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STN	**Plastové nádoby na intravenózne injekcie (ISO 15747: 2018)**	**STN EN ISO 15747** 85 6217

Plastic containers for intravenous injections (ISO 15747:2018)

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. 06/19

Obsahuje: EN ISO 15747:2019, ISO 15747:2018

Oznámením tejto normy sa ruší
STN EN ISO 15747 (85 6217) z februára 2012

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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

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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
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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 (see 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 (see 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 15747:2010), which has been technically revised. The main changes compared to the previous edition are as follows:

— the text of the Introduction has been moved as NOTE to the end of the Scope;

— a metallic reference spike has been defined, in Annex D, to harmonise measurement of insertion point functional properties, for orientation and comparison purpose between different containers;

— the test for tightness of the injection point after piercing with a cannula has been revised to better define acceptance criteria;

— the wording of the titles of requirements and related tests procedures has been harmonised for better clarity.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

INTERNATIONAL STANDARD **ISO 15747:2018(E)**

Plastic containers for intravenous injections

1 Scope

This document specifies requirements to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

This document 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.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 2768-2, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

