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ARC466A77, ARC466A78, ARC466A79 Range: Split System Air Conditioning Booklet ID: 3P651499-1, 3P651499-2 Download Device to be used for medical purposesThis article needs to be updated. The reason given is: the section related to E.U. needs further updates (esp. in sections 3.2 and 4.2.2) as the directives 93/42/EEC on medical devices and
90/385/EEC on active implantable medical devices have been fully repealed on 26 May 2021 by Regulation (EU) no. 2017/745 (MDR); furthermore, Brexit triggers updates in these sections (U.K. developed their own regulatory framework); but more updates are triggered as also the relation related to the recognition of conformity assessment
certificates between the European Union andSwitzerland changed since 26 May 2021. Please help update this article to reflect recent events or newly available information. (April 2022)Tongue depressor, a Class I medical device in the United StatesInfusion pump, a Class II medical device in the United StatesArtificial pacemaker, a Class III device in
the United StatesA medical device is any device intended to be used for medical purposes. Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country. As a
general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase.Discovery of what would be considered a medical device by modern standards dates as far back as c.7000 BC in
Baluchistan where Neolithic dentists used flint-tipped drills and bowstrings.[1] Study of archeology and Roman medical literature also indicate that many types of medical devices were in widespread use during the time of ancient Rome.[2] In the United States it was not until the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938 that medical
devices were regulated at all. It was not until later in 1976, that the Medical Device Amendments to the FD&C Act established medical device regulation and oversight as we know it today in the United States.[3][4] Medical device regulation in Europe as we know it today came into effect in 1993 by what is collectively known as the Medical Device
Directive (MDD). On May 26, 2017, the Medical Device Regulation (MDR) replaced the MDD.Medical devices vary in both their intended use and indications for use. Examples range from simple, low-risk devices such as tongue depressors, medical thermometers, disposable gloves, and bedpans to complex, high-risk devices that are implanted and
sustain life. Examples of high-risk devices include, artificial hearts, pacemakers, joint replacements, and CT scans. The design of medical devices constitutes a major segment of the field of biomedical engineering.The global medical device market was estimated to be between $220 and US$250 billion in 2013.[5] The United States controls 40% of the
global market followed by Europe (25%), Japan (15%), and the rest of the world (20%). Although collectively Europe has a larger share, Japan has the second largest country market share. The largest market shares in Europe (in order of market share size) belong to Germany, Italy, France, and the United Kingdom. The rest of the world comprises
regions like (in no particular order) Australia, Canada, China, India, and Iran. This article discusses what constitutes a medical device in these different regions and throughout the article these regions will be discussed in order of their global market share.Medical devices were used for surgery in ancient Rome.A global definition for medical device is
difficult to establish because there are numerous regulatory bodies worldwide overseeing the marketing of medical devices. Although these bodies often collaborate and discuss the definition in general, there are subtle differences in wording that prevent a global harmonization of the definition of a medical device, thus the appropriate definition of a
medical device depends on the region. Often a portion of the definition of a medical device is intended to differentiate between medical devices and drugs, as the regulatory requirements of the two are different. Definitions also often recognize In vitro diagnostics as a subclass of medical devices and establish accessories as medical devices.[citation
needed]Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act[6] defines a device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:recognized in the official National Formulary, or the United States Pharmacopoeia,
or any supplement to themIntended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, orIntended to affect the structure or any function of the body of man or other animals, andwhich does not achieve its primary intended purposes through chemical action
within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o)."According to Article 1 of Council Directive 93/42/EEC,[7] 'medical device' means any "instrument,
apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:diagnosis,
prevention, monitoring, treatment or alleviation of disease,diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,investigation, replacement or modification of the anatomy or of a physiological process,control of conception,and which does not achieve its principal intended action in or on the human body by
pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"Based on the New Approach, rules that relate to safety and performance of medical devices were harmonised in the EU in the 1990s. The New Approach, defined in a European Council Resolution of May 1985,[8] represents an innovative
way of technical harmonisation. It aims to remove technical barriers to trade and dispel the consequent uncertainty for economic operators, to facilitate free movement of goods inside the EU.[citation needed]The previous core legal framework consisted of three directives:[citation needed]Directive 90/385/EEC regarding active implantable medical
devicesDirective 93/42/EEC regarding medical devicesDirective 98/79/EC regarding in vitro diagnostic medical devices (Until 2022, the In Vitro Diagnosis Regulation (IVDR) will replace the EU's current Directive on In-Vitro Diagnostic (98/79/EC)).They aim at ensuring a high level of protection of human health and safety and the good functioning of
the Single Market. These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47 EC.[9]The government of each Member State must appoint a competent authority responsible for medical devices.[10] The competent authority
(CA) is a body with authority to act on behalf of the member state to ensure that member state government transposes requirements of medical device directives into national law and applies them. The CA reports to the minister of health in the member state. The CA in one Member State has no jurisdiction in any other member state, but exchanges
information and tries to reach common positions.In the UK, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) acted as a CA. In Italy it is the Ministero Salute (Ministry of Health) Medical devices must not be mistaken with medicinal products. In the EU, all medical devices must be identified with the CE mark. The
conformity of a medium or high risk medical device with relevant regulations is also assessed by an external entity, the Notified Body, before it can be placed on the market.In September 2012, the European Commission proposed new legislation aimed at enhancing safety, traceability, and transparency.[11] The regulation was adopted in 2017.The
current core legal framework consists of two regulations, replacing the previous three directives:The Medical Devices Regulation (MDR (EU) 2017/745)The In Vitro Diagnostic medical devices regulation (IVDR (EU) 2017/746)The two regulations are supplemented by several guidances developed by the Medical Devices Coordination Group (MDCG).
