

Specification for

Application of EN ISO 9001 to the manufacture of medical devices

The European Standard EN 46001 : 1996 has the status of a British Standard

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/66, Quality systems for the manufacture of medical devices, upon which the following bodies were represented:

- Association of British Certification Bodies
- Association of British Health-care Industries
- Association of Consultants to the Bioscience Industries (ACBI)
- Association of Contact Lens Manufacturers
- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- BLWA Ltd. – The Association of the Laboratory Supply Industry
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Dental Trade Association
- British In Vitro Diagnostics Association
- British Orthopaedic Association
- British Surgical Trades Association
- Dental Laboratories Association Limited
- Department of Health
- Electro Medical Trade Association Limited
- Guild of Hospital Pharmacists
- Institute of Quality Assurance
- Institution of Physics and Engineering in Medicine and Biology
- Medical Sterile Products Association
- Surgical Dressings Manufacturers' Association

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National foreword

This British Standard has been prepared by Technical Committee CH/66 and is the English language version of EN 46001 : 1996 *Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001*, published by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). It supersedes BS EN 46001 : 1994 which is withdrawn. BS EN 46001 supplements the requirements of EN ISO 9001 which, itself, has been implemented as BS EN ISO 9001.

Cross-references

Publication referred to	Corresponding British Standard
EN ISO 8402 : 1995	BS EN ISO 8402 : 1995 <i>Quality management and quality assurance. Vocabulary</i>
EN ISO 9001 : 1994	BS EN ISO 9001 : 1994 <i>Quality systems. Model for quality assurance in design, development, production, installation and servicing</i>

Compliance with a British Standard does not of itself confer immunity from legal obligations.

English version

Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001

Systèmes qualité — Dispositifs médicaux —
Exigences particulières relatives à l'application de
l'EN ISO 9001

Qualitätssicherungssysteme — Medizinprodukte —
Besondere Anforderungen für die Anwendung von
EN ISO 9001

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