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