

First edition
2004-10-15

**Medical devices — Quality management
systems — Guidance on the application
of ISO 13485:2003**

*Dispositifs médicaux — Systèmes de gestion de qualité — Lignes
directrices pour l'application de l'ISO 13485:2003*



Reference number
ISO/TR 14969:2004(E)

© ISO 2004

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 2004

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
Introduction	v
0.1 General	v
0.2 Process approach	v
0.3 Relationship with other standards, guidance documents and regulatory requirements.....	vii
0.4 Compatibility with other management systems	viii
1 Scope.....	1
1.1 General	1
1.2 Application.....	1
2 Normative references	2
3 Terms and definitions.....	2
4 Quality management system	3
4.1 General requirements	3
4.2 Documentation requirements	4
5 Management responsibility.....	9
5.1 Management commitment.....	9
5.2 Customer focus	10
5.3 Quality policy.....	10
5.4 Planning	11
5.5 Responsibility, authority and communication	13
5.6 Management review	14
6 Resource management.....	17
6.1 Provision of resources	17
6.2 Human resources	17
6.3 Infrastructure	19
6.4 Work environment.....	19
7 Product realization	22
7.1 Planning of product realization	22
7.2 Customer-related processes	25
7.3 Design and development.....	27
7.4 Purchasing.....	36
7.5 Production and service provision	39
7.6 Control of monitoring and measuring devices	49
8 Measurement, analysis and improvement.....	51
8.1 General	51
8.2 Monitoring and measurement.....	52
8.3 Control of nonconforming product	56
8.4 Analysis of data.....	58
8.5 Improvement.....	58
Annex A (informative) Terms used in certain regulatory administrations to describe documents referenced in this Technical Report.....	64
Annex B (informative) Analysis of significant changes from ISO 13485:1996 to ISO 13485:2003	65
Bibliography	73