

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

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 February 1997

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First published January 1994
Second edition February 1997

The following BSI references relate to the work on this standard:
Committee reference CH/66
Draft for comment 90/56565 DC

ISBN 0 580 27045 9

Amendments issued since publication

| Amd. No. | Date | Text affected |
|----------|------|---------------|
|----------|------|---------------|

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