

ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 3826-4:2015

Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO

Kunststoffbeutel für menschliches Blut
und Blutbestandteile - Teil 4: Apherese-
Blutbeutelssysteme mit integrierten
Merkmalen (ISO 3826-4:2015)

Poches en plastique souple pour le sang
et les composants du sang - Partie 4:
Systèmes de poches d'aphérèse pour le
sang avec accessoires intégrés (ISO

08/2015



National Foreword

This European Standard EN ISO 3826-4:2015 was adopted as Luxembourgish Standard ILNAS-EN ISO 3826-4:2015.

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ILNAS-EN ISO 3826-4:2015

EUROPEAN STANDARD **EN ISO 3826-4**

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Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015)

Poches en plastique souple pour le sang et les composants du sang - Partie 4: Systèmes de poches d'aphérese pour le sang avec accessoires intégrés (ISO 3826-4:2015)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 4: Apherese-Blutbeutelssysteme mit integrierten Merkmalen (ISO 3826-4:2015)

This European Standard was approved by CEN on 23 April 2015.

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



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European foreword

This document (EN ISO 3826-4:2015) 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 Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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.

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

Endorsement notice

The text of ISO 3826-4:2015 has been approved by CEN as EN ISO 3826-4:2015 without any modification.

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 undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 594-2	—	ISO 594-2:1998
ISO 1135-4	EN ISO 1135-4:— ^a	ISO 1135-4:— ^a
ISO 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 3826-1	EN ISO 3826-1:2013	ISO 3826-1:2013
ISO 3826-2	EN ISO 3826-2:2008	ISO 3826-2:2008
ISO 3826-3	EN ISO 3826-3:2007	ISO 3826-3:2006
ISO 8536-4	EN ISO 8536-4:2013 and EN ISO 8536-4:2013/A1:2013	ISO 8536-4:2010 and Amd.1:2013
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 10993-5	EN ISO 10993-5:2009	ISO 10993-5:2009
ISO 10993-10	EN ISO 10993-10:2013	ISO 10993-10:2010
ISO 10993-11	EN ISO 10993-11:2009	ISO 10993-11:2006
ISO 10993-12	EN ISO 10993-12:2012	ISO 10993-12:2012
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 15747	EN ISO 15747:2011	ISO 15747:2010
ISO 23908	EN ISO 23908:2013	ISO 23908:2011
^a To be published.		

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, Medical devices

Once this standard is cited in the Official Journal of the European Communities 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.

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 / Directive 90/385/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 Table of References, 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 Directive 93/42/EEC, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2.1, 6.2.3, 6.2.7, 6.2.8, 6.2.9, 6.2.10, 6.2.11, 6.3, 7	7.2	Only the protection to the patients is explicitly addressed. The part of ER 7.2 regarding the packaging is not fully addressed. For packaging, see Clause 7 of this part of EN ISO 3826.
5.1 to 5.8, 6.2, 6.3, 6.4	7.3	Only the first half sentence of ER 7.3 is addressed. ER covered by biological evaluation.
6.2.7, 6.2.10, 6.3, 6.4	7.5 (first and second paragraph)	The part of ER 7.5 relating to phthalates is not explicitly covered. Only the first sentence is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993 series of standards.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.3.1, 5.3.3, 5.4, 5.5.1, 5.5.4, 5.9.1, 5.10.3, 5.10.5, 5.11, 6.1, 6.2.1, 6.2.2, 6.2.6, 6.2.7, 6.2.10, 6.2.11, 6.4.2	7.6	
5, 6	8.1	The part of ER 8.1 relating to easy handling is not addressed. Manufacturing processes are not covered. Only sterility of product is covered.
7	8.3	
6.2.1, 6.2.2	8.4	
6.2.1	8.5	
5.8, 5.9, 5.10, 5.11	9.1	Restrictions indicated on the label or in the instructions for use are not addressed.
4, 5.4	9.2	
6.2.7, 6.2.8, 6.2.9, 6.2.10	12.7.1	Only resistance to mechanical stress is addressed.
8.2 to 8.6	13.1	
8.1	13.2	EN ISO 15223-1 and EN ISO 3826-2 are addressed when using symbols.
8.2 to 8.6	13.3	The part of ER 13.3 related to authorized representative is not addressed. 13.3 d) is only covered if the batch number is preceded by the word 'LOT'. 13.3 f) Requirement indication of single use must be consistent across the Community is not addressed in this part of EN ISO 3826. 13.3 g) and h) are not addressed in this part of EN ISO 3826.
8.2 to 8.6	13.4	

WARNING — Other requirements and other EU Directives can be applicable to the product(s) falling within the scope of this part of EN ISO 3826.