

# SVENSK STANDARD

## SS-EN ISO 8362-4:2011

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### **Behållare för injektionsvätskor – Del 4: Injektionsflaskor och injektionsampuller tillverkade av formgjutet glas (ISO 8362-4:2011)**

### **Injection containers and accessories – Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)**

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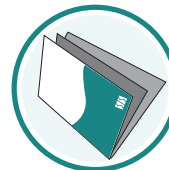
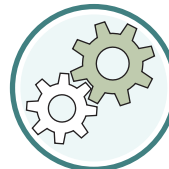
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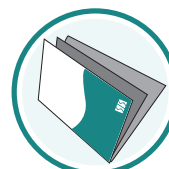
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Europastandarden EN ISO 8362-4:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 8362-4:2011.

Denna standard ersätter SS-EN ISO 8362-4:2004, utgåva 1.

The European Standard EN ISO 8362-4:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 8362-4:2011.

This standard supersedes the Swedish Standard SS-EN ISO 8362-4:2004, edition 1.

**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 8362-4:2011/  
Relations to other parts under the same general title - Extract from the Foreword of  
ISO 8362-4:2011**

ISO 8362 consists of the following parts, under the general title *Injection containers and accessories*:

- Part 1: *Injection vials made of glass tubing*
- Part 2: *Closures for injection vials*
- Part 3: *Aluminium caps for injection vials*
- Part 4: *Injection vials made of moulded glass*
- Part 5: *Freeze drying closures for injection vials*
- Part 6: *Caps made of aluminium-plastics combinations for injection vials*
- Part 7: *Injection caps made of aluminium-plastics combinations without overlapping plastics part*

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

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EUROPEAN STANDARD

**EN ISO 8362-4**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2011

ICS 11.040.20

Supersedes EN ISO 8362-4:2004

English Version

## Injection containers and accessories - Part 4: Injection vials made of moulded glass (ISO 8362-4:2011)

Réipients et accessoires pour produits injectables - Partie  
4: Flacons en verre moulé (ISO 8362-4:2011)

Injektionsbehältnisse und Zubehör - Teil 4:  
Injektionsflaschen aus Hüttenglas (ISO 8362-4:2011)

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

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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 8362-4:2011) 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 8362-4:2004.

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### Endorsement notice

The text of ISO 8362-4:2011 has been approved by CEN as a EN ISO 8362-4:2011 without any modification.

## Introduction

The purpose of this part of ISO 8362 is to specify the shape, dimensions and capacities of, and performance requirements for, glass vials intended for medical use. Containers made from moulded glass are considered to be suitable for the packaging and storage of injectable preparations until they are administered for medicinal purposes. Such containers can be made from different types of glass, which can affect the chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance, whereas those made from soda-lime-silica glass will have a lower chemical resistance but one that is adequate for the purpose for which the containers are intended. The chemical resistance of the internal surface of containers made from soda-lime-silica glass can be improved by a treatment during production to produce a chemical resistance equal to that of containers made from borosilicate glass for single use. This level of chemical resistance will be maintained as long as the interior surface is not destroyed by chemical attack, in which case it will be reduced to that of untreated soda-lime-silica glass.

Because containers can be made from different types of glass and because it is the chemical behaviour of the internal surface that is important when they are filled with injectable preparations, it is essential to specify test procedures by which this performance can be measured. The procedures specified in this part of ISO 8362 will allow this performance based on the hydrolytic resistance to be measured and, from the result of measurement, it is possible to classify containers into their correct category. The procedures also allow containers to be tested and to determine whether the hydrolytic resistance is due to the composition of the glass, or to a treatment of the internal surface.