[12]Article 2, Paragraph 4, of the Pharmaceutical Affairs Law (PAL)[13] defines medical devices as "instruments and apparatus intended for use in diagnosis, cure or prevention of diseases in humans or other animals; intended to affect the structure or functions of the body of man or other animals."Bags of medical supplies and defibrillators at the
York Region EMS Logistics Headquarters in Ontario, CanadaThe term medical device, as defined in the Food and Drugs Act, is "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder or
abnormal physical state, or its symptoms, in a human being; the restoration, correction or modification of a body function or the body structure of a human being; the diagnosis of pregnancy in a human being; or the care of a human being during pregnancy and at and after the birth of a child, including the care of the child. It also includes a
contraceptive device but does not include a drug."[14]The term covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Health Canada reviews medical devices to assess their safety, effectiveness, and quality before authorizing their sale in Canada.
[15] According to the Act, medical device does not include any device that is intended for use in relation to animals.[16]This section does not cite any sources. Please help improve this section by adding citations to reliable sources. Unsourced material may be challenged and removed. (June 2022) (Learn how and when to remove this message)India
has introduced National Medical Device Policy 2023.[17] However, certain medical devices are notified as DRUGS under the Drugs & Cosmetics Act. Section 3 (b) (iv) relating to definition of "drugs" holds that "Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or
animals" are also drugs.[18] As of April 2022, 14 classes of devices are classified as drugs.A stethoscope (U.S. FDA product code BZS), a popular Class I medical device as determined by the U.S. FDA, ubiquitous in hospitals.The regulatory authorities recognize different classes of medical devices based on their potential for harm if misused, design
complexity, and their use characteristics. Each country or region defines these categories in different ways. The authorities also recognize that some devices are provided in combination with drugs, and regulation of these combination products takes this factor into consideration.Classifying medical devices based on their risk is essential for
maintaining patient and staff safety while simultaneously facilitating the marketing of medical products. By establishing different risk classifications, lower risk devices, for example, a stethoscope or tongue depressor, are not required to undergo the same level of testing that higher risk devices such as artificial pacemakers undergo. Establishing a
hierarchy of risk classification allows regulatory bodies to provide flexibility when reviewing medical devices.[citation needed]Main article: Medical device manufacturingFurther information: Federal Food, Drug, and Cosmetic Act Medical devicesThis section duplicates the scope of other articles, specifically Medical device manufacturing. Please
discuss this issue and help introduce a summary style to the section by replacing the section with a link and a summary or by splitting the content into a new article. (March 2019)Under the Food, Drug, and Cosmetic Act, the U.S. Food and Drug Administration recognizes three classes of medical devices, based on the level of control necessary to
assure safety and effectiveness.[19]Class IClass IIClass IIIDevice ClassRiskFDA Regulatory ControlExamplesClass ILow RiskGeneral ControlsTongue Depressor, Electric Toothbrush, Bandages, Hospital BedsClass IIMedium RiskGeneral Controls + Pre-Market Notification (510K)Catheters, Contact Lenses, Pregnancy Test KitsClass IIIHigh RiskGeneral
Controls + Special controls (510K) + Pre-Market Approval (PMA)Pacemakers, Defibrillators, Implanted prosthetics, Breast implantsThe classification procedures are described in the Code of Federal Regulations, Title 21, part 860 (usually known as 21 CFR 860).[20]Class I devices are subject to the least regulatory control and are not intended to help
support or sustain life or be substantially important in preventing impairment to human health, and may not present an unreasonable risk of illness or injury.[21] Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.[22]Class II devices are subject to special labeling requirements, mandatory
performance standards and postmarket surveillance.[22] Examples of Class II devices include acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, surgical drapes, stereotaxic navigation systems, and surgical robots.[19][22][23][24][25]Class III devices are usually those that support or sustain human life, are of substantial
importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury and require premarket approval.[22][19] Examples of Class III devices include implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.[22]The classification of medical
devices in the European Union is outlined in Article IX of the Council Directive 93/42/EEC and Annex VIII of the EU medical device regulation. There are basically four classes, ranging from low risk to high risk, Classes I, IIa, IIb, and III (this excludes in vitro diagnostics including software, which fall in four classes: from A (lowest risk) to D (highest
risk)):[26]Device ClassRiskExamplesClass I (Class I, Class Is, Class Im, Class Ir)Low RiskTongue Depressor, Wheelchair, SpectaclesClass IIAMedium RiskHearing aidsClass IIBMedium to High RiskVentilators, Infusion pumpsClass IIIHigh RiskPacemakers, Defibrillators, Implanted prosthetics, Breast implantsClass I Devices: Non-invasive, everyday
devices or equipment. Class I devices are generally low risk and can include bandages, compression hosiery, or walking aids. Such devices require only for the manufacturer to complete a Technical File.Class Is Devices: Class Is devices are similarly non-invasive devices, however this sub-group extends to include sterile devices. Examples of Class Is
devices include stethoscopes, examination gloves, colostomy bags, or oxygen masks. These devices also require a technical file, with the added requirement of an application to a European Notified Body for certification of manufacturing in conjunction with sterility standards.Class Im Devices: This refers chiefly to similarly low-risk measuring devices.
