

# Medical Devices, Healthcare and Informatics

Essential information for medical device manufacturers, healthcare practitioners and users of healthcare information

**Standards** | **Books** | **Guidance** | **Seminars**

*Equipping business with knowledge*

# Medical Devices, Healthcare and Informatics

Essential information for medical device manufacturers, healthcare practitioners and users of healthcare information

**According to the European Medical Device Directive (93/42/EEC), a medical device is "...any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:**

- **Diagnosis, prevention, monitoring, treatment or alleviation of disease**
- **Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap**
- **Investigation, replacement or modification of the anatomy or of a physiological process**
- **Control of conception.**

**... and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means..."**

For that reason the medical devices sector is highly regulated with standards, rules and legislation. To help manufacturers sift through the minefield of regulations, BSI Business Information can help with best practice guidelines, standards, supporting documentation and seminars.

If you design, develop, produce, install or service any medical device you need to comply with the requirements set out in European Directives:

- Active Implantable Medical Devices (AIMD) Council Directive 90/385/EEC (1990)
- Medical Devices Directive (MDD) Council Directive 93/42/EEC (1992)
- In Vitro Diagnostic Directive (IVDD) Council Directive 98/79/EC (1998)

BSI publishes standards on a wide range of medical devices including dental equipment, neurosurgical implants, prosthetics, anaesthetic and respiratory equipment, imaging equipment and much more!

Included in this collection are standards on the evaluation, validation and sterilization of medical devices and their use in the healthcare sector as well as a whole section on health informatics.

This brochure includes a selection of some of the most popular titles published in 2003, 2004 and 2005.

For a listing of all standards and publications in your area, please visit [www.bsonline.bsi-global.com](http://www.bsonline.bsi-global.com) and register to view the BSI collection.

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*Please note: Inclusion of specific standards in this brochure does not assume that they fall within the scope of all EU Directives. You will need to do the necessary checks.*

# General Medical Devices including Quality Control, Risk and Terminology

## BS EN ISO 13485:2003 Medical devices. Quality management systems. Requirements for regulatory purposes



This standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements.

**Contents:** Scope, application, terms and definitions; Quality management system, general requirements and documentation requirements; Management responsibility, resource management, product realization, measurement, analysis and improvement; Correspondence between BS EN ISO 13485:2003 and BS EN ISO 13485:1996; Explanation of differences between BS EN ISO 13485:2003 and BS EN ISO 9001:2000.

*BS EN ISO 13485:2003 supersedes BS EN ISO 13485:2001 and BS EN ISO 13488:2001 which will be withdrawn in July 2006.*

ISBN 0 580 42306 9 Price £140\*, £70 BSI Subscribing Members

## PD ISO/TR 14969:2004 Medical Devices. Quality management systems. Guidance on the application of ISO 13485:2003.



This technical report provides guidance for the application of BS EN ISO 13485. It can be used to better understand the requirements of BS EN ISO 13485 and to illustrate some of the variety of methods and approaches available for meeting best practice guidelines.

The guidance given in this technical report is applicable to the design, development, production, installation and servicing of medical devices of all kinds. The principles and examples contained in PD ISO/TR 14969:2004 can be useful as background information for those representing quality management system assessors, conformity assessment bodies and regulator enforcement bodies.

ISBN 0 580 44699 9 Price £140\*, £70 BSI Subscribing Members

## Medical Devices: ISO 13485 and ISO 9001

Dennis Green



This book is for those who are responsible for seeking compliance with the requirements of the quality management systems standard ISO 13485 on medical devices. There are many aspects of this standard that are identical to ISO 9001, meaning that accredited certification to both standards can be achieved at the same time, relatively easily. In addition the continual improvement aspect of ISO 9001 can offer real gains and competitive advantage to those who manufacture and service medical devices.

The book takes the reader through the clauses of both standards, providing essential information on ISO 13485, ISO 9001 and quality management system auditing.

**Contents:** Preface; Background to quality and quality assurance; Quality systems standards and quality management systems standards; ISO 13485 and ISO 9001; Quality management system; Management responsibility; Resource management; Product realization; Measurement, analysis and improvement; Design and development; Justifiable exclusions; Guideline audit questions.

BSI order ref BIP 2071 ISBN 0 580 45644 7 Price £50\*

## BS EN 980:2003 Graphical symbols for use in the labelling of medical devices

This document specifies graphical symbols for use in the information supplied by the manufacturer with medical devices (including in vitro diagnostic medical devices).

**Contents:** General requirements; Symbols already in use; New symbols; Examples of uses of symbols given in this standard; Clauses addressing essential requirements or other provisions of the Council Directive 93/42/EEC; and 90/385/EEC concerning medical devices and active implantable medical devices respectively; Clauses addressing essential requirements or other provisions of the European Parliament and the Council Directive 98/79/EC on in vitro diagnostic medical devices.

ISBN 0 580 42460 X Price £92\*, £46 for BSI Subscribing Members

## PD CR 14230:2001 Global medical device nomenclature for the purpose of regulatory data exchange

This report lists terms, definitions and codes for medical devices. The listing is structured such that it can be used for the purpose of regulatory data exchange.

ISBN 0 580 38708 9 Price £282\*, £141 BSI Subscribing Members

## BS EN ISO 14971:2001 Medical devices. Application of risk management to medical devices



This publication specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories, including in vitro diagnostic medical devices. It also specifies a procedure to estimate and evaluate the identified risks, control these risks and monitor the effectiveness of the control. The requirements of BS EN ISO 14971:2001 are applicable to all stages of the lifecycle of a medical device, but do not apply to clinical judgements relating to the use of a medical device and it does not specify acceptable risk levels.

ISBN 0 580 37084 4 Price £120\*, £60 BSI Subscribing Members

## BS EN 455-1:2000 Medical gloves for single use. Requirements and testing for freedom from holes

ISBN 0 580 36697 9 Price £52\*, £26 BSI Subscribing Members

## BS EN 455-2:2000 Medical gloves for single use. Requirements and testing for physical properties

ISBN 0 580 36698 7 Price £52\*, £26 BSI Subscribing Members

## BS EN 13795-1:2002 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment. General requirements for manufacturers, processors and products

This standard gives general guidance on the characteristics of single-use and reusable surgical gowns, surgical drapes and clean air suits used as medical devices for patients, clinical staff and equipment. It is intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures.

ISBN 0 580 40866 3 Price £64\*, £32 BSI Subscribing Members

# General Medical Devices including Quality Control, Risk and Terminology

## BS EN 13795-2:2004 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment. Test methods

ISBN 0 580 44954 8 Price £52\*, £26 BSI Subscribing Members

## BS EN ISO 22612:2005 Clothing for protection against infectious agents. Test method for resistance to dry microbial penetration

There are numerous examples of situations where bacteria may migrate through a barrier material in the dry state carried by organic or inorganic particles. The dry penetration of bacteria-carrying skin scales through an operating gown or a clean air suit is one example. Penetration through a packaging material during storage is another.

This document describes a test method, with the associated equipment, that may be used to determine a material's resistance to dry penetration of bacteria on particles in the size range most typical for human skin scales.

ISBN 0 580 4563 9 Price £64\*, £32 BSI Subscribing Members

## BS 5726:2005 Microbiological safety cabinets. Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets. Recommendations and guidance

This British Standard gives recommendations and guidance on information to be supplied by the purchaser to the vendor and to the installer, on siting, and on use, for microbiological safety cabinets as specified in BS EN 12469.

