

The GMDN and UDI work together

The GMDN Code is not the same as the UDI!

Device Type =
Unique Device Identifier
From a single supplier
(e.g. 12345678909874)



Device Group = GMDN Term
All suppliers use same code
(e.g. GMDN Code 47017)



Umdns Code Gmdn Code

Czech Republic



Umdns Code Gmdn Code:

WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff World Health Organization, 2020-05-11

Technical specifications of radiotherapy equipment for cancer treatment, 2021-03-05

Global atlas of medical devices 2022 World Health Organization, 2022-11-24

WHO Technical Specifications of Neonatal Resuscitation Devices World Health Organization, 2016-10-21 The WHO technical specifications for neonatal resuscitation devices were developed based on existing international standards evidence based publications from reliable sources and field expert experience For equipment without prior technical specifications recommendations were made based on a literature research depending on quality and significance of evidence The purpose of WHO technical specifications for Neonatal resuscitation devices is to provide a minimum standard baseline to meet the increasing demand to procure good quality affordable accessible and appropriate neonatal resuscitation devices The specifications are intended to support policy makers managers procurement officers manufacturers regulators and nongovernmental agencies especially in low and middle income countries to select procure use reprocess and decommission appropriate neonatal resuscitation equipment The end goal is to save the children particularly in low resource settings

Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated World Health Organization, 2023-09-21 To provide technical specifications to blood pressure measuring device with cuff automated and semi automated for manufacturers who intend to seek their WHO prequalification PQ Manufacturers should consider the technical specifications outlined as minimum requirements for participating in the PQ programme in order to ensure that the blood pressure measurement device has been designed evaluated and validated in conformity with these requirements and is therefore safe and effective

Technical Specifications for Oxygen Concentrators World Health Organization, 2016-10-25 The purpose of this guidance document is for the appropriate selection procurement utilization and maintenance of oxygen concentrators This document also focuses on recommendations for the appropriate use and maintenance of oxygen concentrators in an effort to increase the availability management and quality of oxygen concentrators and ultimately to improve health outcomes in LRS This document is intended to serve as a resource for the planning and provision of local and national oxygen concentrator systems for use by administrators clinicians and technicians who are interested in improving access to oxygen therapy and reducing global mortality associated with hypoxaemia

World Congress on Medical Physics and Biomedical Engineering, June 7-12, 2015, Toronto, Canada David A. Jaffray, 2015-07-13 This book presents the proceedings of the IUPEM World Biomedical Engineering and Medical Physics a tri annual high level policy meeting dedicated exclusively to furthering the role of biomedical engineering and medical physics in medicine The book offers papers about emerging issues related to the development and sustainability of the role and impact of medical physicists and biomedical engineers in medicine and healthcare It provides a unique and important

forum to secure a coordinated multileveled global response to the need demand and importance of creating and supporting strong academic and clinical teams of biomedical engineers and medical physicists for the benefit of human health *WHO neonatal resuscitation manikin* ,2021-10-15 The United Nations Commission on Life Saving Commodities UNCLSC 2012 defined 13 health products to end preventable deaths of woman and children One of those 13 products is the neonatal resuscitator is indispensable medical device to save newborns from asphyxia at birth For the efficient use of neonatal resuscitation training of healthcare professionals using neonatal resuscitation manikins is the most effective approach Critical lifesaving trainings calls for the need of neonatal resuscitation manikins with the right features The purpose of the WHO neonatal resuscitation manikin technical specifications is to provide a minimum standard baseline to meet the increasing demand to procure good quality affordable accessible and appropriate neonatal resuscitation manikins Towards the development of this baseline this document includes compilation of available scientific evidence from technical literature international publications expert reviews and an industry survey which was conducted by WHO medical devices team