Included in this category are: thermometers, droppers, and non-invasive blood pressure measuring devices. Once again the manufacturer must provide a technical file and be certified by a European Notified Body for manufacturing in accordance with metrology regulations.Class Ir Devices: Reusable surgical instruments include devices like opthalmic
scissors or needle holders. Under the MDR, a manufacturer of Class Ir devices must be certified by a Notified Body with regard to reusability aspects.Class IIa Devices: Class IIa devices generally constitute low to medium risk and pertain mainly to devices installed within the body in the short term. Class IIa devices are those which are installed
within the body for only between 60 minutes and 30 days. Examples include hearing-aids, blood transfusion tubes, and catheters. Requirements include technical files and a conformity test carried out by a European Notified Body.Class IIb Devices: Slightly more complex than IIa devices, class IIb devices are generally medium to high risk and will
often be devices installed within the body for periods of 30 days or longer. Examples include ventilators and intensive care monitoring equipment. Identical compliance route to Class IIa devices with an added requirement of a device type examination by a Notified Body. Note: Some parts of the regulations diffrentiate between Class IIb and Class IIb
implantable devices, that is, some rules of the MDR apply specifically to Class IIb implantable and Class III devices, e.g. Article 52 paragraph 4 of the MDR.Class III Devices: Class III devices are strictly high risk devices. Examples include balloon catheters, prosthetic heart valves, pacemakers, etc. The steps to approval here include a full quality
assurance system audit, along with examination of both the device's design and the device itself by a European Notified Body.The authorization of medical devices is guaranteed by a Declaration of Conformity. This declaration is issued by the manufacturer itself, but for products in Class Is, Im, Ir, IIa, IIb or III, it must be verified by a Certificate of
Conformity issued by a Notified Body. A Notified Body is a public or private organisation that has been accredited to validate the compliance of the device to the European Directive. Medical devices that pertain to class I (on condition they do not require sterilization or do not measure a function) can be marketed purely by self-certification.The
European classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact, or incorporation of a medicinal product. Certified medical devices should have the CE mark on the packaging, insert leaflets, etc.. These
packagings should also show harmonised pictograms and EN standardised logos to indicate essential features such as instructions for use, expiry date, manufacturer, sterile, do not reuse, etc.In November 2018, the Federal Administrative Court of Switzerland decided that the "Sympto" app, used to analyze a woman's menstrual cycle, was a medical
device because it calculates a fertility window for each woman using personal data. The manufacturer, Sympto-Therm Foundation, argued that this was a didactic, not a medical process. the court laid down that an app is a medical device if it is to be used for any of the medical purposes provided by law, and creates or modifies health information by
calculations or comparison, providing information about an individual patient.[27]Medical devices (excluding in vitro diagnostics) in Japan are classified into four classes based on risk:[13]Device ClassRiskClass IInsignificantClass IILowClass IIIHigh Risk on MalfunctionClass IVHigh Risk could cause life-threateningClasses I and II distinguish between
extremely low and low risk devices. Classes III and IV, moderate and high risk respectively, are highly and specially controlled medical devices. In vitro diagnostics have three risk classifications.[28]For the remaining regions in the world, the risk classifications are generally similar to the United States, European Union, and Japan or are a variant
combining two or more of the three countries' risk classifications.[citation needed]The ASEAN Medical Device Directive (AMDD) has been adopted by several southeast Asian countries. The nations are at varying stages of adopting and implementing the Directive. The AMDD classification is risk-based and defines four levels: A - Low Risk, B - Low to
Moderate Risk, C - Moderate High Risk, and D - High Risk.[29]The classification of medical devices in Australia is outlined in section 41BD of the Therapeutic Goods Act 1989 and Regulation 3.2 of the Therapeutic Goods Regulations 2002, under control of the Therapeutic Goods Administration. Similarly to the EU classification, they rank in several
categories, by order of increasing risk and associated required level of control. Various rules identify the device's category[30]Medical device categories in AustraliaClassificationLevel of riskClass ILowClass I - measuring or Class I - supplied sterile or class IIaLow - mediumClass IIbMedium - highClass IIIHighActive implantable medical devices
(AIMD)HighSpinal boards wait to be used at the York Region EMS logistics headquarters in OntarioThe Medical Devices Bureau of Health Canada recognizes four classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device. Class I devices present the lowest potential risk and do not require a
licence. Class II devices require the manufacturer's declaration of device safety and effectiveness, whereas Class III and IV devices present a greater potential risk and are subject to in-depth scrutiny.[15] A guidance document for device classification is published by Health Canada.[31]Canadian classes of medical devices correspond to the European
Council Directive 93/42/EEC (MDD) devices:[31]Class I (Canada) generally corresponds to Class I (ECD)Class II (Canada) generally corresponds to Class IIa (ECD)Class III (Canada) generally corresponds to Class IIb (ECD)Class IV (Canada) generally corresponds to Class III (ECD)Examples include surgical instruments (Class I), contact lenses and
ultrasound scanners (Class II), orthopedic implants and hemodialysis machines (Class III), and cardiac pacemakers (Class IV).[32]Medical devices in India are regulated by Central Drugs Standard Control Organisation (CDSCO). Medical devices under the Medical Devices Rules, 2017 are classified as per Global Harmonization Task Force (GHTF)
based on associated risks.The CDSCO classifications of medical devices govern alongside the regulatory approval and registration by the CDSCO is under the DCGI. Every single medical device in India pursues a regulatory framework that depends on the drug guidelines under the Drug and Cosmetics Act (1940) and the Drugs and Cosmetics runs
under 1945. CDSCO classification for medical devices has a set of risk classifications for numerous products planned for notification and guidelines as medical devices.[citation needed]Device ClassRiskExamplesClass ALow RiskTongue depressors, Wheelchairs, Spectacles, Alcohol SwabsClass BLow to Moderate RiskHearing aids, ThermometersClass
CModerate to High RiskVentilators, Infusion pumpsClass DHigh RiskPacemakers, Defibrillators, Implanted prosthetics, Breast implantsSee also: Cancer Diagnostic ProbeIran produces about 2,000 types of medical devices and medical supplies, such as appliances, dental supplies, disposable sterile medical items, laboratory machines, various
biomaterials and dental implants. 400 Medical products are produced at the C and D risk class with all of them licensed by the Iranian Health Ministry in terms of safety and performance based on EU-standards.Some Iranian medical devices are produced according to the European Union standards.Some producers in Iran export medical devices and
supplies which adhere to European Union standards to applicant countries, including 40 Asian and European countries.Some Iranian producers export their products to foreign countries.[33]Following Brexit, the UK medical device regulation was closely aligned with the EU medical device regulation, including classification. The regulation 7 of the
Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), classified general medical devices into four classes of increasing levels of risk: Class I, IIa, IIb or III in accordance with criteria in the UK medical devices regulations, Annex IX (as modified by Schedule 2A to the UK medical devices regulations).
