

ISO 15798:2022-01 (E)

Ophthalmic implants - Ophthalmic viscosurgical devices

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Intended performance	3
5	Design attributes	4
5.1	General	4
5.2	Characterization of the components	4
5.3	Characterization of the finished product	4
5.3.1	General	4
5.3.2	Absolute complex viscosity	5
5.3.3	Chemical and biological contaminants	5
5.3.4	Concentration	5
5.3.5	Elasticity	5
5.3.6	Molecular mass distribution	5
5.3.7	Osmolality	5
5.3.8	Particulates	6
5.3.9	pH	6
5.3.10	Refractive index	6
5.3.11	Shear viscosity	6
5.3.12	Spectral transmittance	6
5.4	Usability	7
6	Design evaluation	7
6.1	General	7
6.2	Evaluation of biological safety	7
6.2.1	General	7
6.2.2	Bacterial endotoxins test	8
6.2.3	Clearance of residual OVD from the anterior chamber	8
6.2.4	Degradation and toxicokinetics	8
6.2.5	Evaluation of inflammation and intraocular pressure	8
6.3	Clinical evaluation	8
6.3.1	General	8
6.3.2	Clinical investigation design	9
6.3.3	Corneal endothelial cell density	9
6.3.4	Postoperative inflammation	9
6.3.5	Post-operative intraocular pressure change	10
6.3.6	Adverse events	10
7	Sterilization	10
8	Product stability	11
9	Integrity and performance of the delivery system	11
10	Packaging	11
10.1	Protection from damage during storage and transport	11

10.2	Maintenance of sterility in transit	11
11	Information to be supplied by the manufacturer	11
	Annex A (normative) Intraocular implantation test	13
	Annex B (informative) Patient numbers for clinical investigation of intraocular pressure	16
	Annex C (informative) Analyses of OVD clinical data	17
	Bibliography	19