ISBN 0 580 45590 4 Price £52\*, £26 BSI Subscribing Members

## BS EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinets

This European Standard specifies basic requirement for microbiological safety cabinets (MSCs) with respect to safety and hygiene. It sets the minimum performance criteria for safety cabinets for works with micro-organisms and specifies test procedures for microbiological safety cabinets with respect to protection of the worker and the environment, product protection and cross-contamination.

ISBN 0 580 34869 5 Price £120\*, £60 BSI Subscribing Members

## BS 4751:2005 Mobile sanitary chairs

This British Standard specifies design and performance requirements and gives test methods for mobile sanitary chairs.

It also gives requirements for user information and labelling. It is applicable to mobile sanitary chairs for use by children and adults, including sanitary chairs that are intended to be used also as shower chairs, of both the type propelled by the user and the type propelled by an attendant. This British Standard does not apply to commode chairs.

ISBN 0 580 45503 3 Price £64\*, £32 BSI Subscribing Members

## BS 4886:1988 Specification for hospital bedsteads

This British Standard specifies requirements for the surface finish, dimensions, construction and strength of bedsteads suitable for general purposes in hospitals and similar institutions. This standard is applicable to bedsteads of either fixed or variable height.

ISBN 0 580 16748 8 Price £64\*, £32 BSI Subscribing Members

## BS 1694:1990 Specification for hospital ward cots for children

This British Standard specifies requirements for children's cots suitable for general purpose use in hospitals and similar institutions. This standard does not apply to cribs, travelling cots, cots that are convertible into beds, and domestic cots. This standard does not apply to cot mattresses.

ISBN 0 580 18691 1 Price £52\*, £26 BSI Subscribing Members

## BS EN ISO 4074:2002 Natural latex rubber condoms. Requirements and test methods

ISBN 0 580 39421 2 Price £128\*, £64 BSI Subscribing Members

**BSI Business Information runs Medical Devices Seminars. See page 9 for details**

BSI ORDER REF	TITLE	ISBN	LIST PRICE*	MEMBER PRICE
BS EN 13726-1:2002	Test methods for primary wound dressings. Aspects of absorbency	0 580 39510 3	£64	£32
BS EN 13726-2:2002	Test methods for primary wound dressings. Moisture vapour transmission rate of permeable film dressings	0 580 39511 1	£52	£26
BS EN 13726-3:2003	Test methods for primary wound dressings. Waterproofness	0 580 41799 9	£52	£26
BS EN 13726-4:2003	Test methods for primary wound dressings. Conformability	0 580 41800 6	£52	£26
BS EN 13726-6:2003	Test methods for primary wound dressings. Odour control	0 580 41798 0	£52	£26

\*P&P applicable (see back cover for details). All prices, content and publishing dates may be subject to change. All information correct at time of printing.

## Quality of Care in Residential Homes for the Elderly

Dennis Green

This book is for owners, managers and senior staff of residential care homes in England and Wales who aspire to provide the best possible service to their residents at all times. It explains how the ISO 9001 quality management standard can provide a template for getting things right and continually striving to make them even better. The book will also be invaluable for local authorities with responsibilities for the care of elderly people in care homes.

**Contents:** Introduction; Home documentation; Process diagrams; Quality management system; Management responsibility; Resource management; Product realization; Measurement, analysis and improvement; Mandatory procedures for ISO 9001; Guideline audit questions.

**BSI order ref** BIP 2072 **ISBN** 0 580 45645 5 **Price** £30\*



## Quality Patient Care in Hospitals

Dennis Green

This book is intended for those who work in NHS and private hospitals in the UK – anyone keen to improve the department in which he or she works and who wishes to give the best possible service to their patients at all times.

Recent developments, including the formation of the Commission for Healthcare Audit and Inspection (CHA) and the National Service Frameworks (NSFs), are increasing the scrutiny of hospitals and the quality of care they offer. The ISO 9001 standard offers a great opportunity for further improvements to be made to our hospitals. Over half a million organizations worldwide have been certificated to the standard, including many private hospitals and individual; hospital departments, which have seen the benefits to be had from a systematic approach to quality and continuous improvement.

**Contents:** Introduction; Hospital documentation; Process diagrams; Quality management system; Management responsibility; Resource management; Product realization; Measurement, analysis and improvement; Design and development: justifiable exclusion; Mandatory procedures for ISO 9001; Clinical audit: guideline questions.

**BSI order ref** BIP 2073 **ISBN** 0 580 45646 3 **Price** £30\*



## Beyond Registration

Steve Tanner, Mike Bailey and Charles Pertwee



This is the new book for those registered to BS EN ISO 9001 and who are seeking continual improvement. The publication shows you how to improve your organization's performance by outlining several business improvement models and approaches, and comparing them with ISO 9001. The book also demonstrates how ISO 9001 provides support to and is consistent with those models and approaches. If you are serious about world-class performance, but don't know how to go about it, then Beyond Registration is your starting point.

**Contents:** Business improvement models – ISO 9001, The Malcolm Baldrige Award, The EQFM Excellence Model®; Business improvement approaches – Balanced Scorecard, Benchmarking, Best Value, BQSR, BPIR, BPR, Charter Mark, FMEA, IIP, Kaizen, Lean Thinking, PCF, Six Sigma, SPC, TQM.

**BSI order ref** BIP 2020 **ISBN** 0 580 42589 4 **Price** £25\*



## Understanding ISO 9001:2000 and Process-based Management Systems

Ian Rosam and Rob Peddle



The first book in this series explains why ISO 9001:2000 is very different to the previous versions, and why it 'moves the goalposts' for the standard. It covers process management and systems thinking, which are the essential pre-requisites for ensuring customer satisfaction whilst not neglecting other stakeholders. It helps you understand why applying the standard in the way intended should be an inevitable decision in all board rooms.

**Contents:** Business first/Standards second – The context; ISO 9001:2000 in overview –

The 'what'; Business Process Management – The 'how'; ISO 9001:2000 in more detail – The 'gap'; Where next – The 'implementation plan'.

**BSI order ref** BIP 2013 **ISBN** 0 580 41425 6 **Price** £45\*

## Creating a Process-based Management System for ISO 9001:2000 and Business Improvement

Ian Rosam and Rob Peddle



This book gives practical guidance on the creation and implementation of a process-based management system that meets the requirements of your business first and then ISO 9001:2000. Applicable to any organization, this approach is critical for both long term value and organizationwide involvement.

How the process-based management system is used as a framework for business improvement is also illustrated in the book. Practical examples and case studies are given throughout to demonstrate best practice and approaches.

**Contents:** The process-based management system in context; The process approach; Designing your management system; Process design (mapping and understanding processes); Procedure design – linking supporting information to processes; Linking of processes; Key performance indicators (KPIs); Implementing the system; Case studies.

**BSI order ref** BIP 2014 **ISBN** 0 580 41546 5 **Price** £45\*

## Process Management Auditing for ISO 9001:2000

Carl Ford and Ian Rosam



Moving away from compliance-based auditing this final book in the series challenges the mindset of auditors to 'think effectiveness'. It shows how process management auditing is a key business tool to:

- Gain meaningful information on which to base decision-making
- Identify opportunities for genuine business improvements
- Improve the effectiveness of activity undertaken – not just confirm that you are doing it
- Cover the requirements of ISO 9001:2000

Highly practical and descriptive, the book shows how you can add greater value from auditing activity and be able to demonstrate it.

**Contents:** Putting the process approach into context; The requirements of ISO 9001:2000 – an auditor's perspective; The system-process-procedure relationship; Auditing tools and techniques; Planning and preparing a process audit; Carrying out a process audit – compliance vs effectiveness; Identifying and reporting findings – moving beyond compliance; Assessing improvements; What personal attributes do auditors need?; Conclusion and the way forward.