[34]Main article: Validation and verification (medical devices)Validation and verification of medical devices ensure that they fulfil their intended purpose. Validation or verification is generally needed when a health facility acquires a new device to perform medical tests.[citation needed]The main difference between the two is that validation is focused
on ensuring that the device meets the needs and requirements of its intended users and the intended use environment, whereas verification is focused on ensuring that the device meets its specified design requirements.[citation needed]The ISO standards for medical devices are covered by ICS 11.100.20 and 11.040.01.[35][36] The quality and risk
management regarding the topic for regulatory purposes is convened by ISO 13485 and ISO 14971. ISO 13485:2016 is applicable to all providers and manufacturers of medical devices, components, contract services and distributors of medical devices. The standard is the basis for regulatory compliance in local markets, and most export markets.[37]
[38][39] Additionally, ISO 9001:2008 sets precedence because it signifies that a company engages in the creation of new products. It requires that the development of manufactured products have an approval process and a set of rigorous quality standards and development records before the product is distributed.[40] Further standards are IEC
60601-1 which is for electrical devices (mains-powered as well as battery powered), EN 45502-1 which is for Active implantable medical devices, and IEC 62304 for medical software. The US FDA also published a series of guidances for industry regarding this topic against 21 CFR 820 Subchapter HMedical Devices.[41] Subpart B includes quality
system requirements, an important component of which are design controls (21 CFR 820.30). To meet the demands of these industry regulation standards, a growing number of medical device distributors are putting the complaint management process at the forefront of their quality management practices. This approach further mitigates risks and
increases visibility of quality issues.[42]Starting in the late 1980s,[43] the FDA increased its involvement in reviewing the development of medical device software. The precipitant for change was a radiation therapy device (Therac-25) that overdosed patients because of software coding errors.[44] FDA is now focused on regulatory oversight on
medical device software development process and system-level testing.[45]A 2011 study by Dr. Diana Zuckerman and Paul Brown of the National Center for Health Research, and Dr. Steven Nissen of the Cleveland Clinic, published in the Archives of Internal Medicine, showed that most medical devices recalled in the last five years for "serious health
problems or death" had been previously approved by the FDA using the less stringent, and cheaper, 510(k) process. In a few cases, the devices had been deemed so low-risk that they did not they did not undergo any FDA regulatory review. Of the 113 devices recalled, 35 were for cardiovascular issues.[46] This study was the topic of Congressional
hearings re-evaluating FDA procedures and oversight.A 2014 study by Dr. Diana Zuckerman, Paul Brown, and Dr. Aditi Das of the National Center for Health Research, published in JAMA Internal Medicine, examined the scientific evidence that is publicly available about medical implants that were cleared by the FDA 510(k) process from 2008 to
2012. They found that scientific evidence supporting "substantial equivalence" to other devices already on the market was required by law to be publicly available, but the information was available for only 16% of the randomly selected implants, and only 10% provided clinical data. Of the more than 1,100 predicate implants that the new implants
were substantially equivalent to, only 3% had any publicly available scientific evidence, and only 1% had clinical evidence of safety or effectiveness.[47] The researchers concluded that publicly available scientific evidence on implants was needed to protect the public health.[citation needed]In 20142015, a new international agreement, the Medical
Device Single Audit Program (MDSAP), was put in place with five participant countries: Australia, Brazil, Canada, Japan, and the United States. The aim of this program was to "develop a process that allows a single audit, or inspection to ensure the medical device regulatory requirements for all five countries are satisfied".[48]In 2017, a study by Dr.
Jay Ronquillo and Dr. Diana Zuckerman published in the peer-reviewed policy journal Milbank Quarterly found that electronic health records and other device software were recalled due to life-threatening flaws. The article pointed out the lack of safeguards against hacking and other cybersecurity threats, stating "current regulations are necessary
but not sufficient for ensuring patient safety by identifying and eliminating dangerous defects in software currently on the market".[49] They added that legislative changes resulting from the law entitled the 21st Century Cures Act "will further deregulate health IT, reducing safeguards that facilitate the reporting and timely recall of flawed medical
software that could harm patients".A study by Dr. Stephanie Fox-Rawlings and colleagues at the National Center for Health Research, published in 2018 in the policy journal Milbank Quarterly, investigated whether studies reviewed by the FDA for high-risk medical devices are proven safe and effective for women, minorities, or patients over 65 years
of age.[50] The law encourages patient diversity in clinical trials submitted to the FDA for review, but does not require it. The study determined that most high-risk medical devices are not tested and analyzed to ensure that they are safe and effective for all major demographic groups, particularly racial and ethnic minorities and people over 65.
