

**In vitro diagnostic  
medical devices —  
Measurement of  
quantities in samples  
of biological origin  
— Requirements for  
certified reference  
materials and the  
content of supporting  
documentation (ISO  
15194:2009)**

ICS 11.100.10

## National foreword

This British Standard is the UK implementation of EN ISO 15194:2009. It supersedes BS EN 12287:1999 which is withdrawn.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.

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### Amendments/corrigenda issued since publication

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31 January 2016	Implementation of CEN Correction Notice 12 August 2009: Supersession details updated

English Version

**In vitro diagnostic medical devices - Measurement of quantities  
in samples of biological origin - Requirements for certified  
reference materials and the content of supporting  
documentation (ISO 15194:2009)**

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 (ISO  
15194:2009)

In-Vitro-Diagnostika - Messung von Größen in Proben  
biologischen Ursprungs - Anforderungen an zertifizierte  
Referenzmaterialien und an den Inhalt der  
Begleitdokumentation (ISO 15194:2009)

This European Standard was approved by CEN on 16 April 2009.

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