
Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires

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

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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.