**BSI order ref** BIP 2015 **ISBN** 0 580 41547 3 **Price** £45\*

\*P&P applicable (see back cover for details). All prices, content and publishing dates may be subject to change. All information correct at time of printing.

# Aids for Disabled or Handicapped People

## **BS ISO 7176-24:2004** Wheelchairs. Requirements and test methods for user-operated stair-climbing devices

This part of BS ISO 7176 is written as a response to the need for a common language in the field of stair-climbing devices, to give a means of evaluating important safety issues, and to establish a means of qualifying and quantifying the performance of user-operated stair-climbing devices under the various conditions and environments encountered in their operation.

It is applicable to user-operated stair-climbing chairs and user-operated stair-climbing wheelchair carriers where the stair-climbing device climbs backwards up the stairs, with the user facing downstairs, and climbs down the stairs in a forward position with the user facing downstairs. It also includes ergonomic, labelling and disclosure requirements. This part of BS ISO 7176 specifies tests to demonstrate the stair-climbing device's ability to perform safely on stairs with a pitch of 35° or higher, if claimed by the manufacturer.

**ISBN** 0 580 44908 4 **Price** £140\*, £70 BSI Subscribing Members

## **BS EN ISO 11199-2:2005** Walking aids manipulated by both arms. Requirements and test methods. Rollators



This part of BS EN ISO 11199 specifies requirements and methods of testing the static stability braking capabilities, static strength and fatigue of rollators being used as walking aids with wheels, manipulated by the hands, without accessories, unless specified in the particular test procedure. This part of BS EN ISO 11199 also gives requirements relating to safety, ergonomics, performance, and information supplied by the manufacturer including marking and labelling.

The requirements and tests are based on every-day usage of rollators as walking aids, for a maximum user mass as specified by the manufacturer. It includes rollators specified for a user mass of no less than 35 kg.

**ISBN** 0 580 45992 6 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN ISO 11199-3:2005** Walking aids manipulated by both arms. Requirements and test methods. Walking tables



This part of BS EN ISO 11199 specifies requirements and methods of testing the static stability, braking capabilities, static strength and fatigue of walking tables without accessory equipment, unless specified in the particular test procedure. It also gives requirements relating to safety, ergonomics and performance, marking, labelling and information supplied by the manufacturer.

BS EN ISO 11199-3 includes all walking tables with three or more wheels or tips against the walking surface and having arm supports in the shape of a horizontal supporting table or two horizontal forearm supports. The requirements and tests are based on everyday usage of walking tables as walking aids, for a maximum user mass as specified by the manufacturer. This document covers walking tables specified for a user mass of not less than 35 kg.

**ISBN** 0 580 45892 X **Price** £106\*, £53 BSI Subscribing Members

## **BS ISO 10542-4:2004** Technical systems and aids for disabled or handicapped persons. Wheelchair tiedown and occupant-restraint systems. Clamp-type tiedown systems

BS ISO 10542-4 specifies test methods and requirements for design and performance, instructions to installers and users, and product marking and labelling of wheelchair tiedown and occupant-restraint systems (WTORS).

It is applicable only to WTORS that use clamp-type tiedown to secure wheelchairs when used as a forward facing seat by an adult passenger or driver of a motor vehicle. This part of BS ISO 10542 is applicable primarily to complete WTORS, but a portion of this part of BS ISO 10542 can also be applied to components and sub-assemblies sold separately and for replacement parts. This document is applicable to WTORS intended for use with all types of manual and powered wheelchairs, including scooters with three or more wheels.

**ISBN** 0 580 44995 5 **Price** £52\*, £26 BSI Subscribing Members

## **BS ISO 10542-5:2004** Technical systems and aids for disabled or handicapped persons. Wheelchair tiedown and occupant-restraint systems. Systems for specific wheelchairs

BS ISO 10542-5 specifies test methods as well as requirements for design and performance, for instructions and warnings to installers and users, and for product marking and labelling of wheelchair tiedown and occupant restraint systems (WTORS).

It applies only to WTORS that are intended to be used with particular makes and models of wheelchairs when used as a forward-facing seat by a passenger or a driver of a motor vehicle.

This part of BS ISO 10542 applies to WTORS intended for use with manual or powered wheelchairs, including scooters with three or more wheels, intended for use by children or adults of mass equal to or greater than 22 kg. It applies primarily to complete WTORS, but portions of this international standard can also be applied to components and subassemblies sold separately and for replacement parts.

**ISBN** 0 580 44234 9 **Price** £64\*, £32 BSI Subscribing Members

## **BS 5446-3:2005** Fire detection and fire alarm devices for dwellings. Specification for smoke alarm kits for deaf and hard of hearing people



Smoke alarms for use in dwellings have been available for many years, and are specified in BS 5446-1. These devices are intended to warn of the presence of a potential fire condition by emitting a loud piercing sound. However, people with hearing loss can be unaware of such an alarm sound. There are recognized methods of alerting deaf and hard of hearing people, including the use of vibro-tactile and visual alarm devices. To provide a fire warning for those who are deaf or hard of hearing, it has become common practice for such devices to be coupled to domestic smoke alarms.

BS 5446-3 specifies the requirements and test methods for kits and their components used to create smoke alarm systems for deaf and hard of hearing people. It also specifies requirements and test methods for smoke alarm kits intended for use in leisure accommodation vehicles (LAVs).

*BS 5446-3 applies to domestic dwellings only.*

**ISBN** 0 580 45647 1 **Price** £106\*, £53 BSI Subscribing Members

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**See page 11 for details**

\*P&P applicable (see back cover for details). All prices, content and publishing dates may be subject to change. All information correct at time of printing.

## BS EN ISO 10993-1:2003 Biological evaluation of medical devices. Evaluation and testing

BS EN ISO 10993-1 describes the general principles governing the biological evaluation of medical devices; the categorization of devices based on the nature and duration of their contact with the body; and the selection of appropriate tests.

ISBN 0 580 42731 5 Price £92\*, £46 BSI Subscribing Members

## BS EN ISO 10993-3:2003 Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity

BS EN ISO 10993-3 specifies strategies for hazard identification and tests on medical devices for the biological aspects of genotoxicity, carcinogenicity, and reproductive and developmental toxicity. It is applicable for evaluation of a medical device whose potential for genotoxicity, carcinogenicity or reproductive toxicity has been identified. Guidance on selection of tests is provided in BS EN ISO 10993-1.

ISBN 0 580 42881 8 Price £92\*, £46 BSI Subscribing Members

## BS EN ISO 10993-4:2002 Biological evaluation of medical devices. Selection of tests for interactions with blood

This part of BS EN ISO 10993 provides general requirements for evaluating the interactions of medical devices with blood. It describes a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of contact as defined in BS EN ISO 10993-1; the fundamental principles governing the evaluation of the interaction of devices with blood; the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

BS EN ISO 10993-4 describes biological evaluation in general terms and may not necessarily provide sufficient guidance for test methods for a specific device.

ISBN 0 580 40720 9 Price £120\*, £60 BSI Subscribing Members

## BS EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects. General requirements

This part of BS EN ISO 14155 defines procedures for the conduct and performance of clinical investigations of medical devices. It specifies general requirements intended to protect human subjects, ensure the scientific conduct of the clinical investigation, assist sponsors, monitors, investigators, ethics committees, regulatory authorities and bodies involved in the conformity assessment of medical devices.

This part of BS EN ISO 14155 is not applicable to in vitro diagnostic medical devices.

