

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

ICS 03.120.10; 11.040.01

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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