

**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 It supersedes BS EN 12287:1999 which is withdrawn.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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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)

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