ISBN 0 580 41393 4 Price £106\*, £53 BSI Subscribing Members

## BS EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects. Clinical investigation plans

BS EN ISO 14155-2 provides requirements for the preparation of a Clinical Investigation Plan (CIP) for the clinical investigation of medical devices. The compilation of a CIP in accordance with the requirements of this standard and adherence to it will help in optimizing the scientific validity and reproducibility of the results of a clinical investigation. This standard does not apply to in vitro diagnostic medical devices.

ISBN 0 580 41910 X Price £64\*, £32 BSI Subscribing Members

## BS EN 14476:2005 Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 1)



This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectants or antiseptic products for instruments, surfaces or hands that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products – with water.

This document is applicable to a broad spectrum of viruses and to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example, in hospitals, in community medical facilities, and in dental institutions; in clinics of schools, of kindergartens, and of nursing homes; and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

ISBN 0 580 45989 6 Price £106\*, £53 BSI Subscribing Member

## BS EN 556-2:2003 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices

*NOTE For the purpose of the EU Directive(s) for medical devices, designating that a medical device is 'STERILE' is only permissible when a validated sterilization process has been applied.*

*Requirements for validation and routine control of aseptic processes are specified in BS EN 13824.*

ISBN 0 580 43213 0 Price £52\*, £26 BSI Subscribing Members

## BS EN 13824:2004 Sterilization of medical devices. Aseptic processing of liquid medical devices. Requirements

This document specifies requirements for the design and operation of aseptic processing facilities and the validation and routine control of aseptic processes for the preparation of sterile liquid medical devices. It is not applicable to those pharmaceutical products where the requirements of the relevant good manufacturing practices are applicable. Many of the principles included in this document can be applied to certain aseptically processed sterile solid medical devices.

ISBN 0 580 44955 6 Price £128\*, £64 BSI Subscribing Members

## BS EN ISO 17664:2004 Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices

BS EN ISO 17664 specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification. Requirements are specified for processing that consists of all or some of the following activities: preparation at the point of use; preparation, cleaning, disinfection; drying; inspection, maintenance and testing; packaging; sterilization; storage.

ISBN 0 580 43550 4 Price £92\*, £46 for BSI Subscribing Members

## BS EN 12791:2005 Medical area. Surgical hand disinfection



This European Standard specifies a test method simulating practical conditions for establishing whether a product for surgical hand disinfection reduces the release of hand flora according to requirements described in this document when used for the disinfection of the clean hands of volunteers.

For pricing details please call BSI Customer Services: +44 (0)20 8996 9001

# Medical Electrical Equipment

BSI ORDER REF	TITLE	ISBN	LIST PRICE*	MEMBER PRICE
BS EN 60601-2-4:2003	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of cardiac defibrillators	0 580 42611 4	£128	£64
BS EN 60601-2-5:2001	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of ultrasonic physiotherapy equipment	0 580 37110 7	£92	£46
BS EN 60601-2-17:2004	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment	0 580 43666 7	£106	£53
BS EN 60601-2-33:2002	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of magnetic resonance equipment for medical diagnosis	0 580 40599 0	£140	£70
BS EN 60601-2-43:2001	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of X-ray equipment for interventional procedures	0 580 36434 8	£106	£53
BS EN 60601-2-51:2003	Medical electrical equipment. Particular requirements for safety. Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs	0 580 42728 5	£140	£70
BS EN ISO 21647:2004	Medical electrical equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors	0 580 44897 5	£128	£64

## **BS EN 60601-1-1:2001** Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems

This standard applies to the safety of medical electrical system (defined as a combination of items of equipment, at least one which must be medical electrical equipment and inter-connected by functional connection or use of a multiple portable socket-outlet). It describes the safety requirements necessary to provide protection for the patient, the operator and surroundings.

**ISBN** 0 580 37675 3 **Price** £106\*, £53 BSI Subscribing Members

## **BS EN 60601-1-6:2004** Medical electrical equipment. General requirements for safety. Collateral standard. Usability

This collateral standard specifies requirements for a process to analyse, design, verify and validate the usability, as it relates to safety of medical electrical equipment. It addresses normal use and use errors but excludes abnormal use.

**ISBN** 0 580 44769 3 **Price** £140\*, £70 BSI Subscribing Members

## **BS EN 60601-1-8:2004** Medical electrical equipment. General requirements for safety. Collateral standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

The aim of this standard is to specify basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent alarm signals and consistent control states and their marking for all alarm systems.

**ISBN** 0 580 43417 6 **Price** £140\*, £70 BSI Subscribing Members

## **PD IEC/TR 60788:2004** Medical electrical equipment. Glossary of defined terms

This technical report comprises all defined terms used in the IEC standards and technical reports which fall under the scope of medical electrical equipment.

**ISBN** 0 580 43503 2 **Price** £182\*, £91 BSI Subscribing Members

## **PD IEC/TR 60878:2003** Graphical symbols for electrical equipment in medical practice

This technical report provides a comprehensive compilation, for easy reference, of graphical symbols (graphics, title, description) and safety signs for medical electrical equipment. The graphical symbols are grouped in sections according to their specific field of application.

**ISBN** 0 580 42858 3 **Price** £182\*, £91 BSI Subscribing Members

## **BS EN 61010-2-101:2002** Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment

**ISBN** 0 580 40819 1 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN 61676:2002** Medical electrical equipment. Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology

**ISBN** 0 580 41113 3 **Price** £106\*, £53 BSI Subscribing Members

\*P&P applicable (see back cover for details). All prices, content and publishing dates may be subject to change. All information correct at time of printing.

**BS EN 62220-1:2004** Medical electrical equipment. Characteristics of digital X-ray imaging devices. Determination of the detective quantum efficiency

This part of BS EN 62220 specifies the method for the determination of the detective quantum efficiency (DQE) of digital X-ray imaging devices as a function of exposure and of spatial frequency for the working conditions in the range of the medical application as specified by the manufacturer. It is also applicable to projection digital X-ray imaging devices producing images in digital format that are used for medical diagnosis. It is restricted to digital X-ray imaging devices that are used for radiographic imaging, such as CR systems, selenium-based systems, flat panel detectors, optically coupled CCD detectors, and digital X-ray image intensifiers used for single exposures. This part of BS EN 62220 is not applicable to digital X-ray imaging devices intended to be used in mammography or in dental radiography; computed tomography; systems in which the X-ray field is scanned across the patient; and devices for dynamic imaging (where series of images are acquired, as in fluoroscopic or cardiac imaging).

ISBN 0 580 43335 8 Price £92\*, £46 BSI Subscribing Members

**PD IEC/TR 62266:2002** Medical electrical equipment. Guidelines for implementation of DICOM in radiotherapy

ISBN 0 580 39515 4 Price £120\*, £60 BSI Subscribing Members



**BS EN ISO 9919:2005** Medical electrical equipment. Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use



This international standard specifies particular requirements for the basic safety and essential performance of pulse oximeter equipment intended for use on humans. This includes any part necessary for normal use, e.g. the pulse oximeter monitor, pulse oximeter probe, probe cable extender. These requirements also apply to pulse oximeter equipment, including pulse oximeter monitors, pulse oximeter probes and probe cable extenders, that has been reprocessed. The intended use of pulse oximeter equipment includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate on patients in healthcare institutions as well as on patients in home care.

This international standard is not applicable to pulse oximeter equipment intended for use in laboratory research applications nor to oximeters that requires a blood sample from the patient. It is not applicable to pulse oximeter equipment solely intended for foetal use. It is not applicable to remote or slave (secondary) devices that display SpO2 values that are located outside of the patient environment.

