

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
EN 285:2015

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September 2018

ICS 11.080.10

English Version

Sterilization - Steam sterilizers - Large sterilizers

Sérialisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

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En 285 Sterilization

Tim Sandle



En 285 Sterilization:

Block's Disinfection, Sterilization, and Preservation Gerald McDonnell, 2020-06-26 With more international contributors than ever before Block's Disinfection Sterilization and Preservation 6th Edition is the first new edition in nearly 20 years of the definitive technical manual for anyone involved in physical and chemical disinfection and sterilization methods The book focuses on disease prevention rather than eradication and has been thoroughly updated with new information based on recent advances in the field and understanding of the risks the technologies available and the regulatory environments

Validation of Pharmaceutical Processes James P. Agalloco, Frederick J. Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive The many chapters added to the prior compilation examine va Antisepsis, Disinfection, and Sterilization

Gerald E. McDonnell, 2020-07-10 Antisepsis Disinfection and Sterilization Types Action and Resistance by Gerald E McDonnell is a detailed and accessible presentation of the current methods of microbial control Each major category such as physical disinfection methods is given a chapter in which theory spectrum of activity advantages disadvantages and modes of action of the methods are thoroughly and clearly presented Sufficient background on the life cycles and general anatomy of microorganisms is provided so that the reader who is new to microbiology will better appreciate how physical and chemical biocides work their magic on microbes Other topics in the book include Evaluating the efficacy of chemical antiseptics and disinfectants and of physical methods of microbial control and sterilization Understanding how to choose the proper biocidal product and process for specific applications Classic physical and chemical disinfection methods such as heat cold non ionizing radiation acids oxidizing agents and metals Newer chemical disinfectants including isothiazolones micro and nano particles and bacteriophages as control agents Antisepsis of skin and wounds and the biocides that can be used as antiseptics Classic methods of physical sterilization such as moist heat and dry heat sterilization ionizing radiation and filtration along with newer methods including the use of plasma or pulsed light Chemical sterilization methods that use ethylene oxide formaldehyde or a variety of other oxidizing agents A detailed look at the modes of action of biocides in controlling microbial growth and disrupting microbial physiology Mechanisms that microorganisms use to resist the effects of biocides The second edition of Antisepsis Disinfection and Sterilization Types Action and Resistance is well suited as a textbook and is outstanding as a reference book for facilities managers and application engineers in manufacturing plants hospitals and food production facilities It is also essential for public health officials healthcare professionals and infection control practitioners

Medical Device Guidelines and Regulations Handbook Prakash Srinivasan Timiri Shanmugam, Pugazhenthana Thangaraju, Nandakumar Palani, Thamizharasan Sampath, 2022-04-22 This comprehensive resource features in depth discussions of important guidelines and regulations needed to understand and

properly meet medical device code related requirements Focusing on the practical application of the regulations the Medical Device Guidelines and Regulations Handbook delivers clear explanations real world examples and annotation on the applicable provisions that will allow you to safely and confidently choose materials and processes for medical device development testing and manufacturing A critical resource for researchers and professionals in the medical device field Thoroughly covers ISO 10993 ISO 22442 ISO 14971 ISO 13485 ISO 21534 REACH RoHS CLP EU MDR Presents simplified guidelines and regulation points *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 Decontamination in 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 Hospital-Acquired Infection Zsolt Filetoth, 2008-04-30 Hospital acquired infections HAI are complications of health care which affect on average 10 percent of patients admitted to hospital world wide They have serious public health implications by changing the quality of life of patients and sometimes causing disability or even death The purpose of this comprehensive text is to provide nurses and junior doctors with an understanding of the basics of infection control by explaining the methods employed and their purpose The book is based on lectures presented by the author at training courses for nurses and doctors and gives simple understandable and essential information that is vital knowledge for medical staff in hospitals *Industrial Sterilization* G. Briggs Phillips, William S. Miller, 1973 **Springer Handbook of Medical Technology** Rüdiger Kramme, Klaus-Peter Hoffmann, Robert Steven Pozos, 2011-10-02 This concise user oriented and up to date desk reference offers a broad introduction to the fascinating world of medical technology fully considering today's progress and further development in all relevant fields The Springer Handbook of Medical Technology is a systemized and well structured guideline which distinguishes itself through simplification and condensation of complex facts This book is an indispensable resource for professionals working directly or indirectly with medical systems and appliances every day It is also meant for graduate and post graduate students in hospital management medical engineering and medical physics

