



BSI Standards Publication

**In vitro diagnostic medical devices — Requirements
for international harmonisation protocols
establishing metrological traceability of values
assigned to calibrators and human samples**

National foreword

This British Standard is the UK implementation of [ISO 21151:2020](#).

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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Published by BSI Standards Limited 2020

ISBN 978 0 539 01126 5

ICS 11.100.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2020.

Amendments/corrigenda issued since publication

Date	Text affected
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