Irish Standard
I.S. EN ISO 15747:2011

Plastic containers for intravenous injections (ISO 15747:2010)

I.S. EN ISO 15747:2011

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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I.S. EN ISO 15747:2011

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15747

October 2011

ICS 11.040.20

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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Page

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.

I.S. EN ISO 15747:2011

INTERNATIONAL STANDARD

ISO 15747

Second edition
2010-04-15

Plastic containers for intravenous injections

Récipients en plastique pour injections intraveineuses

Reference number
ISO 15747:2010(E)

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15747 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 15747:2003), which has been technically revised. Especially Annex C was totally revised in order to refer to the International Standards of the ISO 10993 series, which specifies the biological assessment of medical products.

Introduction

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