BS EN ISO 19001:2013

Incorporating corrigendum August 2013

BSI Standards Publication

In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

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National foreword

This British Standard is the UK implementation of EN ISO 19001:2013. It supersedes BS EN 12376:1999 which is withdrawn.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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Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19001

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English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO 19001:2013)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie (ISO 19001:2013)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller von in-vitro-diagnostischen Reagenzien für biologische Färbungen (ISO 19001:2013)

This European Standard was approved by CEN on 14 March 2013.

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