

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2011)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14534:2015 sisaldab Euroopa standardi EN ISO 14534:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14534:2015 consists of the English text of the European standard EN ISO 14534:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.01.2015.	Date of Availability of the European standard is 28.01.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 11.040.70

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage [www.evs.ee](http://www.evs.ee); phone +372 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

English Version

## Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2011)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Exigences fondamentales (ISO 14534:2011)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Grundlegende Anforderungen (ISO 14534:2011)

This European Standard was approved by CEN on 7 January 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.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Foreword

The text of ISO 14534:2011 has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14534:2015 by Technical Committee CEN/TC 170 "Ophthalmic optics" 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 July 2015, and conflicting national standards shall be withdrawn at the latest by July 2015.

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 14534:2011.

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 relationship with EU Directive(s), 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

**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 10993-1	EN ISO 10993-1:2009 + AC:2010	ISO 10993-1:2009 + Cor.1:2010
ISO 11978	EN ISO 11978:2014	ISO 11978:2014
ISO 11980	EN ISO 11980:2012	ISO 11980:2012
ISO 11986	EN ISO 11986:2010	ISO 11986:2010
ISO 11987	EN ISO 11987:2012	ISO 11987:2012
ISO 13212	EN ISO 13212:2014	ISO 13212:2014
ISO 14155	EN ISO 14155:2011 + AC:2011	ISO 14155:2011 + Cor.1:2011
ISO 14729:2001 + Amd.1:2010	EN ISO 14729:2001 + A1:2010	ISO 14729:2001 + Amd.1:2010
ISO 14730	EN ISO 14730:2014	ISO 14730:2014
ISO 14971	EN ISO 14971:2007	ISO 14971:2007
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 18369-1	EN ISO 18369-1:2006	ISO 18369-1:2006
ISO 18369-2	EN ISO 18369-2:2012	ISO 18369-2:2012
ISO 22442 (all parts)	EN ISO 22442-1:2007, EN ISO 22442-2:2007, EN ISO 22442-3:2007, —	ISO 22442-1:2007, ISO 22442-2:2007, ISO 22442-3:2007, ISO/TR 22442-4:2010,

**Endorsement notice**

The text of ISO 14534:2011 has been approved by CEN as EN ISO 14534:2015 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 European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 10, 11	7.2	
4, 7	7.3	
4	7.5	
4, 11	7.6	
4, 10, 11	8.1	
7	8.2	
10, 11	8.3	
9, 10	8.4	
9, 10	8.5	
11	8.6	
11.4	8.7	
4.2, 13.1	9.1	Sub-clause 13.1 makes normative reference to EN ISO 11978. The relevant requirement for contact lenses is provided in EN ISO 11978:2014, Table 1, item 16 h). The relevant requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2, items 10, 16, 19, 20, and 27.
5	9.2	
4	10.1	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
13.1, 13.2, 13.3	13.1	Sub-clause 13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.3.1	13.2	Sub-clause 13.1 makes normative reference to EN ISO 11978. The relevant requirement is provided in EN ISO 11978:2014, sub-clause 4.1.
13.1, 13.2, 13.3	13.3	Sub-clause 13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.2, 13.3	13.4	Sub-clause 13.1 makes normative reference to EN ISO 11978. The labelling requirements on intended purpose for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements on intended purpose for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.2, 13.3	13.5	Sub-clause 13.1 makes normative reference to EN ISO 11978. The relevant labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1, items 2 and 4. The relevant labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2, items 2, 4 and 16.
13.1, 13.2, 13.3	13.6	Sub-clause 13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.

**WARNING** — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.