Decontamination in Hospitals and Healthcare James T. Walker, 2019-11-26 Decontamination in Hospitals and Healthcare Second Edition enables users to obtain detailed knowledge of decontamination practices in healthcare settings including surfaces devices clothing and people with a specific focus on hospitals and dental clinics Offers in depth coverage of all aspects of decontamination in healthcare Examines the decontamination of surgical equipment and endoscopes Expanded to include new information on behavioral principles in decontamination control of microbiological problems waterborne microorganisms pseudomonas and the decontamination of laundry

Disinfection and Decontamination Jeanne Moldenhauer, 2018-11-20 This book describes various methods of decontamination and how the methods work There is a discussion of the various cleaning and disinfection methods utilized along with details of how to qualify these methods It also describes new technologies that may be useful in the battle for decontamination across industries Finally this book provides a single resource on how one can address contamination issues for a variety of manufacturing processes and industries Explores new technologies that may be useful in the battle for decontamination Examines various methods of decontamination and how the methods work Addresses contamination issues for a variety of manufacturing processes and industries Describes how to detect contaminants as well as how to deal with contaminants that are present Includes methods for both decontamination reaction and preventing contamination proactive

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

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals
Tim Sandle, 2025-08-01 Sterility Sterilisation and Sterility Assurance for Pharmaceuticals Technology Validation and Current Regulations Second Edition is an in depth guide to the world of pharmaceutical sterilization This new edition has been updated to reflect the latest standards and regulations ensuring alignment with current practices It explores emerging methods and techniques complemented by new case studies that provide practical examples Readers will gain comprehensive knowledge about sterilization s critical role in healthcare and pharmaceutical manufacturing highlighting the importance of controlling microbial challenges to ensure product safety and patient well being The book discusses sterility sterilization methods such as gamma radiation e beam dry heat steam gas vapor filtration and new techniques like X ray sterilization liquid phase sterilization ultraviolet light supercritical gases and sterilization assurance governance It covers biopharmaceutical manufacturing processes including aseptic filling container and packaging design and cleanroom environments This edition is essential for professionals in pharmaceuticals healthcare and medical device manufacturing providing the knowledge needed to comply with current standards and regulations Includes nine new chapters with many new case studies Offers coverage on the most current standards and regulations Provides full coverage of novel sterilization methods

Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition Stephen P. Denyer, Rosamund M. Baird, 2006-12-26 Microbiological matters continue to exercise considerable influence on product quality In both the pharmaceutical and medical device industries products of greater sophistication along with evolving regulatory requirements are elevating the challenges related to maintaining microbiological integrity Updated to reflect technological and regulatory changes the Guide to Microbiological Control in Pharmaceuticals and Medical Devices Second Edition covers those principal aspects of microbiology that are relevant to the preformulation formulation manufacturing and license application stages involved with the production of pharmaceuticals and medical devices In recognition of the diverse disciplines involved in pharmaceutical and medical device production this work provides a brief introduction to microbiology geared towards the nonmicrobiologist Covering good manufacturing practice in the control of contamination the text explores quality control the preservation of formulations and principles of sterilization including microbiological specific considerations for biotechnological products and other medical devices It also provides additional materials on package

integrity and contamination risks in clean rooms The editors have produced a companion text the Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices see reverse which when paired with the Guide offers a complete theoretical and practical treatment of microbiological control This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development

Ayliffe's Control of Healthcare-Associated Infection Adam Fraiese, Christina Bradley, 2009-05-29 The fifth edition of this classic text is the definitive clinically orientated guide to a critical area within healthcare practice full of sound practical advice for all those involved in the control of infection in a variety of settings Known in previous editions as Control of Hospital Infection the new Ayliffe's Control of Healthcare Associated Infection has again been brought up to date and thoroughly revised to emphasise the broader range of its coverage from the hospital setting including the ward operating theatres kitchens and laundry facilities to health care provision in the community