Design Controls for the Medical Device Industry, Third Edition Marie B. Teixeira,2019-08-02 This third edition provides a substantial comprehensive review of the latest design control requirements as well as proven tools and techniques to ensure a company s design control program evolves in accordance with current industry practice It assists in the development of an effective design control program that not only satisfies the US FDA Quality Systems Regulation QSR and 13485 2016 standards but also meets today s Notified Body Auditors and FDA Investigators expectations The book includes a review of the design control elements such as design planning input output review verification validation change transfer and history as well as risk management inclusive of human factors and usability biocompatibility the FDA Quality System Inspection Technique QSIT for design controls and medical device regulations and classes in the US Canada and Europe Practical advice methods and appendixes are provided to assist with implementation of a compliant design control program and extensive references are provided for further study This third edition Examines new coverage of ISO 13485 2016 design control requirements Explores proven techniques and methods for compliance Contributes fresh templates for practical implementation Provides updated chapters with additional details for greater understanding and compliance Offers an easy to understand breakdown of design control requirements Reference to MDSAP design control requirements [A Guidance Document for Medical Devices](#) Dr. Priyanka Gupta Manglik,2024-08-15 This document offers clear guidance on the development assessment and regulation of medical devices focusing on safety efficacy and compliance Useful for manufacturers regulators and biomedical engineers [Federal Register](#) ,2013-09 **Planning, Writing and Reviewing Medical Device Clinical and Performance Evaluation Reports (CERs/PERs)** Joy Frestedt,2024-09-19 A Practical Guide to Planning Writing and Reviewing Medical Device Clinical Evaluation Reports guides readers through clinical data evaluation of medical devices in compliance with the EU MDR requirements and other similar regulatory requirements

throughout the world This book brings together knowledge learned as the author constructed hundreds of CERs and taught thousands of learners on how to conduct clinical data evaluations This book will support training for clinical engineers clinical evaluation scientists and experts reviewing medical device CERs and will help individual writers teams and companies to develop stronger more robust CERs Identifies and explains data analysis for clinical evaluation of medical devices Teaches readers how to understand and evaluate medical device performance and safety in the context of new regulations Provides analysis of new clinical evaluation criteria in the context of medical device design as well as in hospital deployment and servicing

Sbírka zákonů České republiky Czech Republic,2011 *Textbook of Pharmacovigilance* Guru Prasad Mohanta,Prabal Kumar Manna,2025-06-01 Textbook of Pharmacovigilance Concept and Practice is the comprehensive guide for anyone interested in the essential field of safety monitoring of medicines This second edition retains the easy to understand style of the first edition but with expanded content that covers all aspects from concept to practice of pharmacovigilance With an updated section on India s PV Regulation readers will discover the historical background and evolution of this emerging science as well as the global scenario Additionally the book covers pharmacovigilance of Indian system of medicine with practical case studies on drug withdrawal and causality analysis The book is a must have for professionals who want to learn develop competencies and practice pharmacovigilance in the most effective way possible It provides a comprehensive understanding of the science of pharmacovigilance and a detailed explanation of the pharmacovigilance of Indian system of medicine making it an essential resource for anyone involved in the field Contents 1 Introduction 2 Pharmacovigilance in India 3 Methods in Pharmacovigilance 4 Adverse Drug Reactions Classification Mechanisms and Susceptibility 5 Assessment of Adverse Events Reports 6 Signal Identification and Strengthening 7 Quality Assurance in Pharmacovigilance 8 Periodic Safety Update Reports 9 Pharmacogenetics in Pharmacovigilance 10 Ethical Consideration in Pharmacovigilance 11 Global Scenario in Pharmacovigilance 12 Pharmacovigilance of Ayurveda Siddha Unani and Homeopathic Drugs 13 Materiovigilance in India 14 Haemovigilance in India 15 Pharmacovigilance of Vaccines 16 Case Studies on Drugs Withdrawal 17 Case Studies on Causality Assessment *Pharmacovigilance Essentials* Mukesh Nandave,Anoop Kumar,2024-04-03 The book explores the field of pharmacovigilance its historical context along with its critical role in ensuring the safety of medications across the world From its foundational principles to cutting edge advancements and future challenges this book provides a thorough understanding of the field s intricacies The book begins by establishing the fundamentals of pharmacovigilance emphasizing its significance in monitoring detecting assessing and preventing adverse drug reactions ADRs that occur during the use of medications Delving into the history of pharmacovigilance and regulatory actions the book traces the evolution of the field highlighting significant milestones and the establishment of regulatory frameworks that govern medication safety It explores the pivotal role of regulatory authorities in developing guidelines regulations and policies to safeguard public health A significant aspect covered in the

book is the processing of ADRs providing insights into the steps involved in handling and evaluating ADR reports The book also addresses specialized areas within pharmacovigilance including vaccine safety surveillance herbovigilance monitoring the safety of herbal medicines materiovigilance monitoring the safety of medical devices and hemovigilance ensuring the safety of blood products Additionally the book explores the role of pharmacogenetics in pharmacovigilance highlighting how genetic factors influence individual responses to medications and how this knowledge can be integrated into safety monitoring and risk assessment This book also covers databases used in pharmacovigilance across the globe aggregate reporting and pharmacovigilance systems in EU and non EU countries and the role of artificial intelligence Finally it emphasizes the need for continuous improvement vigilance and proactive measures to adapt to the changing healthcare landscape and address emerging safety concerns The book serves as a comprehensive guide for healthcare professionals researchers regulators and policymakers involved in pharmacovigilance