ISBN 0 580 45853 9 Price £140\*, £70 BSI Subscribing Members

**BS EN 60806:2005** Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis



This standard applies to X-ray tube assemblies containing rotating anode X-ray tubes, for use in medical diagnostic radiology for techniques in which the X-ray pattern will be received simultaneously in all points of the image reception area.

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Medical Devices Directive	3 days	12-14 July, 27-29 September, 22-24 November
Introduction to the Medical Devices Directive 93/42/EEC (MDD)	1 day	8 November
In Vitro Diagnostics Directive	2 days	9/10 November
Corrective & Preventive Action	1 day	17 November
Medical Device Risk Management	2 days	4/5 July, 20/21 September, 15/16 November
Getting to Market with a Medical Device 510(K)	1 day	21 July, 4 October, 30 November
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# Anaesthetic and Respiratory Equipment

## BS EN ISO 18777:2005 Transportable liquid oxygen systems for medical use. Particular requirements



This international standard specifies requirements for the safety and essential performance of transportable liquid oxygen systems which are used as a supply source for oxygen therapy. These devices usually consist of a portable unit to be carried by or with the patient whilst in use and the vessel used to refill the portable unit. The requirements of this international standard which replace or modify the requirements of IEC 60601-1:1998 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

ISBN 0 580 45686 2 Price £106\*, £53 BSI Subscribing Members

## BS EN ISO 18778:2005 Respiratory equipment. Infant monitors. Particular requirements



This international standard specifies requirements for the safety and essential performance of monitors used to detect apparent life-threatening events in sleeping or resting children under three years of age. It applies to devices used in home care applications. These monitors are generally used without continual professional supervision. This document also applies to the accessories, e.g. probes and cables necessary to apply the monitor to the patient.

ISBN 0 580 45684 6 Price £106\*, £53 BSI Subscribing Members

## BS EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures. Particular requirements



This international standard specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the patient's demand when used in home care applications. These devices are generally used without continual professional supervision. These devices are also used in health care facilities / institutions.

This international standard covers two types of conserving devices: conserving devices intended for continuous use and those not intended for continuous use. It covers active devices only, e.g. pneumatically or electrically controlled devices, and does not cover devices such as reservoir cannulas. In addition, it includes conserving devices which are part of a system, e.g. pressure regulators, oxygen concentrators or liquid oxygen vessels.

ISBN 0 580 45685 4 Price £106\*, £53 BSI Subscribing Members

## BS EN ISO 5356-1:2004 Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets

This document specifies dimensional and gauging requirements for cones and sockets intended for connecting anaesthetic and respiratory equipment, e.g. in breathing systems, anaesthetic-gas scavenging systems and vaporizers. It gives requirements for the following conical connectors:

- 8.5 mm size intended for use in paediatric breathing systems
- 15 mm and 22 mm sizes intended for general use in breathing systems
- 22 mm latching connectors (including performance requirements)
- 23 mm size intended for use with vaporizers, but not for use in breathing systems
- 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.

ISBN 0 580 43872 4 Price £92\*, £46 for BSI Subscribing Members

## BS EN ISO 5366-1:2004 Anaesthetic and respiratory equipment. Tracheostomy tubes. Tubes and connectors for use in adults

This part of ISO 5366 specifies requirements for tracheostomy tubes made of plastics materials and/or rubber having inside diameters of 6.5mm or greater. Such tubes are primarily designed for patients who require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. This part of BS EN ISO 5366 is not applicable to specialized tubes, and does not address flammability of tracheostomy tubes.

ISBN 0 580 44187 3 Price £92\*, £46 BSI Subscribing Members

## BS EN ISO 7376:2003 Anaesthetic and respiratory equipment. Laryngoscopes for tracheal intubation

This international standard specifies general requirements for laryngoscopes and critical dimensions for the handle and lamp of hook-on type laryngoscopes. It is applicable only to instruments with an electrical power source for illuminating the larynx, since electrical safety requirements may be more stringent for instruments connected to mains or external power packs.

This document is not applicable to surgical instruments known by the same generic name and does not apply to:

- The blade form or handle design, except for general requirements and the interchangeability aspects of the connection between the blade and the handle
- The measurement and specification of the lamp illumination intensity;
- Flexible laryngoscopes, or laryngoscopes designed for surgery
- Laryngoscopes powered from mains electricity supply
- Laryngoscopes connected by light-transmitting cables to external light sources.

ISBN 0 580 43254 8 Price £92\*, £46 BSI Subscribing Members

## BS EN ISO 8835-4:2004 Inhalational anaesthesia systems. Anaesthetic vapour delivery devices

BS EN ISO 8835-4 specifies particular requirements for the essential performance of anaesthetic vapour delivery devices (AVDDs). It is applicable to AVDDs which are a component of an anaesthetic system and are intended to be continuously operator-attended. This document does not apply to AVDDs intended for use with flammable anaesthetics and AVDDs intended for use within anaesthetic breathing systems (e.g. draw-over vaporizers).

ISBN 0 580 45631 5 Price £92\*, £46 BSI Subscribing Members

## BS EN ISO 8835-5:2004 Inhalational anaesthesia systems. Anaesthesia ventilators

Part 5 of BS EN ISO 8835 specifies particular requirements for the essential performance of anaesthetic ventilators. It is applicable to anaesthetic ventilators which are always a component of an anaesthetic system and are intended to be continuously attended by an operator. BS EN ISO 8835-5 is not applicable to anaesthetic ventilators intended for use with flammable anaesthetics.

ISBN 0 580 43853 8 Price £92\*, £46 BSI Subscribing Members

## DD ISO/TS 18835:2004 Inhalational anaesthesia systems. Draw-over vaporizers and associated equipment

ISBN 0 580 44556 9 Price £52\*, £26 BSI Subscribing Members

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### **BS EN ISO 10651-2:2004 Lung ventilators. Home care ventilators for ventilator-dependent patients**

BS EN ISO 10651-2 specifies requirements for lung ventilators intended for home applications for those patients who are dependent on ventilatory support. Such ventilators are considered life-supporting equipment, are frequently used in locations where driving power is not reliable, and are often supervised by non-healthcare personnel with different levels of training.

This documents does not apply to cuirass and "iron-lung" ventilators nor is it applicable to ventilators intended only to augment the ventilation of spontaneously breathing patients.

**ISBN** 0 580 44139 3 **Price** £120\*, £60 BSI Subscribing Members

### **BS EN ISO 10651-6:2004 Lung ventilators. Home-care ventilatory support devices**

BS EN ISO 10651-6 specifies the basic safety and essential performance requirements for home-care ventilatory support devices, intended mainly for use in home care but which could be used elsewhere (e.g. in healthcare facilities) for appropriate patients for whom the use of a home-care ventilator complying with BS EN ISO 10651-2 is not required.

**ISBN** 0 580 44140 7 **Price** £106\*, £53 BSI Subscribing Members

### **BS EN 13544-2:2002 Respiratory therapy equipment. Tubing and connectors**

This standard specifies requirements for tubing to be used with equipment for the therapeutic administration of respirable gases in domiciliary, ambulance and hospital practice including the interface to the equipment i.e. nipples and screw threaded connectors. This tubing is mainly used with oxygen, air or mixtures of these gases. The interface specifications are given to ensure interchangeability of respiratory therapy equipment thereby enabling patients to receive continuous treatment in all these clinical situations.

**ISBN** 0 580 40664 4 **Price** £64\*, £32 BSI Subscribing Members

### **BS EN ISO 15001:2004 Anaesthetic and respiratory equipment. Compatibility with oxygen**

This international standard specifies minimum requirements for the oxygen compatibility of materials, components and devices for anaesthetic and respiratory applications which can come in contact with oxygen in normal condition or in single fault condition at gas pressures greater than 50 kPa.

