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**BS EN ISO 8536-1:2011**



BSI Standards Publication

# Infusion equipment for medical use

Part 1: Infusion glass bottles (ISO 8536-1:2011)

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This British Standard is the UK implementation of EN ISO 8536-1:2011. It supersedes BS EN ISO 8536-1:2008 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 70688 2

ICS 11.040.20

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2011.

**Amendments issued since publication**

Date	Text affected
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## 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)

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of an identical text or by endorsement, at the latest by March 2012, and conflicting national standards shall be withdrawn at the latest by March 2012.

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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

### Endorsement notice

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

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## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 8536-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 8536-1:2006), of which it constitutes a minor revision.

The principle changes to the third edition are the updating of normative references to ISO 4802-1 and ISO 4802-2, and the addition of a note at the start of Clause 8.

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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## 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.

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# 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.