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ISO - ISO 15223-2:2010 - Medical devices — Symbols to be ...
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ISO 15223-2:2010 - Techstreet
Description / Abstract: ISO 15223-2, 1st Edition, January 15, 2010 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation. This part of ISO 15223 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

ISO 15223-2 : Medical devices - Symbols to be used with ...
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BS ISO 15223-2:2010 - BSI - Standards
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ISO 15223-2:2010 - Estonian Centre for Standardisation
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BS ISO 15223-2:2010 - Techstreet
The ISO 15223 series of International Standards addresses symbols that can be used to convey information that is essential for the safe and proper use of medical devices. As such, in most regulatory domains the symbols are required to be presented with the device.

ISO 15223-2:2010(en), Medical devices ? Symbols to be used ...
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AAMI/ISO 15223-2:2010 - Techstreet
ISO 15223-2 was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices. This first edition of ISO 15223-2, together with ISO 15223-1:2007, cancels and replaces ISO 15223:2000, which has been technically revised.

This preview is downloaded from www.sis.se. Buy the entire ...
ISO 15223:2000/Amd 2:2004 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Amendment 2 ... 95.99 2010-01-15. Withdrawal of International Standard Revisions / Corrigenda. Now withdrawn ISO 15223:2000/Amd 2:2004 Revised by ISO 15223-1:2007 ISO 15223-2:2010; Got a question? ...

ISO - ISO 15223:2000/Amd 2:2004 - Medical devices ...
ISO 15223-1:2016 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements. These symbols may be used on the medical device itself, on its packaging or in the associated documentation.

ISO - ISO 15223-1:2016 - Medical devices — Symbols to be ...
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Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the medical device industry, and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects.

The Model recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient regulation to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. It foresees that such countries will progress from basic regulatory controls towards an expanded level to the extent that their resources allow. The Model is written for the legislative, executive, and regulatory branches of government as they develop and establish a system of medical devices regulation. It describes the role and responsibilities of a country's regulatory authority for implementing and enforcing the regulations. Also, it describes circumstances in which a regulatory authority may either "rely on" or "recognize" the work products from trusted regulatory sources (such as scientific assessments, audit, and inspection reports) or from the WHO Prequalification Team. Section 2 of this document recommends definitions of the terms "medical devices" and IVDs. It describes how they may be grouped according to their potential for harm to the patient or user and specifies principles of safety and performance that the device manufacturer must adhere to. It explains how the manufacturer must demonstrate to a regulatory authority that its medical device has been designed and manufactured to be safe and to perform as intended during its lifetime. Section 3 presents the principles of good regulatory practice and enabling conditions for effectively regulating medical devices. It then introduces essential tools for regulation, explaining the function of the regulatory entity and the resources required. Section 4 presents a stepwise approach to implementing and enforcing regulatory controls for medical devices as the regulation progresses from a basic to an expanded level. It describes elements from which a country may choose according to national priorities and challenges. Also, it provides information on when the techniques of reliance and recognition may be considered and on the importance of international convergence of regulatory practice.Section 5 provides a list of additional topics to be considered when developing and implementing regulations for medical devices. It explains the relevance of these topics and provides guidance for regulatory authorities to ensure that they are addressed appropriately. The Model outlines a general approach but cannot provide country-specific guidance on implementation. While it does not offer detailed guidance on regulatory topics, it contains references to relevant documents where further information may be found. It does not detail the responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies, and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of medical devices.

The term 'medical devices' covers a wide range of equipment essential for patient care at every level of the health service, whether at the bedside, at a health clinic or in a large specialised hospital. Yet many countries lack access to high-quality devices, particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices. This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices, based on best practice experience in other countries. Issues highlighted include: the need for harmonised regulations; and the adoption, where appropriate, of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources. These approaches allow emphasis to be placed on locally-assessed needs, including vendor and device registration, training and surveillance and information exchange systems.

This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelsstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

This basic source for identification of U.S. manufacturers is arranged by product in a large multi-volume set. Includes: Products & services, Company profiles and Catalog file.

