

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