

# DIN EN ISO 14729:2011-01 (E)

Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses (ISO 14729:2001 + Amd.1:2010)

---

<b>Contents</b>		<b>Page</b>
Foreword to ISO 14729:2001 .....		3
Introduction .....		4
<b>1</b>	<b>Scope .....</b>	<b>5</b>
<b>2</b>	<b>Normative references .....</b>	<b>5</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>5</b>
<b>4</b>	<b>Principle .....</b>	<b>6</b>
<b>4.1</b>	<b>General .....</b>	<b>6</b>
<b>4.2</b>	<b>Stand-alone test (Inoculum challenge test) .....</b>	<b>6</b>
<b>4.3</b>	<b>Regimen test .....</b>	<b>7</b>
<b>5</b>	<b>Performance requirements .....</b>	<b>7</b>
<b>5.1</b>	<b>Stand-alone test: Primary criteria (see also Table 1) .....</b>	<b>7</b>
<b>5.2</b>	<b>Stand-alone test: Secondary criteria (see also Table 1) .....</b>	<b>8</b>
<b>5.3</b>	<b>Regimen test: Regimen criteria (see also Table 1) .....</b>	<b>8</b>
<b>! 5.4</b>	<b>Test requirements for contact lens care products without rubbing (or mechanical cleaning) and/or rinsing steps .....</b>	<b>8</b>
<b>6</b>	<b>Test methods .....</b>	<b>9</b>
<b>6.1</b>	<b>Materials and reagents .....</b>	<b>9</b>
<b>6.2</b>	<b>Preparation of microbial challenge (Inoculum) .....</b>	<b>10</b>
<b>6.3</b>	<b>Stand-alone procedure .....</b>	<b>11</b>
<b>6.4</b>	<b>Regimen procedure .....</b>	<b>14</b>
<b>Annex A (informative) Test organisms from other culture collections .....</b>		<b>17</b>
<b>Annex B (informative) Example of a membrane filtration procedure .....</b>		<b>18</b>
<b>Annex C (informative) Technical report: Virus testing .....</b>		<b>20</b>
<b>Annex D (informative) Technical report: Acanthamoeba testing .....</b>		<b>21</b>
<b>Annex E (informative) Technical report: Artificial tears (organic soil) in laboratory testing .....</b>		<b>22</b>
<b>Bibliography .....</b>		<b>23</b>