

# DIN EN ISO 15798:2014-02 (E)

## Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2013)

---

<b>Contents</b>		Page
Foreword.....		3
<b>1 Scope.....</b>		<b>4</b>
<b>2 Normative references.....</b>		<b>4</b>
<b>3 Terms and definitions.....</b>		<b>5</b>
<b>4 Intended performance.....</b>		<b>6</b>
<b>5 Design attributes.....</b>		<b>7</b>
5.1 General.....		7
5.2 Characterization of the components.....		7
5.3 Characterization of the finished product.....		7
<b>6 Design evaluation.....</b>		<b>9</b>
6.1 General.....		9
6.2 Evaluation of biological safety.....		9
6.3 Clinical evaluation.....		10
<b>7 Sterilization.....</b>		<b>12</b>
<b>8 Product stability.....</b>		<b>13</b>
<b>9 Integrity and performance of the delivery system.....</b>		<b>13</b>
<b>10 Packaging.....</b>		<b>13</b>
10.1 Protection from damage during storage and transport.....		13
10.2 Maintenance of sterility in transit.....		13
<b>11 Information to be supplied by the manufacturer.....</b>		<b>13</b>
<b>Annex A (normative) Intraocular implantation test.....</b>		<b>15</b>
<b>Annex B (informative) Patient numbers for clinical investigation of intraocular pressure.....</b>		<b>18</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC.....</b>		<b>19</b>
<b>Bibliography.....</b>		<b>22</b>