

Infusion equipment for medical use

Part 2: Closures for infusion bottles

ICS 11.040.20

National foreword

This British Standard is the UK implementation of EN ISO 8536-2:2010. It is identical to ISO 8536-2:2010. It supersedes BS EN ISO 8563-2:2002 which is withdrawn.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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Amendments/corrigenda issued since publication

Comments	Date
31 August 2010	Incorporating corrected version of ISO 8536-2:2010, 15 May 2010; Note in A.3.7 amended

English Version

Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2010)

Matériel de perfusion à usage médical - Partie 2: Bouchons
pour flacons de perfusion (ISO 8536-2:2010)

Infusionsgeräte zur medizinischen Verwendung - Teil 2:
Stopfen für Infusionsflaschen (ISO 8536-2:2010)

This European Standard was approved by CEN on 18 February 2010.

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Foreword

This document (EN ISO 8536-2:2010) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection 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of an identical text or by endorsement, at the latest by September 2010, and conflicting national standards shall be withdrawn at the latest by September 2010.

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Endorsement notice

The text of ISO 8536-2:2010 has been approved by CEN as a EN ISO 8536-2:2010 without any modification.

The corrected version of ISO 8536-2:2010, 15 May 2010 provided a revised English language text incorporating the following editorial corrections:

— Page 6, Note in A.3.7: "50 mm" has been replaced by "50 µm".

Introduction

The purpose of this part of ISO 8536 is to specify the shape and dimensions of and the requirements for elastomeric closures intended for infusion bottles. In order to provide seal integrity of the container closure systems the dimensions of the elastomeric closures have to be compatible with the dimensions of the infusion bottles and the caps as specified in corresponding parts of ISO 8536.

Primary packaging components made of elastomeric materials are an integral part of medicinal products and thus the principles of current Good Manufacturing Practice (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in, e.g. ISO 15378 or GMP Guidelines as published by the European Community and the United States of America.