Artificial intelligence in Pharmaceutical Sciences Mullaicharam Bhupathyaaj,K. Reeta Vijaya Rani,Musthafa Mohamed Essa,2023-11-23 This cutting edge reference book discusses the intervention of artificial intelligence in the fields of drug development modified drug delivery systems pharmaceutical technology and medical devices development This comprehensive book includes an overview of artificial intelligence in pharmaceutical sciences and applications in the drug discovery and development process It discusses the role of machine learning in the automated detection and sorting of pharmaceutical formulations It covers nanosafety and the role of artificial intelligence in predicting potential adverse biological effects FEATURES Includes lucid step by step instructions to apply artificial intelligence and machine learning in pharmaceutical sciences Explores the application of artificial intelligence in nanosafety and prediction of potential hazards Covers application of artificial intelligence in drug discovery and drug development Reviews the role of artificial intelligence in assessment of pharmaceutical formulations Provides artificial intelligence solutions for experts in the pharmaceutical and medical devices industries This book is meant for academicians students and industry experts in pharmaceutical sciences medicine and pharmacology

Technical specifications for pre-market assessment of medical masks World Health Organization,2023-10-19 *Patient Safety* Institute of Medicine,Board on Health Care Services,Committee on Data Standards for Patient Safety,2003-12-20 Americans should be able to count on receiving health care that is safe To achieve this a new health care delivery system is needed a system that both prevents errors from occurring and learns from them when they do occur The development of such a system requires a commitment by all stakeholders to a culture of safety and to the development of improved information systems for the delivery of health care This national health information infrastructure is needed to provide immediate access to complete patient information and decision support tools for clinicians and their patients In addition this infrastructure must capture patient safety information as a by product of care and use this information to design even safer delivery systems Health data standards are both a critical and time sensitive building block of the national health information infrastructure Building on

the Institute of Medicine reports *To Err Is Human* and *Crossing the Quality Chasm* Patient Safety puts forward a road map for the development and adoption of key health care data standards to support both information exchange and the reporting and analysis of patient safety data

Pharmacoepidemiology Brian L. Strom, 2006-01-04 The fourth edition of *Pharmacoepidemiology* is an outstanding and fully comprehensive textbook which will be an essential resource for all interested in the field in academia in regulatory agencies in industry and in the law Brian Strom's classic textbook continues both to reflect the increased maturation of pharmacoepidemiology and to help shape its direction Reviews of previous editions of his celebrated textbook include The book is essential reading for anyone interested in pharmacoepidemiology

INTERNATIONAL JOURNAL OF EPIDEMIOLOGY an excellent textbook and a comprehensive reference which belongs in the library of every pharmaceutical manufacturer and regulator

EUROPEAN JOURNAL OF PUBLIC HEALTH *eBusiness in Healthcare* Ursula Hübner, Marc A. Elmhorst, 2007-10-23 *eProcurement in Healthcare* is a book that aggregates 5 years of experience of three successive R and D projects ELCH GetTogether GROPIS covering technical and organizational issues of eProcurement The projects which were funded partly by the government and partly by industry and hospitals looked at the characteristics of procurement processes and at standard technologies Two of the projects included case studies ELCH GROPIS the third project focused on the development of standard business objects for eProcurement in healthcare GetTogether Together they form a rich source of information worth communicating to a large audience of experts and newcomers alike Results from the projects are supplemented by the contributions of international experts and their particular views on eProcurement which gives the book a global perspective and hence allows its readers to learn from a variety of different approaches Each chapter of the book is structured in a way that satisfies the needs of executives as well as academics A management summary tables and graphics together with key statements of experts allow the quick reader to capture the main message of each chapter whereas background information and reference to the literature address readers who wish to gain a deeper and more comprehensive insight into the field The management summary and the expert statements will appear in boxes separated from the main text by visual cues e.g. background color font size font type

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