SLOVENSKI STANDARD
SIST EN ISO 15747:2019

01-maj-2019

Nadomešča:
SIST EN ISO 15747:2012

Plastični zbiralniki za intravenske injekcije (ISO 15747:2018)

Plastic containers for intravenous injections (ISO 15747:2018)

Kunststoffbehältnisse für intravenöse Injektionen (ISO 15747:2018)

Récipients en plastique pour injections intraveineuses (ISO 15747:2018)

Ta slovenski standard je istoveten z: **EN ISO 15747:2019**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 15747:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15747

March 2019

ICS 11.040.20

Supersedes EN ISO 15747:2011

English Version

Plastic containers for intravenous injections (ISO 15747:2018)

Récipients en plastique pour injections intraveineuses (ISO 15747:2018)

Kunststoffbehältnisse für intravenöse Injektionen (ISO 15747:2018)

This European Standard was approved by CEN on 28 February 2019.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 15747:2019 E

Contents

Page

European foreword

This document (EN ISO 15747:2019) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with CCMC.

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 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15747:2011.

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(s).

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

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 2768-1	—	ISO 2768-1:1989
ISO 2768-2	—	ISO 2768-2:1989
ISO 8536-4	EN ISO 8536-4:2013 + A1:2013	ISO 8536-4:2010 + Amd 1:2013
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15747:2018 has been approved by CEN as EN ISO 15747:2019 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/295 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169]

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.2	4.1.6, 4.2	The part of ER 7.2 relating to packaging is not addressed. 4.1.6 covers ER 7.2 only in respect of particulate contamination. 4.2 covers ER 7.2 only in respect of the substances specified in the Standard.
7.3	4.1.5, 4.2	Only the first half sentence of ER 7.3 is addressed. 4.1.5 covers ER 7.3 first part only in respect of water permeability. 4.2 covers ER 7.3 first part only in respect of the substances specified in the Standard.

7.5	4.1.5, 4.2, 4.3.2	Only the first sentence of ER 7.5 is covered. 4.1.5 covers ER 7.5 first sentence, first paragraph only in respect of water permeability. 4.2 covers ER 7.5 first sentence, first paragraph only in respect of the substances specified in the Standard. 4.3.2 covers ER 7.5 first sentence, first paragraph only in respect of the substances that may have a pyrogenic effect.
7.6	4.1.7, 4.3.1	4.1.7 covers ER 7.6 only in respect of preventing the ingress of substances to the access port.
8.1	4.1.7 to 4.1.10, 4.3.1	4.1.7 covers ER 8.1 only in respect of preventing the ingress of substances to the access port. 4.3.1 covers ER 8.1 only in respect of impermeability for microorganisms into the infusion container.
9.1	4.1.7 to 4.1.11	Restrictions indicated on the label or in the instructions for use are not addressed. 4.1.7 covers ER 9.1 only in respect of the access port cover. 4.1.11 covers ER 9.1 only in respect of the suspension hanger and only if the hanger is not an integral part of the device.
12.7.1	4.1.2, 4.1.3	Only resistance to mechanical stress is addressed. 4.1.2 covers ER 12.7.1 only in respect of temperature and pressure tolerance. 4.1.3 covers ER 12.7.1 in respect of resistance to damage by being dropped.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to the European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 15747

Third edition
2018-09

Plastic containers for intravenous injections

Récipients en plastique pour injections intraveineuses

Reference number
ISO 15747:2018(E)

COPYRIGHT PROTECTED DOCUMENT

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

Published in Switzerland

Contents

Page