

Injection containers and accessories - Part 1: Injection vials made of glass tubing (ISO 8362-1:2009)

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/16

Obsahuje: EN ISO 8362-1:2009/A1:2015, ISO 8362-1:2009/Amd 1:2015

STN EN ISO 8362-1/A1: 2016

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 8362-1:2009/A1

December 2015

ICS 11.040.20

English Version

Injection containers and accessories - Part 1: Injection vials made of glass tubing (ISO 8362-1:2009/Amd 1:2015)

Récipients et accessoires pour produits injectables -Partie 1: Flacons en verre étiré (ISO 8362-1:2009/Amd Injektionsbehältnisse und Zubehör - Teil 1: Injektionsflaschen aus Röhrenglas (ISO 8362-1:2009/Amd 1:2015)

This amendment A1 modifies the European Standard EN ISO 8362-1:2009; it was approved by CEN on 3 October 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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.

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



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

EN ISO 8362-1:2009/A1:2015 (E)

Contents	Page
Furonean foreword	3
European foreword	3

European foreword

This document (EN ISO 8362-1:2009/A1:2015) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use".

This Amendment to the European Standard EN ISO 8362-1:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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.

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

Endorsement notice

The text of ISO 8362-1:2009/Amd 1:2015 has been approved by CEN as EN ISO 8362-1:2009/A1:2015 without any modification.

INTERNATIONAL STANDARD

ISO 8362-1

Third edition 2009-12-15 **AMENDMENT 1** 2015-12-15

Injection containers and accessories —

Part 1: **Injection vials made of glass tubing** AMENDMENT 1

Récipients et accessoires pour produits injectables —
Partie 1: Flacons en verre étiré
AMENDEMENT 1



ISO 8362-1:2009/Amd.1:2015(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.*

Injection containers and accessories —

Part 1:

Injection vials made of glass tubing

AMENDMENT 1

Page 2, <u>Table 1</u>

koniec náhľadu – text ďalej pokračuje v platenej verzii STN