

**BS EN ISO 18113-1:2011**

*Incorporating corrigendum December 2011*



**BSI Standards Publication**

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

Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

**bsi.**

...making excellence a habit.™

**National foreword**

This British Standard is the UK implementation of EN ISO 18113-1:2011. It is identical to ISO 18113-1:2009. It supersedes BS EN ISO 18113-1:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2012

ISBN 978 0 580 77327 3

ICS 11.100.10

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2011.

**Amendments/corrigenda issued since publication**

Date	Text affected
31 January 2012	Implementation of CEN correction notice 9 November 2011: Corrected date of withdrawal in EN foreword

English Version

**In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)**

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 1: Termes, définitions et exigences générales (ISO 18113-1:2009)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 1: Begriffe und allgemeine Anforderungen (ISO 18113-1:2009)

This European Standard was approved by CEN on 20 September 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**