



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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INTERNATIONAL **ISO 21151** STANDARD

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

*Dispositifs médicaux de diagnostic in vitro — Exigences relatives
aux protocoles d'harmonisation internationaux établissant la
traçabilité métrologique des valeurs affectées aux étalons et aux
échantillons humains*



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