

BS EN 15224:2016



BSI Standards Publication

Quality management systems — EN ISO 9001:2015 for healthcare

National foreword

This British Standard is the UK implementation of EN 15224:2016. It supersedes BS EN 15224:2012 which is withdrawn.

BSI, as a member of CEN, is obliged to publish EN 15224:2016 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The UK committee submitted a negative vote at the last stage of voting due to their concerns that the wording of the title and scope are confusing. It is not clearly defined what is classed as 'healthcare' and this could raise potential confusion with standards that define quality management systems applicable to healthcare products. The UK committee prefers the previous title of EN 15224:2012, *Health care services—Quality management systems—Requirements based on EN ISO 9001:2008*.

This version implements CEN correction notice 25 January 2017, which implements corrections to cross-references in sub-clauses 0.1.1, 3.8.2, 3.15 and Annex E.

The UK participation in its preparation was entrusted by Technical Committee CH/100, Healthcare and Medical Equipment, to Subcommittee CH/100/-/2, Healthcare services - Quality management systems.

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.

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

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Amendments/corrigenda issued since publication

Date	Text affected
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