

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 REQUIREMENTS</p> <p>1. The device must be designed and manufactured in such a way that, when used under the conditions set for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other applicable stakeholders, 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, with due to the systematic features 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 business enterprise to which it is to be supplied by the manufacturer.</p>				
<p>4. The characteristics and performance intended to be achieved in accordance with the standards referred to in clause 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 under conditions of use.</p>				
<p>5. The device must be designed, constructed 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 instructions and information provided to the user/operator.</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

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S Ben Porath



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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

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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 ,2007 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

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