Advances in Mutagenesis Research 2 Günter Obe, 2012-12-06 The new field of applied genetic research genetic toxicology and mutation research investigates the mutagenicity and cancerogenicity of chemicals and other agents Permanent changes in genes and chromosomes or genome mutations can be induced by a plethora of agents including ionizing and nonionizing radiations chemicals and viruses Mutagenesis research has two aims 1 to understand the molecular mechanisms leading to mutations and 2 to prevent a thoughtless introduction of mutagenic agents into our environment Both aspects namely basic and applied will be treated in the new series Advances in Mutagenesis Research

Experiment Station Record United States. Office of Experiment Stations, 1920

Materials for Biomedical Engineering Mohamed N. Rahaman, Roger F. Brown, 2021-11-23 MATERIALS FOR BIOMEDICAL ENGINEERING A comprehensive yet accessible introductory textbook designed for one semester courses in biomaterials Biomaterials are used throughout the biomedical industry in a range of applications from cardiovascular devices and medical and dental implants to regenerative medicine tissue engineering drug delivery and cancer treatment Materials for Biomedical Engineering Fundamentals and Applications provides an up to date introduction to biomaterials their interaction with cells and tissues and their use in both conventional and emerging areas of biomedicine Requiring no previous background in the subject this student friendly textbook covers the basic concepts and principles of materials science the classes of materials used as biomaterials the degradation of biomaterials in the biological environment biocompatibility phenomena and the major applications of biomaterials in medicine and dentistry Throughout the text easy to digest chapters address key topics such as the atomic structure bonding and properties of biomaterials natural and synthetic polymers immune responses to biomaterials implant associated infections biomaterials in hard and soft tissue repair tissue engineering and drug delivery and more Offers accessible chapters with clear explanatory text tables and figures and high quality illustrations Describes how the fundamentals of

biomaterials are applied in a variety of biomedical applications Features a thorough overview of the history properties and applications of biomaterials Includes numerous homework review and examination problems full references and further reading suggestions Materials for Biomedical Engineering Fundamentals and Applications is an excellent textbook for advanced undergraduate and graduate students in biomedical materials science courses and a valuable resource for medical and dental students as well as students with science and engineering backgrounds with interest in biomaterials The Book of Mars Samuel Glasstone,1968 For the general reader **Aulton's Pharmaceuticals E-Book** Kevin M.G. Taylor,Michael E. Aulton,2013-07-29 Pharmaceuticals is one of the most diverse subject areas in all of pharmaceutical science In brief it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines An understanding of pharmaceuticals is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely effectively and conveniently to the patient Now in its fourth edition this best selling textbook in pharmaceuticals has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection advances in drug formulations and delivery methods for special groups such as children and the elderly nanomedicine and pharmacognosy At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art New to this edition New editor Kevin Taylor Professor of Clinical Pharmaceutics School of Pharmacy University of London Twenty two new contributors Six new chapters covering parenteral and ocular delivery design and administration of medicines for the children and elderly the latest in plant medicines nanotechnology and nanomedicines and the delivery of biopharmaceuticals Thoroughly revised and updated throughout provides a logical comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor Kevin Taylor Professor of Clinical Pharmaceutics School of Pharmacy University of London Twenty two new contributors Six new chapters covering parenteral and ocular delivery design and administration of medicines for the children and elderly the latest in plant medicines nanotechnology and nanomedicines and the delivery of biopharmaceuticals Thoroughly revised and updated throughout **Russell, Hugo and Ayliffe's Principles and Practice of Disinfection, Preservation and Sterilization** Adam P. Fraiese,Jean-Yves Maillard,Syed Sattar,2013-02-18 The new edition of this established and highly respected text is THE definitive reference in its field It details methods for the elimination or prevention control of microbial growth and features New chapters on bioterrorism and community healthcare New chapters on microbicide regulations in the EU USA and Canada Latest material on microbial resistance to microbicides Updated material on new and emerging technologies focusing on special problems in hospitals dentistry and pharmaceutical practice Practical advice on problems of disinfection and antiseptics in healthcare A systematic review of sterilization methods with uses and advantages outlined for

each Evaluation of disinfectants and their mechanisms of action with respect to current regulations The differences between European and North American regulations are highlighted throughout making this a truly global work ideal for worldwide healthcare professionals working in infectious diseases and infection control

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