

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11607-1:2020/A11

June 2022

ICS 11.080.30

English Version

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2019)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (ISO 11607-1:2019)

This amendment A11 modifies the European Standard EN ISO 11607-1:2020; it was approved by CEN on 13 April 2022.

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This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Iso 11607 1

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UNE-EN ISO 11607-1:2020/A11:2022 Asociación Española de Normalización y Certificación,2022 *UNE-EN ISO 11607-1:2017* ,2017 **Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1: 2006)** ,2006 **BS EN ISO 11607-1:2019 AMD1. Packaging for Terminally Sterilized Medical Devices** British Standards Institution,2022 *Packaging for Terminally Sterilized Medical Devices* Technical Committee ISO/TC 198, Sterilization of Health Care Products,2019 *Packaging for Terminally Sterilized Medical Devices : Part 1. Requirements for Materials, Sterile Barrier Systems and Packaging Systems : ISO 11607-1:2019* ,2019 **Packaging for Terminally Sterilized Medical Devices** ,2014 **Tracked Changes. Packaging for Terminally Sterilized Medical Devices. Guidance on the Application of ISO 11607-1 and ISO 11607-2** British Standards Institution,2022 **Packaging for Terminally Sterilized Medical Devices** Malaysia. Jabatan Standard,2009 *Assurance of Sterility for Sensitive Combination Products and Materials* Byron J. Lambert,Stan Lam,Joyce M. Hansen,Trabue D. Bryans,2019-11-30 Assurance of Sterility for Sensitive Combination Products and Materials New Paradigms for the Next Generation of Medical Devices and Pharmaceuticals discusses the medical device industry and existing challenges regarding the exciting new world of sensitive combination products SCPs and their terminal sterilization This book reassesses the current assumptions to assure the patient s best interests are met in the development of increasingly rigorous sterilization methods used to counteract MRSA and other super bugs In addition the book discusses the special challenges faced with implantable medical devices sterilization requirements and further methods needed for material selection and the design process This book is unique in taking a holistic end to end approach to sterilization with a particular focus on materials selection and product design Introduces sterilization principles at the material selection and design stages Addresses the industry need for new sterilization processes for new medical devices and biomaterials Provides guidance to select the appropriate sterilization technique for newly developed sensitive combination products Examines forward thinking tactics for matching new developments in material compatibility with possible regulatory and QSR strategies *A Practical Guide to Decontamination in Healthcare* Gerald E. McDonnell,Denise Sheard,2012-07-23 Prevention is the first line of defence in the fight against infection As antibiotics and other antimicrobials encounter increasing reports of microbial resistance the field of decontamination science is undergoing a major revival A Practical Guide to Decontamination in Healthcare is a comprehensive training manual providing practical guidance on all aspects of decontamination including microbiology and infection control regulations and standards containment transportation handling cleaning disinfection and sterilization of patient used devices surgical instrumentation endoscopes and quality management systems Written by highly experienced professionals A Practical Guide to Decontaminationin Healthcare comprises a systematic review of decontamination methods with uses and advantages outlined for each Up to date regulations standards

and guidelines are incorporated throughout to better equip healthcare professionals with the information they need to meet the technical and operational challenges of medical decontamination A Practical Guide to Decontamination in Healthcare is an important new volume on state of the art decontamination processes and a key reference source for all healthcare professionals working in infectious diseases infection control prevention and decontamination services **The ASQ**

Certified Medical Device Auditor Handbook Scott A Laman, 2021-02-05 The ASQ Certified Medical Device Auditor Handbook formerly The Biomedical Quality Auditor Handbook was developed by the ASQ Medical Device Division formerly Biomedical Division in support of its mission to promote the awareness and use of quality principles concepts and technologies in the medical device community It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor CMDA certification exam The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge BoK and reference list The combination of this handbook with other reference materials can provide a well rounded background in medical device auditing Updates to this edition include A discussion of data privacy data integrity principles and the Medical Device Single Audit Program MDSAP Current information about federal and international regulations New content regarding human factors and usability engineering general safety and performance requirements labeling validation risk management and cybersecurity considerations A thorough explanation of quality tools and techniques **Medical Device Regulatory Practices** Val Theisz, 2015-08-03 This book is intended to

serve as a reference for professionals in the medical device industry particularly those seeking to learn from practical examples and case studies Medical devices like pharmaceuticals are highly regulated and the bar is raised constantly as patients and consumers expect the best quality healthcare and safe and effective Medical Devices and In Vitro Diagnostics

Christian Baumgartner, Johann Harer, Jörg Schröttner, 2023-08-26 This updatable reference work gives a comprehensive overview of all relevant regulatory information and requirements for manufacturers and distributors around medical and in vitro diagnostic devices in Europe These individual requirements are presented in a practice oriented manner providing the reader with a concrete guide to implementation with main focus on the EU medical device regulations such as MDR 2017 745 and IVD R 2017 746 and the relevant standards such as the ISO 13485 ISO 14971 among others This book offers a good balance of expert knowledge empirical values and practice proven methods Not only it provides readers with a quick overview about the most important requirements in the medical device sector yet it shows concrete and proven ways in which these requirements can be implemented in practice It addresses medical manufacturing companies professionals in development production and quality assurance departments and technical and medical students who are preparing themselves for a professional career in the medical technology industries **Decontamination and Device Processing in**