Therefore, they do not provide information about safety or effectiveness that would help patients and physicians make well informed decisions.In 2018, an investigation involving journalists across 36 countries coordinated by the International Consortium of Investigative Journalists (ICIJ) prompted calls for reform in the United States, particularly
around the 510(k) substantial equivalence process;[51] the investigation prompted similar calls in the UK and Europe Union.[52]Curette in sterile pouch. Porous tyvek material allows gas sterilizationMedical device packaging is highly regulated. Often medical devices and products are sterilized in the package.[53]Sterility must be maintained
throughout distribution to allow immediate use by physicians. A series of special packaging tests measure the ability of the package to maintain sterility. Relevant standards include:ASTM F2097 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical ProductsASTM F2475-11 Standard Guide for Biocompatibility
Evaluation of Medical Device Packaging Materials[54]EN 868 Packaging materials and systems for medical devices to be sterilized, General requirements and test methodsISO 11607 Packaging for terminally sterilized medical devicesPackage testing is part of a quality management system including verification and validation. It is important to
document and ensure that packages meet regulations and end-use requirements. Manufacturing processes must be controlled and validated to ensure consistent performance.[55][56] EN ISO 15223-1 defines symbols that can be used to convey important information on packaging and labeling.ISO 10993 - Biological Evaluation of Medical
DevicesMedical device cleanliness has come under greater scrutiny since 2000, when Sulzer Orthopedics recalled several thousand metal hip implants that contained a manufacturing residue.[57] Based on this event, ASTM established a new task group (F04.15.17) for established test methods, guidance documents, and other standards to address
cleanliness of medical devices. This task group has issued two standards for permanent implants to date: 1. ASTM F2459: Standard test method for extracting residue from metallic medical components and quantifying via gravimetric analysis[58] 2. ASTM F2847: Standard Practice for Reporting and Assessment of Residues on Single Use Implants[59]
3. ASTM F3172: Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices[60]In addition, the cleanliness of re-usable devices has led to a series of standards, including:ASTM E2314: Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a
Microbiologic Method (Simulated Use Test)"[61]ASTM D7225: Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors[62]ASTM F3208: Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices[60]The ASTM F04.15.17 task group is working on several new standards that
involve designing implants for cleaning, selection and testing of brushes for cleaning reusable devices, and cleaning assessment of medical devices made by additive manufacturing.[63] Additionally, the FDA is establishing new guidelines for reprocessing reusable medical devices, such as orthoscopic shavers, endoscopes, and suction tubes.[64] New
research was published in ACS Applied Interfaces and Material to keep Medical Tools pathogen free.[65]Main article: Safety standardsMain article: Medical device manufacturingMedical device manufacturing requires a level of process control according to the classification of the device. Higher risk; more controls. When in the initial R&D phase,
manufacturers are now beginning to design for manufacturability. This means products can be more precision-engineered to for production to result in shorter lead times, tighter tolerances and more advanced specifications and prototypes. These days, with the aid of CAD or modelling platforms, the work is now much faster, and this can act also as a
tool for strategic design generation as well as a marketing tool.[66]Failure to meet cost targets will lead to substantial losses for an organisation. In addition, with global competition, the R&D of new devices is not just a necessity, it is an imperative for medical device manufacturers. The realisation of a new design can be very costly, especially with
the shorter product life cycle. As technology advances, there is typically a level of quality, safety and reliability that increases exponentially with time.[66]For example, initial models of the artificial cardiac pacemaker were external support devices that transmits pulses of electricity to the heart muscles via electrode leads on the chest. The electrodes
contact the heart directly through the chest, allowing stimulation pulses to pass through the body. Recipients of this typically developed an infection at the entrance of the electrodes, which led to the subsequent trial of the first internal pacemaker, with electrodes attached to the myocardium by thoracotomy. Future developments led to the isotope-power source that would last for the lifespan of the patient.[pageneeded]Main article: Medical softwareWith the rise of smartphone usage in the medical space, in 2013, the FDA issued to regulate mobile medical applications and protect users from their unintended use, soon followed by European and other regulatory agencies. This guidance
distinguishes the apps subjected to regulation based on the marketing claims of the apps.[67] Incorporation of the guidelines during the development phase of such apps can be considered as developing a medical device; the regulations have to adapt and propositions for expedite approval may be required due to the nature of 'versions' of mobile
application development.[68][69]On September 25, 2013, the FDA released a draft guidance document for regulation of mobile medical applications, to clarify what kind of mobile apps related to health would not be regulated, and which would be.[70][71]Further information: Medical device hijackMedical devices such as pacemakers, insulin pumps,
operating room monitors, defibrillators, and surgical instruments, including deep-brain stimulators, can incorporate the ability to transmit vital health information from a patient's body to medical professionals.[72] Some of these devices can be remotely controlled. This has engendered concern about privacy and security issues,[73][74] human error,
and technical glitches with this technology. While only a few studies have looked at the susceptibility of medical devices to hacking, there is a risk.[75][76][77] In 2008, computer scientists proved that pacemakers and defibrillators can be hacked wirelessly via radio hardware, an antenna, and a personal computer.[78][79][80] These researchers
showed they could shut down a combination heart defibrillator and pacemaker and reprogram it to deliver potentially lethal shocks or run out its battery. Jay Radcliff, a security researcher interested in the security of medical devices, raised fears about the safety of these devices. He shared his concerns at the Black Hat security conference.[81]
Radcliff fears that the devices are vulnerable and has found that a lethal attack is possible against those with insulin pumps and glucose monitors. Some medical device makers downplay the threat from such attacks and argue that the demonstrated attacks have been performed by skilled security researchers and are unlikely to occur in the real
