

# DIN EN ISO 16671:2026-03 (E)

## Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2025)

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>2</b>
<b>4 Intended performance</b> .....	<b>2</b>
<b>5 Design attributes</b> .....	<b>2</b>
5.1 General.....	2
5.2 Chemical description and contaminants.....	3
5.3 Water used.....	3
5.4 Characterization of the finished product.....	3
5.4.1 General.....	3
5.4.2 pH and buffering capacity.....	3
5.4.3 Osmolality.....	4
5.4.4 Spectral transmittance.....	4
5.4.5 Particulates.....	4
<b>6 Design evaluation</b> .....	<b>5</b>
6.1 General.....	5
6.2 Evaluation of biological safety.....	5
6.2.1 General.....	5
6.2.2 Bacterial endotoxins test.....	5
6.2.3 Intraocular irritation and inflammation.....	5
6.3 Clinical evaluation.....	6
<b>7 Sterilization</b> .....	<b>6</b>
<b>8 Product stability</b> .....	<b>6</b>
<b>9 Packaging</b> .....	<b>7</b>
9.1 Protection from damage during storage and transport.....	7
9.2 Maintenance of sterility in transit and storage.....	7
<b>10 Information supplied by the manufacturer</b> .....	<b>7</b>
<b>Annex A (informative) Example of a suitable method for pH measurement and buffer capacity determination</b> .....	<b>9</b>
<b>Annex B (normative) Particulate contamination: visible particulates</b> .....	<b>10</b>
<b>Annex C (normative) Light obscuration test method for particulate contamination: sub-visible particles</b> .....	<b>11</b>
<b>Annex D (normative) Microscopic test method for particulate contamination: sub-visible particles</b> .....	<b>13</b>
<b>Annex E (normative) Intraocular irrigation test</b> .....	<b>18</b>
<b>Annex F (normative) Clinical investigation</b> .....	<b>20</b>
<b>Annex G (informative) Analyses of OIS clinical data</b> .....	<b>22</b>
<b>Annex H (informative) Sample size calculation</b> .....	<b>24</b>
<b>Bibliography</b> .....	<b>26</b>