Carbon-based nanomaterials are rapidly emerging as one of the most fascinating materials in the twenty-first century. Chemical Functionalization of Carbon Nanomaterials: Chemistry and Applications provides a thorough examination of carbon nanomaterials, including their variants and how they can be chemically functionalized. It also gives a comprehensive overview of current advanced applications of functionalized carbon nanomaterials, including the automotive, packaging, coating, and biomedical industries. The book covers modern techniques to characterize chemically functionalized carbon nanomaterials as well as characterization of surface functional groups. It includes contributions from international leaders in the field who highlight the multidisciplinary and

interdisciplinary flexibility of functionalized carbon nanomaterials. The book illustrates how natural drawbacks to carbon nanomaterials, such as low solubility, can be countered by surface modifications and shows how to make modifications. It discusses developments in the use of carbon nanomaterials in several critical areas in scientific research and practice, including analytical chemistry, drug delivery, and water treatment. It explores market opportunities due to the versatility and increasing applicability of carbon nanomaterials. It also gives suggestions on the direction of the field from its current point, paving the way for future developments and finding new applications. Chemical Functionalization of Carbon Nanomaterials: Chemistry and Applications is a significant collection of findings in a rapidly developing field. It gives an in-depth look at the current achievements of research and practice while pointing you ahead to new possibilities in functionalizing and using carbon nanomaterials.

Evidence-Based Practice in Clinical Social Work introduces the key ideas of evidence-based clinical social work practice and their thoughtful application. It intends to inform practitioners and to address the challenges and needs faced in real world practice. This book lays out the many strengths of the EBP model, but also offers perspectives on its limitations and challenges. An appreciative but critical perspective is offered throughout. Practical issues (agency supports, access to research resources, help in appraising research) are addressed - and some practical solutions offered. Ethical issues in assessment/diagnosis, working with diverse families to make treatment decisions, and delivering complex treatments requiring specific skill sets are also included.

Vols. for 1970-71 includes manufacturers' catalogs.

Lasso peptides form a growing family of fascinating ribosomally-synthesized and post-translationally modified peptides produced by bacteria. They contain 15 to 24 residues and share a unique interlocked topology that involves an N-terminal 7 to 9-residue macrolactam ring where the C-terminal tail is threaded and irreversibly trapped. The ring results from the condensation of the N-terminal amino group with a side-chain carboxylate of a glutamate at position 8 or 9, or an aspartate at position 7, 8 or 9. The trapping of the tail involves bulky amino acids located in the tail below and above the ring and/or disulfide bridges connecting the ring and the tail. Lasso peptides are subdivided into three subtypes depending on the absence (class II) or presence of one (class III) or two (class I) disulfide bridges. The lasso topology results in highly compact structures that give to lasso peptides an extraordinary stability towards both protease degradation and denaturing conditions. Lasso peptides are generally receptor antagonists, enzyme inhibitors and/or antibacterial or antiviral (anti-HIV) agents. The lasso scaffold and the associated biological activities shown by lasso peptides on different key targets make them promising molecules with high therapeutic potential. Their application in drug design has been exemplified by the development of an integrin antagonist based on a lasso peptide scaffold. The biosynthesis machinery of lasso peptides is therefore of high biotechnological interest, especially since such highly compact and stable structures have to date revealed inaccessible by peptide synthesis. Lasso peptides are produced from a linear precursor LasA, which undergoes a maturation process involving several steps, in particular cleavage of the leader peptide and cyclization. The post-translational modifications are ensured by a dedicated enzymatic machinery, which is composed of an ATP-dependent cysteine protease (LasB) and a lactam synthetase (LasC) that form an enzymatic complex called lasso synthetase. Microcin J25, produced by Escherichia coli AY25, is the archetype of lasso peptides and the most extensively studied. To date only around forty lasso peptides have been isolated, but genome mining approaches have revealed that they are widely distributed among Proteobacteria and Actinobacteria, particularly in Streptomyces, making available a rich resource of novel lasso peptides and enzyme machineries towards lasso topologies.