

STN	Očné implantáty Očné endotamponáže (ISO 16672: 2020)	STN EN ISO 16672 19 5302
------------	---	--

Ophthalmic implants - Ocular endotamponades (ISO 16672:2020)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

Obsahuje: EN ISO 16672:2021, ISO 16672:2020

Oznámením tejto normy sa ruší
STN EN ISO 16672 (19 5302) z januára 2016

134049

EUROPEAN STANDARD

EN ISO 16672

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2021

ICS 11.040.70

Supersedes EN ISO 16672:2015

English Version

**Ophthalmic implants - Ocular endotamponades (ISO
16672:2020)**Implants ophtalmiques - Produits de tamponnement
endoculaires (ISO 16672:2020)Ophthalmische Implantate - Okulare Endotamponaden
(ISO 16672:2020)

This European Standard was approved by CEN on 19 November 2019.

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, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels**

EN ISO 16672:2021 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 16672:2021) 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 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 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.

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 supersedes EN ISO 16672:2015.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16672:2020 has been approved by CEN as EN ISO 16672:2021 without any modification.

INTERNATIONAL STANDARD

ISO
16672

Third edition
2020-06

Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires



Reference number
ISO 16672:2020(E)

© ISO 2020

ISO 16672:2020(E)**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended performance	3
5 Design attributes	3
5.1 General	3
5.2 Chemical description and contaminants	3
5.3 Density	4
5.4 Gaseous expansion	4
5.5 Interfacial tension	4
5.6 Kinematic viscosity	4
5.7 Dynamic viscosity	4
5.8 Molecular mass distribution	4
5.9 Particulates	5
5.10 Refractive index	5
5.11 Spectral transmittance	5
5.12 Surface tension	5
5.13 Vapour pressure	5
6 Design evaluation	5
6.1 General	5
6.2 Evaluation of biological safety	6
6.2.1 General	6
6.2.2 Bacterial endotoxins test	6
6.2.3 Intraocular implantation test	6
6.2.4 Ethylene oxide	6
6.3 Clinical investigation	7
7 Sterilization	7
8 Product stability	7
9 Integrity and performance of the delivery system	7
10 Packaging	8
10.1 Protection from damage during storage and transport	8
10.2 Maintenance of sterility in transit	8
11 Information supplied by the manufacturer	8
Annex A (normative) Intraocular implantation test	10
Annex B (informative) Clinical investigation	11
Annex C (informative) Method for quantifying incompletely fluorinated contaminants in perfluorocarbon liquids	14
Bibliography	16

ISO 16672:2020(E)

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 16672:2015), which has been technically revised.

The main changes compared to the previous edition are as follows:

- a) the following terms and their definitions have been included: "secondary packaging", surgical invasive medical product" and "minimum utilization pressure";
- b) the subclause on chemical description and contaminants has been substantially revised;
- c) the bacterial endotoxin limit has been revised from 0,5 to 0,2 Endotoxin Units per ml;
- d) the total level of EO in the product has been revised: it shall not exceed 1,25 µg/dose for EO and 5,0 µg/dose for ethylene chlorohydrin (ECH);
- e) minimum utilization pressure has been included in the list of information supplied by the manufacturer;
- f) [B.2.2](#) giving the clinical variables in a clinical investigation has been revised;
- g) [Annex C](#) "Method for quantifying incompletely fluorinated contaminants in perfluorocarbon liquids" has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Ophthalmic implants — Ocular endotamponades

1 Scope

This document applies to ocular endotamponades (OE), a group of non-solid surgically invasive medical devices introduced into the vitreous cavity of the eye to flatten and position a detached retina onto the retinal pigment epithelium (RPE), or to tamponade the retina.

With regard to the safety and efficacy of OE, this document specifies requirements for their intended performance, design attributes, pre-clinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 1041+A1, *Information supplied by the manufacturer with medical devices*

OECD Guidelines for the Testing of Chemicals, Section 1: Physical-Chemical properties, Test No. 104: Vapour Pressure

koniec náhľadu – text ďalej pokračuje v platenej verzii STN