It applies to anaesthetic and respiratory equipment such as medical gas pipeline systems, pressure regulators, terminal units, medical supply units, flexible connections, flow-metering devices, anaesthetic workstations and lung ventilators.

Aspects of compatibility that are addressed by this document include cleanliness, resistance to ignition and the toxicity of products of combustion and/or decomposition.

**ISBN** 0 580 41972 X **Price** £128\*, £64 BSI Subscribing Members

### **DD ISO/TS 16628:2003 Tracheobronchial tubes. Recommendations for size designation and labelling**

This technical specification provides recommendations to assist manufacturers in establishing a standard method of size designation for tracheobronchial tubes and their parts. A tracheobronchial tube is a double-lumen tracheal tube that facilitates selective ventilation to one or both lungs. It is designed for either right or left mainstem bronchus placement, and has both a tracheal and a bronchial cuff.

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# In Vitro Medical Devices

## **BS EN 591:2001** Instructions for use for in vitro diagnostic instruments for professional use

This standard specifies the requirements for the contents of instructions for use for in vitro diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use. This standard can also be applied to accessories. However it is not applicable to field repair instructions.

**ISBN** 0 580 37232 4 **Price** £52\*, £26 BSI Subscribing Members

## **BS EN 592:2002** Instructions for use for in vitro diagnostic instruments for self-testing

This European Standard specifies the requirements for the contents of instructions for use for in vitro diagnostic instruments including apparatus and equipment for self-testing. This standard can also be applied to accessories, however it is not applicable to field repair instructions.

**ISBN** 0 580 39652 5 **Price** £52\*, £26 BSI Subscribing Members

## **BS EN 13532:2002** General requirements for in vitro diagnostic medical devices for self-testing

This European Standard specifies general requirements for in vitro diagnostic medical devices (IVD MDs) for self-testing in order to ensure that IVD MDs for self-testing are safe and suitable for the purposes as specified by the manufacturer. This standard does not address medical aspects of IVD MDs for self-testing.

**ISBN** 0 580 29682 7 **Price** £52\*, £26 BSI Subscribing Members

## **BS EN 13612:2002** Performance evaluation of in vitro diagnostic medical devices

This European Standard applies to the performance evaluation of in vitro diagnostic medical devices (IVD MDs) including IVD MDs for self-testing. It specifies the responsibilities and general requirements for the planning, conduct, assessment and documentation of a performance evaluation study by the manufacturer. It does not apply to specific evaluation plans for certain IVD MDs or a specific use.

In particular, this standard applies to IVD MDs to show evidence to notified bodies and national authorities by results of a performance evaluation that the IVD MD performs as claimed by the manufacturer establish adequate performance evaluation data originating from appropriate studies or resulting from available literature, and to satisfy the requirements of a quality system for design validation.

**ISBN** 0 580 39650 9 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN 13975:2003** Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects

This European Standard specifies sampling procedure requirements for acceptance testing of finished in vitro diagnostic medical devices, which require EC verification by a notified body. Two different provisions are addressed: verification by testing attributes and/or variables on a statistical basis; and verification by testing a homogeneous batch which has been defined by appropriate means of process validation and in-process control.

This standard specifies requirements and criteria for testing procedures to establish and verify the homogeneity of processes and products. It is also applicable for drawing up sampling plans for finished products according to the requirements laid down for manufacturers' product certification and production quality systems.

**ISBN** 0 580 41510 4 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN 14254:2004** In vitro diagnostic medical devices. Single-use receptacles for the collection of specimens, other than blood, from humans

This standard specifies requirements and test methods for single-use evacuated and non-evacuated receptacles, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination. This standard does not specify requirements for collection needles or needle holders or other accessories used in conjunction with specimen receptacles.

**ISBN** 0 580 44020 6 **Price** £64\*, £32 BSI Subscribing Members

## **BS ISO 15198:2004** Clinical laboratory medicine. In vitro diagnostic medical devices. Validation of user quality control procedures by the manufacturer

This publication describes a process for manufacturers of in vitro diagnostic medical devices to validate quality control procedures they recommend to their users. These quality control procedures are intended to provide users with assurance that device performance is consistent with its intended use and the manufacturers' claims. This international standard applies to all in vitro diagnostic medical devices.

**ISBN** 0 580 44155 5 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 17511:2003** In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials

This European Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices.

External quality assessment (survey) samples, with proven commutability, whose values have been assigned by means of internationally agreed reference measurement systems or internationally agreed conventional reference measurement systems fall within the scope of this European Standard.

**ISBN** 0 580 42473 1 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN ISO 18153:2003** In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

This European Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices.

**ISBN** 0 580 42141 4 **Price** £64\*, £32 BSI Subscribing Members

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## **BS ISO 16428:2005** Implants for surgery. Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

NEW

This international standard specifies standard environmental conditions for the testing of metallic materials intended for implantation, surgical implants, and medical devices. The test conditions described simulate physiological conditions in a simplified manner controlling the test solution, the temperature, the gaseous atmosphere and the proportions of sample size and volume of solution.

These environmental testing conditions can be employed where necessary in combination with various static or dynamic tests where the effect of the physiological environment is to be considered. Typical applications are corrosion fatigue tests and selected fretting and wear tests, as well as general electrochemical tests. Typical articulating joint simulator tests and aspects particular to the dental field are not considered by this international standard. Solutions that attempt to replicate the tribological properties of body fluids, such as those used in wear studies, are outside the scope of this international standard.

ISBN 0 580 45920 9 Price £64\*, £32 BSI Subscribing Members

## **BS 8432:2005** Spinal orthoses. Guide to design

COMING SOON

This British Standard gives guidance on the design of spinal orthoses. It is intended for designers of orthoses, clinicians prescribing orthoses for patients, orthotists, and manufacturers of both commercially available and custom-made orthoses for individual patients. This standard is not applicable to sacro-iliac orthoses (Sb), that is, orthoses that encompass the whole or a part of the sacro-iliac region of the trunk.

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## **BS EN ISO 9713:2004** Neurosurgical implants. Self-closing intracranial aneurysm clips

This standard describes characteristics of self-closing aneurysm clips intended for permanent intracranial implantation and specifies requirements for their marking, packaging, sterilization and for labelling and accompanying documentation. In addition it gives a method for the measurement of closing force.

This standard is not applicable to malleable clips, or clips intended to be used during the course of surgery and removed before wound closure (temporary clips).

ISBN 0 580 43628 4 Price £64\*, £32 BSI Subscribing Members

## **BS ISO 14243-3:2004** Implants for surgery. Wear of total knee joint prostheses. Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

ISBN 0 580 45204 2 Price £64\*, £32 BSI Subscribing Members

## **BS EN 14299:2004** Non-active surgical implants. Particular requirements for cardiac and vascular implants. Specific requirements for arterial stents

This European Standard specifies requirements for arterial stents and endovascular prostheses and their deployment intended to correct or compensate for a defect of an artery. With regard to safety, this standard gives, in addition to BS EN ISO 14630 and BS EN 12006-3, specific requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

This European Standard applies to arterial stents and endovascular prostheses used in the aorta, cervical segments of cerebral arteries, coronary arteries, intra-cerebral arteries, peripheral arteries, pulmonary arteries, supra-aortic arteries and visceral arteries. It also includes endovascular prostheses used to treat aneurysms, arterial stenoses, or other vascular abnormalities.

