BSI Standards Publication

Medical devices — Quality management systems — Requirements for regulatory purposes

National foreword

This British Standard is the UK implementation of EN ISO 13485:2016+A11:2021, incorporating corrigenda March 2016 and December 2016. It is derived from ISO 13485:2016. It supersedes BS EN ISO 13485:2016, which is withdrawn.

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

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

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Amendments/corrigenda issued since publication

Date	Text affected
31 March 2016	Implementation of CEN/CENELEC correction notice March 2016: Annexes ZA, ZB and ZC updated
31 January 2017	Implementation of CEN/CENELEC corrigendum December 2016: European foreword and Annexes ZA, ZB and ZC corrected
30 September 2021	Implementation of CEN/CENELEC amendment A11:2021: European foreword and Annexes ZA and ZB revised, and Annex ZC removed. National Annex NZ added, and Amendments/corrigenda issued since publication table corrected

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English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires (ISO 13485:2016)

Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016)

This European Standard was approved by CEN on 30 January 2016.

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European foreword

This document (EN ISO 13485:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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〖AC〉 This document supersedes EN ISO 13485:2012 and CEN ISO/TR 14969:2005 〈AC〗.

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For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

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The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, ZB and ZC, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

This document includes the corrigendum EN ISO 13485:2016/AC:2018 which corrects the European foreword, Annex ZA, Annex ZB and Annex ZC.

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