world. At the same time, other makers have asked software security experts to investigate the safety of their devices.[82] As recently as June 2011, security experts showed that by using readily available hardware and a user manual, a scientist could both tap into the information on the system of a wireless insulin pump in combination with a glucose
monitor. With the PIN of the device, the scientist could wirelessly control the dosage of the insulin.[83] Anand Raghunathan, a researcher in this study, explains that medical devices are getting smaller and lighter so that they can be easily worn. The downside is that additional security features would put an extra strain on the battery and size and
drive up prices. Dr. William Maisel offered some thoughts on the motivation to engage in this activity. Motivation to do this hacking might include acquisition of private information for financial gain or competitive advantage; damage to a device manufacturer's reputation; sabotage; intent to inflict financial or personal injury or just satisfaction for the
attacker.[84] Researchers suggest a few safeguards. One would be to use rolling codes. Another solution is to use a technology called "body-coupled communication" that uses the human skin as a wave guide for wireless communication. On 28 December 2016, the US Food and Drug Administration released its recommendations that are not legally
enforceable for how medical device manufacturers should maintain the security of Internet-connected devices.[85][86]Similar to hazards, cybersecurity threats and vulnerabilities cannot be eliminated but must be managed and reduced to a reasonable level.[87] When designing medical devices, the tier of cybersecurity risk should be determined early
in the process in order to establish a cybersecurity vulnerability and management approach (including a set of cybersecurity design controls). The medical device design approach employed should be consistent with the NIST Cybersecurity Framework for managing cybersecurity-related risks.In August 2013, the FDA released over 20 regulations
aiming to improve the security of data in medical devices,[88] in response to the growing risks of limited cybersecurity.The number of approved medical devices using artificial intelligence or machine learning (AI/ML) is increasing. As of 2020, there were several hundred AI/ML medical devices approved by the US FDA or CE-marked devices in
Europe.[89][90][91] Most AI/ML devices focus upon radiology. As of 2020, there was no specific regulatory pathway for AI/ML-based medical devices in the US or Europe.[92][90][91] However, in January 2021, the FDA published a proposed regulatory framework for AI/ML-based software,[93][94] and the EU medical device regulation which replaces
the EU Medical Device Directive in May 2021, defines regulatory requirements for medical devices, including AI/ML software.[95]For other types of equipment, see EquipmentThis article needs additional citations for verification. Please help improve this article by adding citations to reliable sources. Unsourced material may be challenged and
removed.Find sources:"Medical device"news newspapers books scholar JSTOR (January 2008) (Learn how and when to remove this message)Medical equipmentMedical equipment (also known as armamentarium[96]) is designed to aid in the diagnosis, monitoring or treatment of medical conditions.There are several basic types:Diagnostic equipment
includes medical imaging machines, used to aid in diagnosis. Examples are ultrasound and MRI machines, PET and CT scanners, and x-ray machines.Treatment equipment includes infusion pumps, medical lasers and LASIK surgical machines.Life support equipment is used to maintain a patient's bodily function. This includes medical ventilators,
incubators, anaesthetic machines, heart-lung machines, ECMO, and dialysis machines.Medical monitors allow medical staff to measure a patient's medical state. Monitors may measure patient vital signs and other parameters including ECG, EEG, and blood pressure.Medical laboratory equipment automates or helps analyze blood, urine, genes, and
dissolved gases in the blood.Diagnostic medical equipment may also be used in the home for certain purposes, e.g. for the control of diabetes mellitus, such as in the case of continuous glucose monitoring.Therapeutic: physical therapy machines like continuous passive range of motion (CPM) machinesAir purifying equipment may be used in the
periphery of the operating room[97] or at point sources including near the surgical site for the removal of surgical plume.[98]The identification of medical devices has been recently improved by the introduction of Unique Device Identification (UDI) and standardised naming using the Global Medical Device Nomenclature (GMDN) which have been
endorsed by the International Medical Device Regulatory Forum (IMDRF).[99]A biomedical equipment technician (BMET) is a vital component of the healthcare delivery system. Employed primarily by hospitals, BMETs are the people responsible for maintaining a facility's medical equipment. BMET mainly act as an interface between doctor and
equipment.There are challenges surrounding the availability of medical equipment from a global health perspective, with low-resource countries unable to obtain or afford essential and life-saving equipment. In these settings, well-intentioned equipment donation from high- to low-resource settings is a frequently used strategy to address this through
individuals, organisations, manufacturers and charities. However, issues with maintenance, availability of biomedical equipment technicians (BMET), supply chains, user education and the appropriateness of donations means these frequently fail to deliver the intended benefits. The WHO estimates that 95% of medical equipment in low- and middle-income countries (LMICs) is imported and 80% of it is funded by international donors or foreign governments. While up to 70% of medical equipment in sub-Saharan Africa is donated, only 10%30% of donated equipment becomes operational.[100] A review of current practice and guidelines for the donation of medical equipment for surgical and
anaesthesia care in LMICs has demonstrated a high level of complexity within the donation process and numerous shortcomings. Greater collaboration and planning between donors and recipients is required together with evaluation of donation programs and concerted advocacy to educate donors and recipients on existing equipment donation
guidelines and policies.[101]The circulation of medical equipment is not limited to donations. The rise of reuse and recycle-based solutions, where gently used medical equipment is donated and redistributed to communities in need, is another form of equipment distribution. An interest in reusing and recycling emerged in the 1980s when the potential
health hazards of medical waste on the East Coast beaches became highlighted by the media.[102] Connecting the large demand for medical equipment and single-use medical devices with a need for waste reduction, as well as the problem of unequal access for low-income communities led to the Congress enacting the Medical Waste Tracking Act of