Healthcare Gerald E. McDonnell, Georgia Alevizopoulou, 2025-01-08 Prevent infections within healthcare spaces with safe and effective device decontamination and processing Prevention is the first line of defense against infection particularly in a

world where microbial resistance to anti infectives like antibiotics is a growing threat Few aspects of managing a healthcare facility are more immediately important to patient care than the safe use of equipment and devices Although some devices are designed for single use many more are designed to be reused and there have been increasing reports of infections and other adverse patient reactions due to these devices in particular when regarding surgical and endoscopic procedures The decontamination or processing of various surfaces spaces and devices associated with patient care is a life saving discipline demanding dedicated resources and education Decontamination and Device Processing in Healthcare Second Edition meets this demand as a comprehensive training and reference manual for the decontamination and processing of equipment and devices used in patient care environments This book is ideal for medical staff involved in the management of devices within healthcare facilities including those purchasing using and processing devices on patients and those responsible for their safety Now fully updated to reflect the latest international regulations standards and best practices this text is an invaluable tool for meeting the challenges of the modern medical facility Readers of the second edition of Decontamination and Device Processing in Healthcare will also find within the text Up to date information based off the current guidelines standards and regulations of Regulatory organizations include the US FDA EU MDR NMPA and other similar international organizations Standard organizations including ISO CEN AAMI BSI DIN and international professional organizations in device processing WFHSS HPSA CAMDR etc nursing AORN EORNA ESGENA infection prevention WHO CDC ECDC and more Detailed discussion of topics including surgical suite management infection prevention and control essentials of anatomy and microbiology safety endoscopy and outpatient areas quality management and many more Description of the steps in device processing ranging from equipment to surgical devices including cleaning disinfection and sterilization Information written to be of value to healthcare educators and administrators as well as clinical professionals Written by experienced professionals with a systematic grasp of key methods and their advantages Decontamination in Healthcare offers a wealth of information for every member of a clinical team

Packaging for Terminally Sterilized Medical Devices. Guidance on the Application of Iso 11607-1 and Iso 11607-2 British Standards Institute Staff,1914-05-31 Packaging materials

Packaging Medical equipment Medical instruments Sterilization hygiene Sterile equipment Packages Wrapping Quality Design Performance Compatibility Seals Test methods Performance testing Quality assurance systems Packaging processes Sealing processes Acceptance approval Verification

The Biomedical Quality Auditor Handbook, Third Edition

Heather Crawford,2017-09-08 The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles concepts and technologies in the biomedical community This third edition correlates to the 2013 exam Body of Knowledge BoK and reference list for ASQ s Certified Biomedical Auditor program It includes updates and corrections to errors and omissions in the second edition Most notably it has been re organized to align more closely with the BoK

Biomedical Engineering & Design Handbook, Volumes I

and II Myer Kutz, 2009-07-13 A State of the Art Guide to Biomedical Engineering and Design Fundamentals and Applications The two volume Biomedical Engineering and Design Handbook Second Edition offers unsurpassed coverage of the entire biomedical engineering field including fundamental concepts design and development processes and applications This landmark work contains contributions on a wide range of topics from nearly 80 leading experts at universities medical centers and commercial and law firms Volume 1 focuses on the basics of biomedical engineering including biomedical systems analysis biomechanics of the human body biomaterials and bioelectronics Filled with more than 500 detailed illustrations this superb volume provides the foundational knowledge required to understand the design and development of innovative devices techniques and treatments Volume 2 provides timely information on breakthrough developments in medical device design diagnostic equipment design surgery rehabilitation engineering prosthetics design and clinical engineering Filled with more than 400 detailed illustrations this definitive volume examines cutting edge design and development methods for innovative devices techniques and treatments Volume 1 covers Modeling and Simulation of Biomedical Systems Bioheat Transfer Physical and Flow Properties of Blood Respiratory Mechanics and Gas Exchange Biomechanics of the Respiratory Muscles Biomechanics of Human Movement Biomechanics of the Musculoskeletal System Biodynamics Bone Mechanics Finite Element Analysis Vibration Mechanical Shock and Impact Electromyography Biopolymers Biomedical Composites Bioceramics Cardiovascular Biomaterials Dental Materials Orthopaedic Biomaterials Biomaterials to Promote Tissue Regeneration Bioelectricity Biomedical Signal Analysis Biomedical Signal Processing Intelligent Systems and Bioengineering BioMEMS Volume 2 covers Medical Product Design FDA Medical Device Requirements Cardiovascular Devices Design of Respiratory Devices Design of Artificial Kidneys Design of Controlled Release Drug Delivery Systems Sterile Medical Device Package Development Design of Magnetic Resonance Systems Instrumentation Design for Ultrasonic Imaging The Principles of X Ray Computed Tomography Nuclear Medicine Imaging Instrumentation Breast Imaging Systems Surgical Simulation Technologies Computer Integrated Surgery and Medical Robotics Technology and Disabilities Applied Universal Design Design of Artificial Arms and Hands for Prosthetic Applications Design of Artificial Limbs for Lower Extremity Amputees Wear of Total Knee and Hip Joint Replacements Home Modification Design Intelligent Assistive Technology Rehabilitators Risk Management in Healthcare Technology Planning for Healthcare Institutions Healthcare Facilities Planning Healthcare Systems Engineering Enclosed Habitat Life Support

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