

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

The European Standard EN 1283 : 1996 has the status of a
British Standard

ICS 11.040.20

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- Association of Renal Technicians
- British Cardiac Society
- British Textile Technology Group
- Department of Health
- Institute of Physics and Engineering in Medicine and Biology
- Medical Sterile Products Association
- National Heart and Lung Institute
- Renal Association
- Royal College of Nursing
- Royal College of Physicians of London
- Royal College of Surgeons of England
- Scottish Office
- Society of Cardiothoracic Surgeons of Great Britain and Ireland
- Society of Perfusionists (of Great Britain and Ireland)
- Vascular Surgical Society of Great Britain

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National foreword

This British Standard has been prepared by Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, and is the English language version of EN 1283 : 1996 *Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits* published by the European Committee for Standardization (CEN). It supersedes BS 7297 : Part 1 : 1990 *Haemodialysers and related equipment — Part 1: Specification for haemodialysers, haemofilters and haemoconcentrators* and BS 7297 : Part 2 : 1990 *Haemodialysers and related equipment — Part 2: Specification for extracorporeal circuits for use with haemodiafilters, haemofilters and haemoconcentrators*, which are withdrawn.

Cross-references

Publication referred to	Corresponding British Standard
EN 556 : 1994	BS EN 556 : 1995 <i>Sterilization of medical devices — Requirements for terminally-sterilized devices to be labelled ‘Sterile’</i>
prEN 980	BS EN 980 <i>Terminology, symbols and information provided with medical devices — Graphical symbols for use in the labelling of medical devices</i> ¹⁾
prEN 1041	BS EN 1041 <i>Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices</i> ¹⁾
EN 30993-1 : 1993	BS EN 30993 <i>Biological evaluation of medical devices</i> Part 1 : 1994 <i>Guidance on selection of tests</i>
prEN 30993-7 : 1995	BS EN ISO 10993 <i>Biological evaluation of medical devices</i> Part 7 : 1996 <i>Ethylene oxide sterilization residuals</i>
prEN 30993-11 : 1996	BS EN ISO 10993 <i>Biological evaluation of medical devices</i> Part 11 : 1996 <i>Test for systemic toxicity</i>
EN 46001 : 1993	BS EN 46001 : 1994 <i>Application of EN 29001 (BS 5750 : Part 1) to the manufacture of medical devices</i>
EN 46002 : 1993	BS EN 46002 : 1994 <i>Application of EN 29002 (BS 5750 : Part 2) to the manufacture of medical devices</i>
HD 395-2-16 : 1989	BS 5724 <i>Medical electrical equipment</i> Part 2 <i>Particular requirements for safety</i> Section 2.16 : 1989 <i>Specification for haemodialysis equipment</i>
ISO 594-2 : 1987	BS 3930 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment</i> Part 2 : 1991 <i>Specification for lock fittings</i>
ISO 7864 : 1988	BS 5081 <i>Sterile hypodermic syringes and needles</i> Part 2 : 1993 <i>Specification for sterile hypodermic needles for single use</i>

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¹⁾ In preparation.

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Descriptors: Medical equipment, dialysis apparatus, haemodialysers, filters, disposable equipment, definition, specifications, performance evaluation, physical properties, tests, information

English version

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

Hémodialyseurs, hémodiafiltres, hémofiltres,
hémoconcentrateurs et leurs circuits extracorporels

Hämodialysatoren, Hämodiafilter, Hämofilter,
Hämokonzentratoren und dazugehörige
Blutschlauchsysteme

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

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