DIN EN ISO 16672:2015-12 (E)

Ophthalmic implants - Ocular endotamponades (ISO 16672:2015)

Contents

Page

European foreword ... **3**

Foreword ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **6**

4 Intended performance ... **8**

5 Design attributes ... **8**
5.1 General ... 8
5.2 Chemical and biological contaminants ... 8
5.3 Chemical description ... 8
5.4 Concentration of the components ... 9
5.5 Density ... 9
5.6 Gaseous expansion ... 9
5.7 Interfacial tension ... 9
5.8 Kinematic viscosity ... 9
5.9 Dynamic viscosity ... 9
5.10 Molecular mass distribution ... 9
5.11 Particulates ... 9
5.12 Refractive index ... 9
5.13 Spectral transmittance ... 10
5.14 Surface tension ... 10
5.15 Vapour pressure ... 10

6 Design evaluation ... **10**
6.1 General ... 10
6.2 Evaluation of biological safety ... 10
6.2.1 General ... 10
6.2.2 Bacterial endotoxins test ... 10
6.2.3 Intraocular implantation test ... 10
6.2.4 Ethylene oxide ... 11
6.3 Clinical investigation ... 11

7 Sterilization ... **11**

8 Product stability ... **12**

9 Integrity and performance of the delivery system ... **12**

10 Packaging ... **12**
10.1 Protection from damage during storage and transport ... 12
10.2 Maintenance of sterility in transit ... 12

11 Information supplied by the manufacturer ... **12**

Annex A (normative) **Intraocular implantation test** ... **14**

Annex B (informative) **Clinical investigation** ... **15**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC** ... **18**

Bibliography ... **20**