

ESSENTIAL REQUIREMENTS CHECKLIST - MEDICAL DEVICE DEFECTIVE 9342/EC

COMPANY:

PRODUCT:

Essential Requirement	A - N/A	Standards / References	Manufacturers Compliance / Notes / Explanation	Location
<p>1. GENERAL PRINCIPLES</p> <p>1. The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, when applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.</p> <p>This shall include:</p> <ul style="list-style-type: none"> - selecting, as far as possible, the state of use, which due to the systematic failures of the device and the environment in which the device is intended to be used, design for patient safety, and - consideration of the technical knowledge, experience, education and training and when applicable the medical and physical conditions of intended users/design for lay professional, disabled or other users. 				
<p>2. The criteria adopted by the manufacturer for the design and construction of the device must conform to safety principles, taking account of the generally acknowledged state of the art.</p> <p>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:</p> <ul style="list-style-type: none"> - eliminate or reduce risks as far as possible inherently with design and construction - where appropriate take adequate protective measures (including where if necessary, to reduce or reduce the space by clearance, - reduce some of the residual risks due to any shortcomings of the protective controls adopted. 				
<p>3. The device must adhere to the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for use in order of the following order:</p>				
<p>4. The characteristics and performance intended to be achieved in accordance with the standards referred to in clauses 1, 2 and 3 must not be adversely affected in such a degree that the clinical condition and safety of the patients and, when applicable, of other persons are compromised during the lifetime of the device as intended by the manufacturer, when the device is subjected to the stresses which are likely to be encountered in use.</p>				
<p>5. The device must be designed, manufactured and packed in such a way that the characteristics and performance during their intended use will not be adversely affected during transport and storage taking account of the environmental and vibrational conditions to be encountered.</p>				
<p>6. Any acceptable risks which may constitute an acceptable risk when weighed against the performance intended.</p>				
<p>7. Documentation of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 2.</p>				

Prepared by Anne Jury Associates

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Revised to include all amendments up to and including Directive 2007/47/EC

Essential Requirements Checklist Medical Device

Cedric Prys-Roberts, Burnell R. Brown

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Handbook of Medical Device Design Richard C. Fries, 2019-08-15 First published in 2001 This handbook has been written to give those professionals working in the development and use of medical devices practical knowledge about biomedical technology regulations and their relationship to quality health care

Medical Device Quality Assurance and Regulatory Compliance Richard C. Fries, 1998-08-11 Acquaints developers of medical devices with the basic concepts and major issues of medical quality assurance and regulatory documents describes the requirements listed in these documents and provides strategies for compliance with these requirements

Reliable Design of Medical Devices Richard C. Fries, 2005-11-21 As medical devices increase in complexity concerns about efficacy safety quality and longevity increase in stride Introduced nearly a decade ago Reliable Design of Medical Devices illuminated the path to increased reliability in the hands on design of advanced medical devices With fully updated coverage in its Second Edition this practical guide continues to be the benchmark for incorporating reliability engineering as a fundamental design philosophy The book begins by rigorously defining reliability differentiating it from quality and exploring various aspects of failure in detail It examines domestic and international regulations and standards in similar depth including updated information on the regulatory and standards organizations as well as a new chapter on quality system regulation The author builds on this background to explain product specification liability and intellectual property safety and risk management design testing human factors and manufacturing New topics include design of experiments CAD CAM industrial design material selection and biocompatibility system engineering rapid prototyping quick response manufacturing and maintainability as well as a new chapter on Six Sigma for design Supplying valuable insight based on years of successful experience Reliable Design of Medical Devices Second Edition leads the way to implementing an effective reliability assurance program and navigating the regulatory minefield with confidence

Design of Biomedical Devices and Systems Second edition Paul H. King, Richard C. Fries, 2008-08-22 The design and functional complexity of medical devices and systems has increased during the past half century evolving from the level of cardiac pacemakers to magnetic resonance imaging devices Such life saving advancements are monumentally advantageous but with so much at stake a step by step manual for biomedical engineers is essential This

Design of Biomedical Devices and Systems, Third Edition Paul H. King, Richard C. Fries, Arthur T. Johnson, 2014-07-29 Apply a Wide Variety of Design Processes to a Wide Category of Design Problems Design of Biomedical Devices and Systems Third Edition continues to provide a real world approach to the design of biomedical engineering devices and or systems Bringing together information on the design and initiation of design projects from several sources this edition strongly emphasizes and further clarifies the standards of design procedure Following the best practices for conducting and completing a design project it outlines the various steps in the design process in a basic flexible and logical order What s New in the Third Edition This latest edition contains a new chapter on biological engineering design a new

chapter on the FDA regulations for items other than devices such as drugs new end of chapter problems new case studies and a chapter on product development It adds mathematical modeling tools and provides new information on FDA regulations and standards as well as clinical trials and sterilization methods Familiarizes the reader with medical devices and their design regulation and use Considers safety aspects of the devices Contains an enhanced pedagogy Provides an overview of basic design issues Design of Biomedical Devices and Systems Third Edition covers the design of biomedical engineering devices and or systems and is designed to support bioengineering and biomedical engineering students and novice engineers entering the medical device market

