DIN EN ISO 11979-5:2006-09 (E)

Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility (ISO 11979-5:2006)

Contents

Page

Foreword 2

Introduction 4

1 Scope 4

2 Normative references 4

3 Terms and definitions 4

4 General requirements applying to biocompatibility evaluation of intraocular lenses 5

5 Physicochemical tests 5

6 Biological tests 8

Annex A (normative) Exhaustive extraction test 10

Annex B (normative) Test for leachables 13

Annex C (normative) Hydrolytic stability 15

Annex D (normative) Photostability test 18

Annex E (normative) Nd-YAG laser exposure test 20

Annex F (informative) Supplemental conditions of test for local effects after implantation 22

Annex G (normative) Ocular implantation test 23

Bibliography 27