



BSI Standards Publication

## Medical devices — Quality management systems — Requirements for regulatory purposes

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## 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 It supersedes BS EN ISO 13485:2016, which is withdrawn.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.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at [www.bsigroup.com/standardsandregulation](http://www.bsigroup.com/standardsandregulation).

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

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| 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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## EUROPÄISCHE NORM

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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.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

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Avenue Marnix 17, B-1000 Brussels**

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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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

**AC** This document supersedes EN ISO 13485:2012 and CEN ISO/TR 14969:2005 **AC**.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

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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