Standard was approved by CEN on 31 August 2011.

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 8536-1:2011) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use".

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 March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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 8536-1:2008.

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Endorsement notice

The text of ISO 8536-1:2011 has been approved by CEN as a EN ISO 8536-1:2011 without any modification.

Introduction

Infusion bottles are suitable primary packaging materials for the storage of infusion solutions until they are administered to the patient. Due to the direct contact between infusion solution and the primary container components and in view of the extended storage periods, it is essential to avoid possible interactions in order to guarantee the patient's safety. Adequate means to achieve this goal include the proper selection of the primary packaging materials, the choice of suitable package design and the availability of specific criteria and methods for testing of individual container systems.