Design of Biomedical Devices and Systems, 4th edition Paul H. King, Richard C. Fries, Arthur T. Johnson, 2018-10-03 This fourth edition is a substantial revision of a highly regarded text intended for senior design capstone courses within departments of biomedical engineering bioengineering biological engineering and medical engineering worldwide Each chapter has been thoroughly updated and revised to reflect the latest developments New material has been added on entrepreneurship bioengineering design clinical trials and CRISPR Based upon feedback from prior users and reviews additional and new examples and applications such as 3D printing have been added to the text Additional clinical applications were added to enhance the overall relevance of the material presented Relevant FDA regulations and how they impact the designer s work have been updated Features Provides updated material as needed to each chapter Incorporates new examples and applications within each chapter Discusses new material related to entrepreneurship clinical trials and CRISPR Relates critical new information pertaining to FDA regulations Presents new material on discovery of projects worth pursuing and design for health care for low resource environments Presents multiple case examples of entrepreneurship in this field Addresses multiple safety and ethical concerns for the design of medical devices and processes

Medical Devices - Materials for Human Contact (Design Guide) Iom Communications, Tuba Yamac, 1998

Medical Device Register ,2005 Contains a list of all manufacturers and other specified processors of medical devices registered with the Food and Drug Administration and permitted to do business in the U S with addresses and telephone numbers Organized by FDA medical device name in alphabetical order Keyword index to FDA established standard names of medical devices

Essential Standards for Biomedical Equipment Safety and Performance Association for the Advancement of Medical Instrumentation, 1985

International Practice of Anaesthesia Cedric Prys-Roberts, Burnell R. Brown, 1996

Basic Outlines on Medical Device Law and Regulation Food and Drug Law Institute Staff, 1996

Techniques and Principles for the Operating Room Matthew Porteous, Susanne Bäuerle, 2010-06-16 Lavishly illustrated succinct coverage of the latest advances in operative fracture care Reflecting the recent dramatic advances in orthopedic trauma care and orthopedic implants this highly practical surgical guide provides step by step descriptions of new state of the art techniques as well as in depth information on classic time tested methods Packed with hundreds of the high quality full color illustrations for which AO books are known the expert authors of this must have text discuss operating room

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Encyclopedia of Medical Devices and Instrumentation John G. Webster,1988-03-24 This objective referenced collection of over 300 articles will cover every aspect of medical devices and instrumentation in four volumes totalling about 3 000 pages The Encyclopedia will define the discipline by bringing together the core of knowledge from all the fields encompassed by the application of engineering physics and computers to problems in medicine Some of the many areas covered will include anaesthesiology burns cardiology clinical chemistry and engineering critical care medicine dermatology dentistry endocrinology genetics gynecology microbiology oncology pharmacology psychiatry radiology surgery and urology Cross references and index included ASQC ... Annual Quality Congress Proceedings ,1997 Medical Device Safety G.R Higson,2001-10-29 Medical Device Safety The Regulation of Medical Devices for Public Health and Safety examines the prospects for achieving global harmonization in medical device regulation and describes a possible future global system Unresolved difficulties are discussed while solutions are proposed An essential book for all those involved in health physics en Managing Service Quality Graham Clark,1990 A Returnable Container System for Medical Device Components Christine S. Block,1999 Proceedings of the ... ASME Design Engineering Technical Conferences ,2006 The Business of Medicine Gary L. Gitnick,Fred Rothenberg,Judy L. Weiner,1991 **Standards Catalogue** ,1998

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Table of Contents Essential Requirements Checklist Medical Device

1. Understanding the eBook Essential Requirements Checklist Medical Device
 - The Rise of Digital Reading Essential Requirements Checklist Medical Device
 - Advantages of eBooks Over Traditional Books
2. Identifying Essential Requirements Checklist Medical Device
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Essential Requirements Checklist Medical Device
 - User-Friendly Interface
4. Exploring eBook Recommendations from Essential Requirements Checklist Medical Device
 - Personalized Recommendations
 - Essential Requirements Checklist Medical Device User Reviews and Ratings
 - Essential Requirements Checklist Medical Device and Bestseller Lists

5. Accessing Essential Requirements Checklist Medical Device Free and Paid eBooks
 - Essential Requirements Checklist Medical Device Public Domain eBooks
 - Essential Requirements Checklist Medical Device eBook Subscription Services
 - Essential Requirements Checklist Medical Device Budget-Friendly Options
6. Navigating Essential Requirements Checklist Medical Device eBook Formats
 - ePub, PDF, MOBI, and More
 - Essential Requirements Checklist Medical Device Compatibility with Devices
 - Essential Requirements Checklist Medical Device Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Essential Requirements Checklist Medical Device
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 - Interactive Elements Essential Requirements Checklist Medical Device
8. Staying Engaged with Essential Requirements Checklist Medical Device
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Essential Requirements Checklist Medical Device
9. Balancing eBooks and Physical Books Essential Requirements Checklist Medical Device
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Essential Requirements Checklist Medical Device
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Essential Requirements Checklist Medical Device
 - Setting Reading Goals Essential Requirements Checklist Medical Device
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Essential Requirements Checklist Medical Device
 - Fact-Checking eBook Content of Essential Requirements Checklist Medical Device
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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