1988.[103] Medical equipment can be donated either by governments or non-governmental organizations, domestic or international.[104] Donated equipment ranges from bedside assistance to radiological equipment.Medical equipment donation has come under scrutiny with regard to donated-device failure and loss of warranty in the case of
previous-ownership. Most medical devices and production company warranties to do not extend to reused or donated devices, or to devices donated by initial owners/patients. Such reuse raises matters of patient autonomy, medical ethics, and legality.[104] Such concerns conflict with the importance of equal access to healthcare resources, and the
goal of serving the greatest good for the greatest number.[105]Medical & Biological Engineering & Computing journalExpert Review of Medical Devices journalUniversity of Minnesota - Medical Devices Center (MDC)University of Strathclyde - Strathclyde Institute of Medical Devices (SIMD)Flinders University - Medical Device Research Institute
(MDRI)Michigan State University - School of Packaging (SoP)[106]IIT Bombay - Biomedical Engineering and Technology (incubation) Centre (BETiC)Assistive technologyClinical engineerDesign history fileDurable medical equipmentElectromagnetic compatibilityElectronic health recordFederal Institute for Drugs and Medical DevicesGHTFHealth
Level 7Home medical equipmentInstruments used in general medicineInstruments used in obstetrics and gynecologyList of common EMC test standardsMedical grade siliconeMedical logisticsMedical technologyPharmacopoeiaSafety engineerTelemedicine^ "Stone age man used dentist drill". 6 April 2006 via news.bbc.co.uk.^ "Surgical Instruments
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Learn More United States Japan India Vietnam Indonesia United Kingdom Spain Brazil Chile South Africa United States Japan India Vietnam Indonesia United Kingdom Spain Brazil Chile South Africa United States Japan India Vietnam Indonesia United Kingdom Spain Brazil Chile South Africa Meeting all air conditioning needs including ventilation, humidification, refrigeration, and freezing Providing trusted support in each country worldwide Pioneering Fluorine Technology Providing Solutions for Life Utilizing IPM motor and inverter technology for greater energy savings We are providing suitable air for every space in all the countries around the world. Perfecting the Air Highest-ranking officer of an organizationIt has been suggested that Executive director be merged into this article. (Discuss) Proposed since May 2025."Chief executive" and "CEO" redirect here. For other uses, see Chief executive (disambiguation) and CEO (disambiguation).A group of Fortune 500 CEOs in 2015A chief executive officer (CEO),[1] also known as a chief executive or managing director, is the top-ranking corporate officer charged with the management of an organization, usually a company or a nonprofit organization.CEOs find roles in various organizations, including public and private corporations, nonprofit organizations, and even some government organizations (notably state-owned enterprises). The governor and CEO of a corporation or company typically reports to the board of directors and is charged with maximizing the value of the business,[1] which may include maximizing the profitability, market share, revenue, or another financial metric. In the nonprofit and government sector, CEOs typically aim at achieving outcomes related to the organization's mission, usually provided by legislation. CEOs are also frequently assigned the role of the main manager of the organization and the highest-ranking officer in the C-suite.[2]The term "chief executive officer" is attested as early as 1782, when an ordinance of the Congress of the Confederation of the United States of America used the term to refer to governors and other leaders of the executive branches of each of the Thirteen Colonies.[3] In draft additions to the Oxford English Dictionary published online in 2011, the Dictionary says that the use of "CEO" as an acronym for a chief executive officer originated in Australia, with the first attestation being in 1914. The first American usage cited is from 1972.[4]The responsibilities of an organization's CEO are set by the organization's board of directors or other authority, depending on the organization's structure. They can be far-reaching or quite limited, and are typically enshrined in a formal delegation of authority regarding business administration. Typically, responsibilities include being an active decision-maker on business strategy and other key policy issues, as well as leader, manager, and executor roles. The communicator role can involve speaking to the press and the public, as well as to the organization's management and employees. The decision-making role entails making high-level decisions regarding policy and strategy. The CEO is responsible for implementing the goals, targets, and strategic objectives as determined by the board of directors.As an executive officer of the company, the CEO reports the status of the business to the board of directors, motivates employees, and drives change within the organization. As a manager, the CEO presides over the organization's day-to-day operations.[5][6][7] The CEO is the person who is ultimately accountable for a company's business decisions, including those in operations, marketing, business development, finance, human resources, etc. The CEO of a political party is often entrusted with fundraising, particularly for election campaigns.The use of the CEO title may be used by for-profit companies or non-profit or charitable organisations, such as the Wikimedia Foundation.In some countries, there is a dual board system with two separate boards, one executive board for the day-to-day business and one supervisory board for control purposes (selected by the shareholders). In these countries, the CEO presides over the executive board and the chairperson presides over the supervisory board, and these two roles will always be held by different people. This ensures a distinction between management by the executive board and governance by the supervisory board. This allows for clear lines of authority. The aim is to prevent a conflict of interest and too much power being concentrated in the hands of one person.In the United States, the board of directors (elected by the shareholders) is often equivalent to the supervisory board, while the executive board may often be known as the executive committee (the division/subsidiary heads and C-level officers that report directly to the CEO).In the United States, and in business, the executive officers are usually the top officers of a corporation, the chief executive officer (CEO) being the best-known type. The definition varies; for instance, the California Corporate Disclosure Act defines "executive officers" as the five most highly compensated officers not also sitting on the board of directors. In the case of a sole proprietorship, an executive officer is the sole proprietor. In the case of a partnership, an executive officer is a managing partner, senior partner, or administrative partner. In the case of a limited liability company, an executive officer is any member, manager, or officer.Main article: Corporate titleDepending on the organization, a CEO may have several subordinate executives to help run the day-to-day administration of