

INTERNATIONAL
STANDARD

ISO
11979-7

Second edition
2006-05-01

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations

*Implants ophthalmiques — Lentilles intraoculaires —
Partie 7: Investigations cliniques*



Reference number
ISO 11979-7:2006 (E)

© ISO 2006

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO Central Secretariat

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Justification for a clinical investigation	1
5 Ethical considerations	1
6 General requirements	2
6.1 General	2
6.2 Additional requirements	2
Annex A (informative) Elements of a clinical investigation	4
Annex B (informative) Evaluation of post-operative adverse event and visual acuity rates	13
Bibliography	18