INTERNATIONAL STANDARD

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Ophthalmic implants — Ophthalmic viscosurgical devices

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques

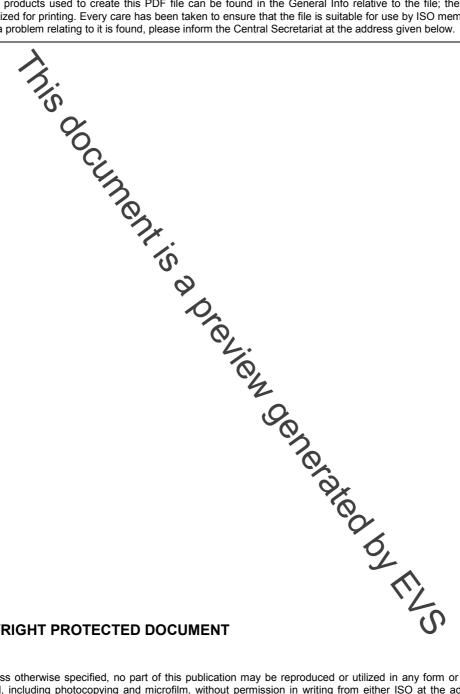


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Foreword

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 Maison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15798 was prepared by Technical Committee ISO/TC 172, Optics and photonics, Subcommittee SC 7, Ophthalmic optics and instruments.

This second edition cancels and replaces the first edition (ISO 15798:2001) which has been technically revised. It also includes the Technical Corrigendum 150 15798:2001/Cor 1:2003.

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Ophthalmic implants — Ophthalmic viscosurgical devices

1 Scope

This International standard is applicable to ophthalmic viscosurgical devices (OVDs), a class of non-active surgical implants with viscous and/or viscoelastic properties, intended for use during surgery in the anterior segment of the human eye. OVDs are designed to create and maintain space, to protect intra-ocular tissues and to manipulate tissues during surgery.

This International Standard specifies requirements with regard to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and information supplied by the manufacturer of these devices.

2 Normative references

The following referenced documents are indispensable for the application 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 — 6: Tests for local effects after implantation

ISO 10993-9, Biological evaluation of medical devices—part 9: Framework for identification and quantification of potential degradation products

ISO 10993-16, Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables

ISO 11135-1, Sterilization of health care products — Ethylene oxide — Patt: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-1, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose

ISO 11137-3, Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects

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 14155-1, Clinical investigation of medical devices for human subjects — Part 1: General requirements

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ISO 14155-2, Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans

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

ISO 15223-2, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 2: Symbol development, selection and validation

ISO 17665-1, Sterilization of the alth care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 22442-1, Medical devices willizing animal tissues and their derivatives — Part 1: Application of risk management

ISO 22442-2, Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling

ISO 22442-3, Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

EN 980, Symbols for use in the labelling of medical evices

EN 1041, Information supplied by the manufacturer of medical devices

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

absolute complex viscosity

 $I\eta^*\ I = [(\eta')^2 + (\eta'')^2]^{0.5}$ absolute value of complex viscosity (3.2)

NOTE Absolute complex viscosity is expressed in pascal seconds (Pa·s).

3.2

complex viscosity

 $\eta^* = \eta' - i \cdot \eta''$

viscosity consisting of a viscous η' and an elastic η'' component where i is an imaginary number defined by $i = (-1)^{0.5}$

3.3

delivery system

sealed container in which the product is supplied and any additional components provided to introduce the product into the eye

3.4

elasticity

tendency of a body to return to its original shape after having been deformed

NOTE Elasticity is quantitatively defined as stress (the force generated within the body) divided by strain (the change in dimensions of the body).