the company, each of whom has specific functional responsibilities referred to as senior executives,[8] executive officers or corporate officers. Subordinate executives are given different titles in different organizations, but one common category of subordinate executive, if the CEO is also the president, is the vice president (VP). An organization may have more than one vice president, each tasked with a different area of responsibility (e.g., VP of finance, VP of human resources). Examples of subordinate executive officers who typically report to the CEO include the chief operating officer (COO), chief financial officer (CFO), chief strategy officer (CSO), chief marketing officer (CMO) and chief business officer (CBO). The public relations-focused position of chief reputation officer is sometimes included as one such subordinate executive officer, but, as suggested by Anthony Johndrow, CEO of Reputation Economy Advisors, it can also be seen as "simply another way to add emphasis to the role of a modern-day CEO where they are both the external face of, and the driving force behind, an organization culture".[9]Brad D. Smith, former CEO of IntuitIn the US, the term "chief executive officer" is used primarily in business, whereas the term "executive director" is used primarily in the not-for-profit sector.[10] These terms are generally mutually exclusive and refer to distinct legal duties and responsibilities.[11] The CEO is the highest-ranking executive in a company, making corporate decisions, managing operations, allocating resources, and serving as the main point of communication between the board of directors and the company.[12]In the UK, chief executive and chief executive officer are used in local government, where their position in law is described as the "head of paid service",[13] and in business and in the charitable sector.[14] As of 2013[update], the use of the term director for senior charity staff is deprecated to avoid confusion with the legal duties and responsibilities associated with being a charity director or trustee, which are normally non-executive (unpaid) roles. The term managing director is often used in lieu of chief executive officer.Business publicists since the days of Edward Bernays (18911995) and his client John D. Rockefeller (18391937) and even more successfully the corporate publicists for Henry Ford, promoted the concept of the "celebrity CEO". Business journalists have often adopted this approach, which assumes that the corporate achievements, especially in the arena of manufacturing, are produced by uniquely talented individuals, especially the "heroic CEO". In effect, journalists celebrate a CEO who takes distinctive strategic actions. The model is the celebrity in entertainment, sports, and politics compare the "great man theory". Guthey et al. argues that "...these individuals are not self-made, but rather are created by a process of widespread media exposure to the point that their actions, personalities, and even private lives function symbolically to represent significant dynamics and tensions prevalent in the contemporary business atmosphere".[15] Journalism thereby exaggerates the importance of the CEO and tends to neglect harder-to-describe broader corporate factors. There is little attention to the intricately organized technical bureaucracy that actually does the work. Hubris sets in when the CEO internalizes the celebrity and becomes excessively self-confident in making complex decisions. There may be an emphasis on the sort of decisions that attract the celebrity journalists.[16]Research published in 2009 by Ulrike Malmendier and Geoffrey Tate indicates that "firms with award-winning CEOs subsequently underperform, in terms both of stock and of operating performance".[17]Main article: Executive compensation ControversyExecutive compensation has been a source of criticism following a dramatic rise in pay relative to the average worker's wage. For example, the relative pay was 20-to-1 in 1965 in the US, but had risen to 376-to-1 by 2000.[18] The relative pay differs around the world, and, in some smaller countries, is still around 20-to-1.[19] Observers differ as to whether the rise is due to competition for talent or due to lack of control by compensation committees.[20] In recent years, investors have demanded more say over executive pay.[21]Main article: Gender diversity In the boardroomLack of diversity amongst chief executives has also been a source of criticism.[22] In 2018, 5% of Fortune 500 CEOs were women.[23] In 2023 the number rose to 10.4% of for Women CEO's of Fortune 500 companies.[24] The reasons for this are explained or justified in various ways, and may include biological sex differences, male and female differences in Big Five personality traits and temperament, sex differences in psychology and interests, maternity and career breaks, hypergamy, phallogocentrism, the existence of old boy networks, tradition, and the lack of female role models in that regard.[25][26][27] Some countries have passed laws mandating boardroom gender quotas.[28] In 2023 Rockefeller Foundation awarded a grant to Korn Ferry to research strategies and then action a plan to help more women to become CEO's.[29]See also: Toxic leaderThere are contentious claims that a significant number of CEO's have psychopathic tendencies, often characterized by power-seeking behavior and dominance. These individuals can often conceal their ruthlessness and antisocial behavior behind a facade of charm and eloquence. Traits such as courage and risk-taking, generally considered desirable, are often found alongside these psychopathic tendencies.Tara Swart, a neuroscientist at MIT Sloan School of Management, has suggested that individuals with psychopathic traits thrive in chaotic environments and are aware that others do not. As a result, they may intentionally create chaos in the workplace.[30][31] This perspective is explored in the book Snakes in Suits, co-authored by Robert D. Hare.However, Scott Lilienfeld has argued that the attention given to psychopathy in the workplace by both the media and scholars has far exceeded the available scientific evidence. Emilia Bunea, writing in Psychology Today, has linked psychopathic traits in managers to workplace bullying, employee dissatisfaction, and turnover intentions. Despite this, Bunea cautions that excessive worry about supposed psychopathic managers could discourage individuals from pursuing careers in corporations and deter employees from addressing issues with difficult bosses.[32]CEO successionCEO of public schoolsCity managerExecutive officerFounder modeGlass cliffList of books written by CEOsList of chief executive officersOccupational Information NetworkPrime ministerUnited States Department of Labor^ a b Lin, Tom C. W. (April 23, 2014). "CEOs and Presidents". UC Davis Law Review. SSRN2428371.^ Westphal, James D.; Zajac, Edward J. (March 1995). "Who Shall Govern? CEO/Board Power, Demographic Similarity, and New Director Selection". Administrative Science Quarterly. 40 (1): 6083. doi:10.2307/2393700. JSTOR2393700.^ "An Ordinance for Regulating the Post Office of the United States of America". Journals of the Continental Congress, 17741789. Vol.23. 1914 [October 1782]. p.670. 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