

Guidance on the

Application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

The European Standard EN 928:1995 has the status of a
British Standard

ICS 11.100

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

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 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 In Vitro Diagnostics Association
- British Orthopaedic Association
- British Surgical Trades Association
- Dental Laboratories Association Limited
- Department of Health
- Electro Medical Trade Association Limited
- GAMBICA (BEAMA Ltd.)
- 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 June 1996

© BSI 03-1999

The following BSI references relate to the work on this standard:
Committee reference CH/66
Draft for comment 92/58310 DC

ISBN 0 580 25746 0

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 928	3
List of references	Inside back cover

National foreword

This British Standard has been prepared by Technical Committee CH/66 and is the English language version of EN 928:1995 *In vitro diagnostic systems — Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices*, published by the European Committee for Standardization (CEN).

BS EN 928 provides guidance on the operation of quality management systems used in the manufacture of in vitro diagnostic medical devices. Similar standards, BS EN 724 and BS EN 50103, cover guidance for the manufacture of non-active medical devices and of active (including active implantable) medical devices, respectively.

Cross-references

Publication referred to	Corresponding British Standard
	BS 5750 <i>Quality systems</i>
EN 29001:1987 ^a	Part 1:1987 <i>Specification for design/development, production, installation and servicing</i>
EN 29002:1987 ^a	Part 2:1987 <i>Specification for production and installation</i>
EN 29004:1987 ^a	Part 0 <i>Principal concepts and applications</i> Section 0.2:1987 <i>Guide to quality management and quality system elements</i>
EN 46001:1993	BS EN 46001:1994 <i>Specification for application of EN 29001 (BS 5750-1) to the manufacture of medical devices</i>
EN 46002:1993	BS EN 46002:1994 <i>Specification for application of EN 29002 (BS 5750-2) to the manufacture of medical devices</i>

^a Since the preparation of this European Standard, EN 29001:1987, EN 29002:1987 and EN 29004:1987 have been superseded by EN ISO 9001:1994, EN ISO 9002:1994 and EN ISO 9004-1:1994. The corresponding British Standards are BS EN ISO 9001:1994, BS EN ISO 9002:1994 and BS EN ISO 9004-1:1994.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.100

Descriptors: Medicine, bioassay, medical equipment, manufacturing, quality, quality assurance, specifications

English version

In vitro diagnostic systems — Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

Systèmes d'analyses médicales in vitro —
Guide d'application des EN 29001 et EN 46001,
et EN 29002 et EN 46002 pour les dispositifs
médicaux de diagnostic in vitro

In-vitro-Diagnostik/Diagnostika — Leitfaden
für die Anwendung von EN 29001 und
EN 46001 sowie EN 29002 und EN 46002 für
Medizinprodukte für die In-vitro-Diagnose

This European Standard was approved by CEN on 1995-03-14. CEN 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 Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

© 1995 All rights of reproduction and communication in any form and by any means reserved in all countries to CEN and its members

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 140, In vitro diagnostic systems, of which the secretariat is held by DIN.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This European Standard needs to be considered in conjunction with both the EN 29000 series of standards and the EN 46000 series of standards. It is intended to provide guidance for industry, certifying bodies and regulatory bodies.

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 May 1996, and conflicting national standards shall be withdrawn at the latest by May 1996.

According to CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	3
4 Guidance on quality system requirements	3
4.1 Management responsibility	3
4.2 Quality system	4
4.3 Contract review	4
4.4 Design control	5
4.5 Document control	6
4.6 Purchasing	7
4.7 Purchaser supplied product	7
4.8 Product identification and traceability	7
4.9 Process control	7
4.10 Inspection and testing	8
4.11 Inspection, measuring and test equipment	9
4.12 Inspection and test status	9
4.13 Control of nonconforming product	9
4.14 Corrective action	9
4.15 Handling, storage, packaging and delivery	10
4.16 Quality records	10
4.17 Internal quality audits	11
4.18 Training	11
4.19 Servicing	11
4.20 Statistical techniques	11
Annex A (informative) Bibliography	12