

# DIN EN ISO 11980:2013-03 (E)

## Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:2012)

---

<b>Contents</b>	<b>Page</b>
Foreword .....	3
Introduction .....	4
1 Scope .....	5
2 Normative references .....	5
3 Terms and definitions .....	5
4 Clinical investigational requirements .....	5
4.1 General .....	5
4.2 Additional requirements .....	5
4.3 Other considerations .....	8
Annex A (informative) Elements of a clinical investigation .....	9
Annex B (informative) Procedures for the evaluation of safety, physiological performance and effect on ocular tissues .....	22
Annex C (informative) The evaluation of visual, refractive and lens performance and subject acceptance .....	27
Bibliography .....	30