ISBN 0 580 43859 7 Price £106\*, £53 BSI Subscribing Members

## **BS ISO 7206-10:2003** Implants for surgery. Partial and total hip joint prostheses. Determination of resistance to static load of modular femoral heads

Part 10 of BS EN ISO 7206 applies to femoral heads of partial or total hip-joint replacements of modular construction (i.e. a head/neck conical taper connection) and describes methods of determining the load required, under specified laboratory conditions, to cause failure of the head (disassembly or fracture). It applies to components made of metallic and non-metallic materials. This document does not cover methods of examining and reporting the test specimens.

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## **BS EN ISO 14630:1998** General requirements for non-active surgical implants

This European Standard specifies general requirements for non-active surgical implants. This standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants and intraocular lenses. With regard to safety, this standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests.

ISBN 0 580 28055 1 Price £64\*, £32 BSI Subscribing Members

## **BS EN 12006-3:1999** Non-active surgical implants. Particular requirements for cardiac and vascular implants. Endovascular devices

This European Standard specifies particular requirements for endovascular devices. With regard to safety, it gives, in addition to BS EN ISO 14630, requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer. This European Standard, in addition to BS EN ISO 14630, provides a method to demonstrate compliance with the relevant Essential Requirements as outlined in general terms in Annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to endovascular devices.

ISBN 0 580 30888 X Price £52\*, £26 BSI Subscribing Members

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# Optics, Optical Instruments and Implants

## **BS 2738-3:2004** Spectacle lenses. Specification for the presentation of prescriptions and prescription orders for ophthalmic lenses

BS 2738-3 specifies the information to be included in prescriptions (prepared by optometrists, ophthalmologists or ophthalmic medical practitioners) and in prescription orders (prepared by optometrists and dispensing opticians and their staff) to enable the correct spectacle lenses for a patient to be supplied. It also specifies the method by which the ophthalmic and other information is to be presented.

**ISBN** 0 580 43900 3 **Price** £52\*, £26 BSI Subscribing Members

## **BS ISO 8600-2:2002** Optics and optical instruments. Medical endoscopes and endoscopic accessories. Particular requirements for rigid bronchoscopes

This publication specifies definitions and requirements for rigid bronchoscopes and their endoscopic accessories used in the practice of anaesthesia and medical endoscopy.

**ISBN** 0 580 40325 4 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 8980-2:2004 (BS 2738-7:2004)** Ophthalmic optics. Uncut finished spectacle lenses. Specifications for progressive power lenses

This part of BS EN ISO 8980 specifies requirements for the optical and geometrical properties for uncut finished progressive spectacle lenses.

**ISBN** 0 580 43538 5 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 8980-3:2004** Ophthalmic optics. Uncut finished spectacle lenses. Transmittance specifications and test methods

This document specifies requirements for the transmittance properties of uncut finished spectacle lenses. It is not applicable to spectacle lenses having particular transmittance or absorption characteristics prescribed for medical reasons or products where specific personal protective equipment transmittance standards apply.

**ISBN** 0 580 45136 4 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN ISO 9337-2:2004** Contact lenses. Determination of back vertex power. Measurement of contact lenses immersed in saline

BS EN ISO 9337-2 describes test methods for the determination of back vertex power of soft contact lenses immersed in saline. It is applicable to finished contact lenses. It is intended that the test methods described should be used by contact lens manufacturers, practitioners and other interested parties and that its provisions will be entrusted to appropriately qualified and experienced people.

**ISBN** 0 580 44214 4 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 10342:2003** Ophthalmic instruments. Eye refractometers

This international standard, together with BS EN ISO 15004, specifies requirements and test methods for eye refractometers using an objective measuring principle. The requirements in this document take precedence over BS EN ISO 15004, if differences exist.

**ISBN** 0 580 41977 0 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 15004:1998** Ophthalmic instruments. Fundamental requirements and test methods

BS EN ISO 15004 specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments. It is also applicable to low-vision aids and tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye. This international standard does not apply to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

**ISBN** 0 580 29352 1 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN ISO 12870:2004** Ophthalmic optics. Spectacle frames. Requirements and test methods

This standard specifies fundamental requirements for unglazed spectacle frames designed for use with all prescription lenses, and is applicable to frames at the point of sale to the retailer, by the manufacturer or supplier. It is applicable to all spectacle frame types including rimless mounts, semi-rimless mounts and folding spectacle frames, and applies to spectacle frames made from natural organic materials.

This document does not address complete custom-made spectacle frames or to products designed specifically to provide personal eye protection.

**ISBN** 0 580 44312 4 **Price** £106\*, £53 BSI Subscribing Members

## **BS EN ISO 14889:2003** Ophthalmic optics. Spectacle lenses. Fundamental requirements for uncut finished lenses

**ISBN** 0 580 41975 4 **Price** £64\*, £32 BSI Subscribing Members

## **BS EN ISO 16671:2003** Ophthalmic implants. Irrigating solutions for ophthalmic surgery

This international standard defines requirements with regards to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer. This document applies to ophthalmic irrigating solutions (OISs), used during ophthalmic surgery. These solutions do not provide any primary immunological, pharmacological or metabolic function.

**ISBN** 0 580 43056 1 **Price** £92\*, £46 BSI Subscribing Members

## **BS EN ISO 16672:2003** Ophthalmic implants. Ocular endotamponades

This international standard applies to ocular endotamponades (OEs), a group of non-solid implants used in ophthalmology to flatten and position a detached retina onto the choroid, or to tamponade the retina. With regard to the safety and efficacy of OEs, this international standard specifies requirements for their intended performance, design attributes, pre-clinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer.

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### BS EN 1639:2004 Dentistry. Medical devices for dentistry. Instruments

This publication specifies general requirements for instruments used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

ISBN 0 580 43915 1 Price £64\*, £32 BSI Subscribing Members

### BS EN 1640:2004 Dentistry. Medical devices for dentistry. Equipment

This European Standard specifies general requirements for items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer.

This European Standard does not include requirements for dental X-ray equipment nor does it apply to any dental instruments connected to an item of dental equipment.

ISBN 0 580 43916 X Price £64\*, £32 BSI Subscribing Members

### BS EN 1641:2004 Dentistry. Medical devices for dentistry. Materials

This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. For the purposes of this standard these materials are defined as restorative materials. Dental implants are specifically excluded and described in BS EN 1642. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

ISBN 0 580 43917 8 Price £52\*, £26 BSI Subscribing Members

### BS EN 1642:2004 Dentistry. Medical devices for dentistry. Dental implants

This European Standard specifies general requirements for dental implants. Surgically implantable dental materials defined as restorative materials are specifically excluded and described in BS EN 1641. This European Standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

ISBN 0 580 43918 6 Price £52\*, £26 BSI Subscribing Members

### BS EN ISO 7494-2:2003 Dentistry. Dental units. Water and air supply

BS EN ISO 7494-2 specifies requirements and test methods for the materials, design and construction of the water and air supply within dental units in order to ensure that the compressed water and air supplied via the dental unit are of appropriate quality. It includes provisions for the prevention of retraction of oral fluids into the water supply of the dental unit. This document does not address prevention of contamination and/or proliferation of hazardous micro-organisms (for example bacteria, viruses) in the dental unit.

ISBN 0 580 41458 2 Price £64\*, £32 BSI Subscribing Members

### BS EN ISO 9997:2000 Dental cartridge syringes

This document specifies requirements and test methods for dental cartridge syringes which are reusable dental syringes of the aspirating, non-aspirating and self-aspirating types using cartridges with dental local anaesthetics. It is not applicable to cartridge syringes having a mechanical-advantage action for creating high pressure.

