

ISO/TR 22979:2006-02 (E)

Ophthalmic implants - Intraocular lenses - Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Monofocal lenses	1
4.1	General	1
4.2	Modification levels (categories)	1
4.3	Clinical investigation with multiple IOL models	2
4.4	Mechanical data analysis	2
5	Multifocal lenses	2
5.1	General	2
5.2	Addition of a parent multifocal optic to a parent monofocal model	3
5.3	Modification of the optical design geometry of a parent multifocal optic	3
Annex A (informative) Examples of modifications to a parent IOL model		4
Annex B (informative) Mechanical data analysis		7
Bibliography		19