
**In vitro diagnostic medical devices —
Information supplied by the
manufacturer (labelling) —**

**Part 1:
Terms, definitions, and general
requirements**

*Dispositifs médicaux de diagnostic in vitro — Informations fournies
par le fabricant (étiquetage) —*

Partie 1: Termes, définitions et exigences générales





COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General terms and definitions for use with in vitro diagnostic medical devices.....	2
3.2 Performance characteristic terms and definitions.....	22
4 General requirements for information supplied by the manufacturer	40
4.1 General.....	40
4.2 Language.....	41
4.3 Symbols and identification colours.....	41
4.4 Values and nomenclature.....	41
4.5 Microbiological state.....	42
4.6 Instructions for use.....	42
4.7 Changes to the IVD medical device.....	43
4.8 Disclosure of residual risks.....	43
4.9 Identification of components.....	43
4.10 Assistance.....	43
Annex A (informative) Performance characteristics of IVD medical devices	44
Bibliography	50