ISBN 0 580 34321 9 Price £64\*, £32 BSI Subscribing Members

### PD CR 12401:2003 Dentistry. Guidance on the classification of dental devices and accessories

This technical report provides guidance on the application of the classification rules in Council Directive 93/42 EEC concerning medical devices as they pertain to dental devices and accessories.

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### BS EN ISO 21530:2004 Dentistry. Materials used for dental equipment surfaces. Determination of resistance to chemical disinfectants

This international standard specifies test methods for determining the resistance to chemical disinfectants of all materials used for external surfaces of dental equipment intended for such disinfection. Three test methods are specified: an immersion test, a spray test and a contact test. The choice of test method to be used is left to the discretion of the party conducting the testing.

This international standard does not address the bactericidal, virucidal and fungicidal effectivity of the disinfectants. It does not provide for testing the possible detrimental effects of applied stress on the resistance of test materials to the test reagents.

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### BS EN ISO 21533:2003 Dentistry. Reusable cartridge syringes intended for intraligamentary injections

This international standard specifies requirements and test methods for reusable cartridge syringes intended for intraligamentary injections. It specifies requirements for dental cartridge syringes with ISO metric thread sizes, and only intended for intraligamentary injections. However, attention is drawn to the existence of a variety of syringes with imperial thread sizes.

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## PD CR 13694:1999 Health informatics. Safety and security related software quality standard for healthcare (SSQS)

This report presents a review of the existing and emerging standards that are, or may be, applicable to healthcare information systems (HISs). The type of standards that are considered are those that focus on the issues of software safety, security, confidentiality, and integrity. This report also provides a discussion of the issues that need to be addressed in compiling a guidance for purchasers and developers of HISs.

This report also examines some standards which do not necessarily concern HISs but instead refer to general computer-based systems. These standards are examined because it is considered that they may be applicable, or adapted, to Healthcare Systems.

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## BS 8401:2003 Health informatics standards. Status as of July 2001. Guide

This British Standard gives guidance on the most important health informatics standards (and equivalent publications) in use in, or appropriate for use in, the UK. The scope of this guide is limited to those standards and publications approved by 9 July 2001. It deals only with standards (either approved or in course of development) developed specifically for use in healthcare.

For example, even though lower-layer communications standards are widely used in health, their use is more or less exactly the same as in fields other than health, and they are therefore omitted. Conversely, where a standard has been developed specifically for use in healthcare – even though the standard is of more general applicability – it has been included.

This guide is intended to be of use to:

- Procurers of systems incorporating health informatics standards
- Implementers of such systems
- Suppliers of such systems
- Those responsible for selecting and approving health informatics standards, e.g. NHS Information Standards Boards.

It is also intended to be of use to:

- Standards developers
- Policy makers
- Consultants
- Those with an interest in the development of health informatics standards.

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## BS 8421-1:2003 Guide to health informatics. Results of healthcare service procedures. Delivery to end-users. General guidance and recommendations

This part of BS 8421 gives general guidance, within health informatics, on the application of standards, specifications and recommendations to the domains of the producers and users of the results of healthcare service procedures. It describes the communication of the results of healthcare service procedures into the remainder of the healthcare arena in the context of patient records as a whole. It also reviews presentation of results using health informatics standards and other more general information technology standards relevant to the communication of results from healthcare service departments to end-users.

This part of BS 8421 uses BS ISO/IEC 10746 to provide a framework for understanding the communication of results from healthcare service departments to end-users for the purposes of producing system specifications for interoperability.

Recommendations are made for the use of healthcare standards profiles for the results of healthcare procedures.

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## BS ISO 22857:2004 Health informatics. Guidelines on data protection to facilitate trans-border flows of personal health information

This international standard provides guidance on data protection requirements to facilitate the transfer of personal health data across national borders. It covers both the data protection principles that should apply to international transfers and the security policy which an organisation should adopt to ensure compliance with those principles. Where a multilateral treaty between a number of countries has been agreed e.g. the EU Data Protection Directive, the terms of that treaty will take precedence.

BS ISO 22857 aims to facilitate international health-related applications involving the transfer of personal health data. It seeks to provide the means by which data subjects, such as patients, may be assured that health data relating to them will be adequately protected when sent to, and processed in, another country.

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# Health Informatics - Medical Device Communication

**BS EN 1064:2005** Health informatics.  
Standard communication protocol.  
Computer-assisted electrocardiography (ECG)



This document specifies the common conventions required for the cart-to-host as well as cart-to-cart interchange of specific patient data (demographic, recording, ...), ECG signal data, ECG measurement and ECG interpretation results. This document specifies the content and structure of the information which is to be interchanged between digital ECG carts and computer ECG management systems, as well as other computer systems where ECG data can be stored.

ISBN 0 580 45655 2 Price £182\*, £91 BSI Subscribing Members

**BS EN 12052:2004** Health informatics. Digital imaging.  
Communication, workflow and data management

This document addresses the exchange of digital images, and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information.

This document is intended to facilitate interoperability of medical imaging equipment by specifying a set of protocols to be followed by devices claiming conformance to the standard; the syntax and semantics of commands and associated information data models that ensure effective communication between implementations of the standard; information that must be supplied with an implementation for which conformance to the standard is claimed.

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**DD CEN/TS 14271:2003** Health informatics.  
File exchange format for vital signs

This standard covers the off-line storage of biosignals, time-stamped measurement, events, enumerations and alerts. It defines a file data structure and not a message data structure. This standard does not support data compression. DD CEN/TS 14271 includes a method to encapsulate or refer to one of many medical images, digital video and audio files but the intention is neither to define a new format for medical or other images, video nor audio.

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**PD ISO/TR 16056-1:2004** Health informatics.  
Interoperability of telehealth systems and networks.  
Introduction and definitions

This report includes a brief introduction to interoperability of telehealth systems and networks and definitions of telehealth and related terms. An appendix describing the Telehealth Technical Reference Architecture has been also included to define more clearly the various components of a telehealth system and the elements that need to be addressed in formulating a set for requirements for these various requirements.

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**PD ISO/TR 16056-2:2004** Health informatics.  
Interoperability of telehealth systems and networks.  
Real-time systems

This report builds on PD ISO/TR 16056-1 and focuses on the technical standards related to real-time applications, (including video, audio and data conferencing) and interoperability aspects of telehealth systems and networks. Specifically, this document addresses four main areas:

- Standards for real-time telehealth systems
- Interoperability issues in telehealth applications
- Requirements for interoperable telehealth systems and networks
- Framework for interoperable architectures.

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**PD ISO/TR 21730:2005** Health informatics.  
Use of mobile wireless communication and  
computing technology in healthcare facilities.  
Recommendations for the management of  
unintentional electromagnetic interference with  
medical devices



This international standard provides guidance for the deployment, use and management of mobile wireless communication and computing equipment in the healthcare facility in a way that helps mitigate potential hazards due to electromagnetic interference (EMI) with medical devices.

The recommendations recognize the different resources, needs, concerns and environments of healthcare organizations around the world and provide detailed management guidelines for healthcare organizations that desire full deployment of mobile wireless communication and computing technology throughout their facility, as well as selective restrictions for healthcare organizations that have decided comprehensive management procedures are not feasible, practical, or desirable at the present time. They also distinguish between controlled systems used by doctors and staff for healthcare-specific communication and health informatics transport vs. non-controlled (personal) mobile wireless equipment randomly brought into the facility by visitors, patients, and the healthcare organization workforce.

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## PD ISO/TR 15489-2:2001 Information and Documentation. Records Management. Guidelines

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