

DIN EN ISO 14534:2011-06 (E)

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2011)

Contents		Page
Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	Safety and performance	6
5	Risk assessment	6
6	Design	7
7	Materials	7
8	Clinical evaluation	7
9	Manufacturing	7
10	Microbiological requirements	8
10.1	Contact lenses	8
10.1.1	Lenses delivered sterile	8
10.1.2	Lenses delivered non-sterile	8
10.1.3	Trial lenses	8
10.2	Contact lens care products	8
10.3	Other accessories for contact lenses	8
11	Packaging	9
12	Shelf-life and discard date	9
13	Labelling and information supplied by the manufacturer	9
13.1	General	9
13.2	Additional information requirements for contact lenses	9
13.3	Additional information requirements for contact lens care products	10
Bibliography		11
Annex ZA (informative) Relationship between this International Standard and the Essential Requirements of E Directive 93/42 EEC		15C