INTERNATIONAL STANDARD

ISO 15194

Second edition 2009-05-01

In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation

Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs dans les échantillons d'origine biologique — Exigences relatives aux matériaux de référence certifiés et au contenu de la documentation associée



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.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2009

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

•	•	•	•	•	•	•	•	•	•		İ	٧	,
•	•	•	•	•	•	•		•	•			٧	,
			•	•		•			•	•		1	
			•			•	•					1	

Page

Forewo	ordiv	,
Introdu	uctionv	,
1	Scope	1
2	Normative references	l
3	Terms and definitions	2
4	Systematic format of properties in the supporting documentation of a certified reference material	4
4.1	Format of properties	
4.2	Construction of systematic designations	5
4.3	Trivial names	5
5 5.1	Properties, production, and characterization of a certified reference material	
5.2	Properties	
5.3	Production and characterization	
6	Content of supporting documentation	3
6.1	Supporting documentation	
6.2	Label	3
6.3	Certificate	ĵ
6.4	Certification report	7
Annex	A (informative) Certified reference materials with nominal properties or ordinal quantities 15	5
Bibliog	graphy10	3