SLOVENSKI STANDARD
SIST EN 13503-8:2000

01-november-2000

Oļ esni vsadki (implantati) - Intraokularne leļ e - 8. del: Osnovne zahteve (ISO 11979-8:1999, spremenjen)

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979 -8:1999, modified)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen (ISO 11979-8:1999, modifiziert)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales (ISO 11979-8:1999, modifié)

Ta slovenski standard je istoveten z: **EN 13503-8:2000**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN 13503-8:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 13503-8

March 2000

ICS 11.040.70

English version

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:1999, modified)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales (ISO 11979-8:1999, modifié)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen (ISO 11979-8:1999, modifiziert)

This European Standard was approved by CEN on 20 January 2000.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

This European Standard has been prepared 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 September 2000, and conflicting national standards shall be withdrawn at the latest by September 2000.

This European Standard 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 standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

European Standard EN 13503 was developed by CEN/TC 170, *Ophthalmic optics* in cooperation with ISO/TC 172/SC 7, *Ophthalmic optics and instruments*, and is published in several parts under the general title *Ophthalmic implants - Intraocular lenses*:

Part 1: Vocabulary
Part 2: Optical properties and test methods
Part 3: Mechanical properties and test methods
Part 4: Labelling and information
Part 5: Biocompatibility
Part 6: Shelf-life and transport stability
Part 7: Clinical investigations
Part 8: Fundamental requirements

It always was and still is the intention of the Technical Committees CEN/TC 170 and ISO/TC 172/SC 7 to prepare identical ISO and CEN Standards on Intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of CEN/TC 170 and ISO/TC 172/SC 7 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards become available.

EN 13503 is the modified ISO 11979. The main difference between both series of standards is that ISO 11979 is based on the reference to ISO 14155 *Clinical investigation of medical devices* while EN 13503 is based on the reference to EN 540 *Clinical investigation of medical devices for human subjects*.

In the present European Standard, modifications with regard to ISO 11979-8 are indicated by strike-out or underlining and cross references are given where possible.

Endorsement notice

The text of the International Standard ISO 11979-8:1999 was approved by CEN as a European Standard with agreed commun modifications as given in the Foreword and indicated in the text by strike-out and underlining.

Introduction

This Part of EN 13503 provides fundamental requirements of general nature for intraocular lenses. It refers to other standards applicable to intraocular lenses for specific methods and requirements.

It always was and still is the intention of the Technical Committees CEN/TC 170 and ISO/TC 172/SC 7 to prepare identical ISO and CEN (European Commitee for Standardization) standards on intraocular lenses. However, during the preparation of Part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of CEN/TC 170 and ISO/TC 172/SC 7 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards become available.

1 Scope

This Part of EN 13503 specifies fundamental requirements for all types of intraocular lenses (IOLs) intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

NOTE If a test method contained in a standard referenced by this part of EN 13503 is not suitable for a certain design or for a certain application, the manufacturer may devise an alternative test method if validation and rationale for that method is documented.

2 Normative references

~~The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.~~

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

~~ISO 10993-7:1995, *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*~~
EN ISO 11979-1:1999 *Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary*
EN ISO 11979-2:1999 *Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods*
EN 13503-3: -[1], *Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods*
EN ISO 11979-4:-[1] *Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information*
EN 13503-5:-[1] *Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility*
EN 13503-6:-[1] *Ophthalmic implants - Intraocular lenses - Part 6: Shelf life and transport stability*
EN 13503-7:-[1] *Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations*

1) To be published.

3 Terms and definitions

For the purposes of this Part of EN 13503, the terms and definitions given in EN ISO 11979-1 apply.

4 Safety and performance

The safety of the IOL shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis.

The manufacturer shall ensure that the IOL conforms to applicable requirements in EN ISO 11979-2 and EN 13503-3. The manufacturer shall record and justify any deviations from EN ISO 11979-2 and EN 13503-3.

In addition, all information shall be retained by the manufacturer in compliance with applicable regulatory requirements.

5 Materials

The manufacturer shall have documented evidence that demonstrates the IOL to be biocompatible by assessment in accordance with EN 13503-5.

NOTE Manufacturers should take into consideration previous clinical experience and data when determining the extent of further pre-clinical testing (see also clause 6). See EN ISO 10993-1 for guidance on testing for biocompatibility.

6 Clinical evaluation

The IOL shall be demonstrated to be clinically safe and effective by one of the following:

a) having undergone clinical evaluation in accordance with EN 13503-7;

b) being supported by retrospective data which provide a level of assurance of safety and effectiveness which is equivalent to a clinical assessment in accordance with EN 13503-7.

~~c) being a minor modification of a parent model for which safety and effectiveness has been established in accordance with ISO 11979-7.~~

~~NOTE Examples of modifications that may be considered minor are given in ISO 11979-7.~~

7 Manufacturing

Intraocular lenses shall be manufactured in accordance with documented specified design attributes.

8 Sterilization

The manufacturer shall ensure that the IOL in its packaging (see clause 9) will maintain its sterility up to the expiration date stated.

NOTE EN 556 specifies requirements for terminally sterilized medical devices to be labelled "Sterile". The current standards describing procedures for validating methods of sterilization are:

a) steam sterilization (ISO 11134 and EN 554);
b) ethylene oxide sterilization (ISO 11135 and EN 550); and
c) radiation sterilization (ISO 11137 and EN 552).

Whichever method of sterilization is used, the manufacturer shall have documented evidence to demonstrate both the effectiveness of the method and its validation.

9 Packaging and shelf life

The packaging shall be so designed that, under conditions specified by the manufacturer for storage, transport and handling, the IOL will be protected against damage and deterioration which would impair its safety in use (see requirements in EN 13503-6). In addition, the packaging shall be so designed that, at the expiration date, the IOL will still conform to clauses 4 and 8 of this Part of EN 13503.

10 Labelling and information

The IOL as marketed shall be supplied with labelling and information in accordance with EN ISO 11979-4.

ANNEX ZA (informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

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

The following clauses of this standard, as detailed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1: Correspondence between this European Standard and EU Directives

Clauses/sub-clauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC	Comments
4	I.1 I.3 II.9.2 II.12.7	For optical properties reference to EN ISO 11979-2; For mechanical properties reference to EN 13503-3
5	I.1 II.7.1 II.7.3 II.7.5 II.7.6 II.9.2	For biocompatibility reference to EN 13503-5 and EN ISO 10993-1; Interaction with YAG-laser reference to EN 13503-5.
6	I.1 I.4 I.6 II.7.6 II.9.2 II.14	For clinical investigation reference to EN 13503-7
8	I.1 I.2 II.8.1 II.8.4	Sterility requirement
9	I.3 I.5 II.8.3 II.8.6 II.9.2	For shelf-life and transport reference to EN 13503-6
10	II.8.7 II.13.1 II.13.2 II.13.3 II.13.5 II.13.6	For labelling and information reference to EN ISO 11979-4