BRITISH STANDARD

BS EN ISO 13485:2003

Incorporating corrigenda June 2007, February 2008 and August 2009

Medical devices — Quality management systems — Requirements for regulatory purposes

ICS 03.120.10; 11.040.01

BSI British Standards

National foreword

This British Standard is the UK implementation of EN ISO 13485:2003, incorporating corrigendum June 2007. It is identical with ISO 13485:2003, incorporating corrigendum August 2009. It supersedes BS EN ISO 13485:2001, BS EN ISO 13488:2001 and BS EN 46003:1999 which are withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/1, Quality systems for medical devices.

A list of organizations represented on this subcommittee 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.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments/corrigenda issued since publication

Date	Comments
31 January 2008	Implementation of CEN corrigendum June 2007
29 February 2008	Missing text reinstated to Introduction: subclauses **0.3** and **0.3.1**
31 January 2010	Implementation of ISO corrigendum August 2009. "ISO 9001" replaced with "ISO 9001:2000" in subclauses **0.3**, **0.4** and **1.1**; Annex B, first paragraph; and Annex B table, right-hand column. Bibliography item [6] replaced

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

July 2003

ICS 03.120.10; 11.040.01

Supersedes EN 46003:1999, EN ISO 13485:2000 and EN ISO 13488:2000
Incorporating corrigendum June 2007

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Dispositifs médicaux - Systèmes de manegement de la qualité - Exigences à des fins réglementaires (ISO 13485:2003)

Qualitätssicherungssysteme - Medizinprodukte - Systemanforderungen zur Erfüllung gesetzlicher Anforderungen (ISO 13485:2003)

This European Standard was approved by CEN on 16 June 2003.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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