ISO 11979-10:2018-03 (E)

Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms,definitionsandabbreviatedterms 2
3.1 Terms and definitions 2
3.2 Abbreviated terms 2

4 Optical requirements 2

5 Mechanical requirements 2

6 Biocompatibilityrequirements 2

7 Shelf-lifeandtransportstabilityrequirements 2

8 Fundamental requirements 2

9 Justificationforaclinicalinvestigation 3

10 General clinical requirements 3
10.1 General 3
10.2 Design of a clinical investigation 3
10.2.1 Requirements for all types of phakic IOLs 3
10.2.2 Additional requirements for PTIOLs 3
10.2.3 Additional requirements for PMIOLs 4
10.3 Characteristics 4
10.3.1 General 4
10.3.2 Characteristics applying to the clinical evaluations for all types of phakic IOLs 4
10.3.3 Additional characteristics applying to PTIOLs 5
10.3.4 Additional characteristics applying to PMIOLs 5
10.4 Duration of the investigation 5
10.5 Enrolment 5
10.6 Bilateral implantation 5
10.7 Surgical technique 6
10.8 Examination and treatment of subjects 6
10.9 Adverse events reports 6
10.10 Inclusion and exclusion criteria 6
10.10.1 General criteria for all phakic IOLs 6
10.10.2 Additional criteria for PTIOLs 9
10.10.3 Additional criteria for multifocal IOLs 9

11 Informationsuppliedbythemanufacturer 9

Annex A (informative) Elements in a phakic IOL clinical investigation 10

Annex B (informative) Statistical methods and sample size calculations 16

Bibliography 17