Veenisisesteks süstideks mõeldud plastanumad (ISO 15747:2010)

Plastic containers for intravenous injections (ISO 15747:2010)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15747:2011 sisaldab Euroopa standardi EN ISO 15747:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15747:2011 consists of the English text of the European standard EN ISO 15747:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.10.2011.	Date of Availability of the European standard text 19.10.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 15747

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Supersedes EN ISO 15747:2010

English Version

Plastic containers for intravenous injections (ISO 15747:2010)

Récipients en plastique pour injections intraveineuses (ISO 15747:2010)

Kunststoffbehältnisse für intravenöse Injektionen (ISO 15747:2010)

This European Standard was approved by CEN on 20 September 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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 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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Ref. No. EN ISO 15747:2011: E

Foreword

This document (EN ISO 15747:2011) 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 April 2012, and conflicting national standards shall be withdrawn at the latest by April 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 15747:2010.

This new edition contains a revised Annex ZA.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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 15747:2010 has been approved by CEN as EN ISO 15747:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2, 4.3.2	7.1	Only chemical toxicity is addressed (in clause 4.2). Only pyrogenic and toxic effects are addressed (in clause 4.3.2).
4.1.4, 4.1.6, 4.2	7.2	The part of ER 7.2 regarding the packaging is not addressed.
4.1.2, 4.1.5, 4.2	7.3	Only the first half sentence of ER 7.3 is addressed.
4.1.2, 4.1.5, 4.2, 4.3.2	7.5	Only the first sentence of ER 7.5 is covered.
4.1.7 to 4.1.10, 4.3.1	7.6	
4.1.7 to 4.1.11, 4.3.1	8.1	
4.1.7 to 4.1.11	9.1	Restrictions indicated on the label or in the instructions for use are not addressed.
4.1.2, 4.1.3	12.7.1	Only resistance to mechanical stress is addressed.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Introduction

In some countries, national or regional pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this International Standard.

Plastic containers for intravenous injections

1 Scope

This International Standard contains requirements that relate to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

This International Standard is applicable to plastic containers for parenterals having one or more chambers and having a total nominal capacity in the range of 50 ml to 5 000 ml such as film bags or blow-moulded plastic bottles for direct administration of infusion (injection) solutions.

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 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 10993 (all parts), *Biological evaluation of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
access port
area of the infusion container consisting of the insertion point and the injection point, if applicable

3.2
cover
part that protects the access port during storage and also provides evidence that the infusion container has been tampered with

NOTE The cover can also envelop the entire container (e.g. outer bag).

3.3
empty container
raw container with identification, which is suitable for the acceptance, storage and administration of the injection solution

3.4
hanger
that part of the container that is used to hang it up