

Biological evaluation of medical devices —

Part 12: Sample preparation and reference materials

The European Standard EN ISO 10993-12:1996 has the status of a
British Standard

ICS 11.100

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/26, Biological testing of medical and dental materials and devices, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Clinical Pathologists
- Association of Contact Lens Manufacturers
- British Medical Association
- British Orthopaedic Association
- British Society for Dental Research
- Department of Health
- Electro Medical Trade Association Limited
- Home Office
- Institution of Physics and Engineering in Medicine and Biology
- Laboratory of the Government Chemist
- Medical Sterile Products Association
- National Blood Authority
- Royal College of Pathologists
- Royal College of Surgeons of England
- Society for Tissue Viability
- Sterilised Suture Manufacturers' Association
- Surgical Dressings Manufacturers' Association

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National foreword

This Part of BS EN ISO 10993 has been prepared by Technical Committee CH/26, and is the English language version of EN ISO 10993-12:1996 *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*, published by the European Committee for Standardization (CEN). It is identical with ISO 10993-12:1996, published by the International Organization for Standardization (ISO).

Cross-references

Publication referred to	Corresponding British Standard
EN ISO 9000-1:1994 (ISO 9000-1:1994)	BS EN ISO 9000-1:1994 <i>Quality management and quality assurance standards. Guidelines for selection and use</i>
ISO 9000-3:1991	BS 5750-13:1991 <i>Quality systems. Guide to the application of BS 5750-1 to the development, supply and maintenance of software</i>
ISO 9000-4:1993	BS 5750-14:1993 <i>Quality systems. Guide to dependability programme management</i>

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 10, 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.

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Descriptors: Medical equipment, medical devices, tests, biological tests, bioassay, test specimens, specimen preparation, reference materials

English version

Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

(ISO 10993-12:1996)

Evaluation biologique des dispositifs médicaux — Partie 12: Préparation des échantillons et matériaux de référence
(ISO 10993-12:1996)

Biologische Beurteilung von Medizinprodukten — Teil 12: Probenvorbereitung und Referenzmaterialien
(ISO 10993-12:1996)

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

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