SLOVENSKI STANDARD
SIST EN ISO 15798:2013/A1:2017

01-december-2017

Očesni vsadki (implantati) - Očesni kirurški pripomočki - Dopolnilo A1 (ISO 15798:2013/Amd 1:2017)

Ophthalmic implants - Ophthalmic viscosurgical devices - Amendment 1 (ISO 15798:2013/Amd 1:2017)

Ophthalmische Implantate - Viskoelastische Substanzen - Änderung 1 (ISO 15798:2013/Amd 1:2017)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques - Amendement 1 (ISO 15798:2013/Amd 1:2017)

Ta slovenski standard je istoveten z: **EN ISO 15798:2013/A1:2017**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 15798:2013/A1:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15798:2013/A1

October 2017

ICS 11.040.70

English Version

Ophthalmic implants - Ophthalmic viscosurgical devices - Amendment 1 (ISO 15798:2013/Amd 1:2017)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques - Amendement 1 (ISO 15798:2013/Amd 1:2017)

Ophthalmische Implantate - Viskoelastische Substanzen - Änderung 1 (ISO 15798:2013/Amd 1:2017)

This amendment A1 modifies the European Standard EN ISO 15798:2013; it was approved by CEN on 10 October 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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

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European foreword

This document (EN ISO 15798:2013/A1:2017) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 15798:2013 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2018, and conflicting national standards shall be withdrawn at the latest by April 2018.

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 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, 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 15798:2013/Amd 1:2017 has been approved by CEN as EN ISO 15798:2013/A1:2017 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 version of the ISO or IEC standard, as listed below.

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

Table — Correlation 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
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-2	EN ISO 10993-2:2006	ISO 10993-2:2006
ISO 10993-6	EN ISO 10993-6:2009	ISO 10993-6:2007
ISO 10993-9	EN ISO 10993-9:2009	ISO 10993-9:2009
ISO 10993-16	EN ISO 10993-16:2010	ISO 10993-16:2010
ISO 11135-1 [a]	EN ISO 11135-1:2007 [a]	ISO 11135-1:2007 [a]
ISO 11137-1	EN ISO 11137-1:2015	ISO 11137-1:2006 + ISO 11137-1:2006/Amd 1:2013
ISO 11137-2	EN ISO 11137-2:2015	ISO 11137-2:2013
ISO 11137-3	EN ISO 11137-3:2006	ISO 11137-3:2006
ISO 11607-1	EN ISO 11607-1:2009 + EN ISO 11607-1:2009/A1:2014	ISO 11607-1:2006 + ISO 11607-1:2006/Amd 1:2014
ISO 13408-1	EN ISO 13408-1:2015	ISO 13408-1:2008 + ISO 13408-1:2008/Amd 1:2013
ISO 14155	EN ISO 14155:2011 + EN ISO 14155:2011/AC:2011	ISO 14155:2011 + ISO 14155:2011/Cor 1:2011
ISO 14630	EN ISO 14630:2012	ISO 14630:2012
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 15223-2	—	ISO 15223-2:2010
ISO 17665-1	EN ISO 17665-1:2006	ISO 17665-1:2006
ISO 22442-1	EN ISO 22442-1:2015	ISO 22442-1:2015
ISO 22442-2	EN ISO 22442-2:2015	ISO 22442-2:2015
ISO 22442-3	EN ISO 22442-3:2007	ISO 22442-3:2007
EN 980 [b]	EN 980:2008 [b]	—
EN 1041	EN 1041:2008+A1:2013	—

[a] Withdrawn. The version available at the time of publication of the present document is EN ISO 11135:2014 (ISO 11135:2014).

[b] Withdrawn. The version available at the time of publication of the present document is EN ISO 15223-1:2012 (ISO 15223-1:2012, Corrected version 2017-03).

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/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council 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	7	Standard Clause 7 covers Directive Annex 1 ER 7.2 in respect of sterilization only.
7.3	6.2	Standard Clause 6.2 covers Directive Annex 1 ER 7.3 in respect of biological safety only. The last part of Directive Annex 1, ER 7.3 relating to medicinal products is not covered.
8.1	7	Standard Clause 7 does cover Directive Annex 1 ER 8.1 in respect of final sterilization only and does not cover design and manufacturing.

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
8.2	5.3.3	Standard Clause 5.3.3, covers Directive Annex 1, ER 8.2 in respect of the identification of and risk analysis of biological contaminants only.
8.3	7, 8, 10	Standard Clause 7 covers Directive Annex 1, ER 8.3 in respect of final sterilization only. Standard Clause 8 covers Directive Annex 1, ER 8.3 in respect of shelf life stability only. Standard Clause 10 covers Directive Annex 1, ER 8.3 in respect of transit storage and handling sterility only.
8.4	7	Standard Clause 7 covers Directive Annex 1, ER 8.4 in respect of the sterilization process only.
9.1	9	Standard Clause 9 covers Directive Annex 1 ER 9.1 in respect of the delivery cannula only.
13.1	11	For more detailed information see the below mapping of sub-items of ER 13 to the corresponding rows of Standard Clause 11, Table 1.
13.3 a)	11	Standard Clause 11, Table 1, rows 1, 2 and 3 cover ER 13.3 a).
13.3 b)	11	Standard Clause 11, Table 1, rows 3 and 5 cover ER 13.3 b).
13.3 c)	11	Standard Clause 11, Table 1, row 14 covers ER 13.3 c).
13.3 d)	11	Standard Clause 11, Table 1, row 17 covers ER 13.3 d).
13.3 e)	11	Standard Clause 11, Table 1, row 16 covers ER 13.3 e).
13.3 f)	11	Standard Clause 11, Table 1, row 13 covers ER 13.3 f).
13.3 i)	11	Standard Clause 11, Table 1, rows 8 and 15 cover ER 13.3 i) for the aspects detailed in the Standard.
13.3 k)	11	Standard Clause 11, Table 1, rows 12 and 15 cover ER 13.3 k) for the aspect detailed in the Standard.
13.3 m)	11	Standard Clause 11, Table 1, row 14 covers ER 13.3 m).

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
13.4	11	Standard Clause 11, Table 1, rows 4, 5, 9 and 10 cover ER 13.4.
13.6 a)	11	Standard Clause 11, Table 1 covers ER 13.6 for the aspects detailed above in respect to the coverage of items of ER 13.3 only.
13.6 b)	11	Standard Clause 11, Table 1, rows 5, 6, 7 and 12 cover ER 13.6 b).
13.6 q)	11	Standard Clause 11, Table 1, row 18 covers ER 13.6 q).

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this 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.