
**Biological evaluation of medical
devices —**

**Part 20:
Principles and methods for
immunotoxicology testing of medical
devices**

Évaluation biologique des dispositifs médicaux —

*Partie 20: Principes et méthodes relatifs aux essais
d'immunotoxicologie des dispositifs médicaux*



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 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 0111
Fax + 41 22 749 0947
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Risk assessment and risk management.....	2
5 Identification of hazards	2
6 Methods of assessment of immunotoxicity.....	4
6.1 General.....	4
6.2 Inflammation.....	5
6.3 Immunosuppression.....	5
6.4 Immunostimulation.....	7
6.5 Hypersensitivity	7
6.6 Auto-immunity.....	7
7 Extrapolation of data provided by pre-clinical assays	7
Annex A (informative) Current state of knowledge.....	8
Annex B (informative) Clinical experience with medical devices	12
Annex C (informative) Flow chart for immunotoxicity testing.....	14
Bibliography	15