

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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8536-1:2011 sisaldab Euroopa standardi EN ISO 8536-1:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 30.09.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.09.2011.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8536-1:2011 consists of the English text of the European standard EN ISO 8536-1:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 01.09.2011.

The standard is available from Estonian standardisation organisation.

ICS 11.040.20

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EUROPEAN STANDARD

EN ISO 8536-1

NORME EUROPÉENNE

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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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.

Infusion equipment for medical use —

Part 1: Infusion glass bottles

1 Scope

This part of ISO 8536 specifies the dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It is applicable only to infusion bottles for single use.

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 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 4802-1:2010, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2:2010, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

ISO 7458, *Glass containers — Internal pressure resistance — Test methods*

ISO 7459, *Glass containers — Thermal shock resistance and thermal shock endurance — Test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.