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Category	Title	Regulatory Region	Latest Version	Link	Fee	Audience	Comment
Regulatory - binding	QMSR Quality Management System Regulation	FDA	2026-02-02	https://www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments	Free	Regulatory Affairs	Abstract: The QMSR amends and replaces the current Quality System Regulation (QSR, 21 CFR Part 820) by incorporating the international standard ISO 13485:2016 by reference, along with some supplemental FDA requirements
Regulatory - binding	MDR Medical Device Regulation Regulation (EU) 2017/745	CE	2023-03-15	https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#:text=Regulation%20(EU)%202023%2F607_in%20vitro%20diagnostic%20medical%20devices	Free	Regulatory Affairs	Abstract: A comprehensive regulatory framework for medical devices in the European Union, primarily to enhance patient safety and increase transparency.
Regulatory - binding	IVDR In vitro diagnostic Regulation Regulation (EU) 2017/745	CE	2024-07-09	https://health.ec.europa.eu/medical-devices-sector/vitro-diagnostics_en	Free	Regulatory Affairs	Comment: legislative framework governing the placing on the market, availability, and putting into service of in vitro diagnostic medical devices (IVDs) in the European Union.
Regulatory - binding	The current Electronic Instructions for Use [eIFU] framework is set by Implementing Regulation (EU) 2021/2226, which has been significantly expanded by Implementing Regulation (EU) 2025/1234.	CE	2025-06-25	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R2226-20250716	Free	Regulatory Affairs, Risk Management, Design & Usability	Comment: Relevant how to specify requirements for an eIFU Abstract: The EU regulation on eIFU (Electronic Instructions for Use) governs when and how medical device manufacturers can replace the traditional paper-based Instructions for Use with a digital version.
Regulatory - binding	EU AI ACT	Any	2026	https://artificialintelligenceact.eu/	Free	Any	Comment: Relevant to everyone
Regulatory - guidance	Proposal for a regulation to simplify rules on medical and in vitro diagnostic devices: Act + Annex	CE	2025-12-16	https://health.ec.europa.eu/publications/proposal-regulation-simplify-rules-medical-and-vitro-diagnostic-devices_en	Free	Regulatory Affairs	Comment: This will (in its final, published form) significantly change the MDR / IVDR Abstract: Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I
IEC Standards	IEC 62366-1:2015 + AMD1:2020 Medical devices – Part 1: Application of usability engineering to medical devices	CE	2021		> 200 €	Any	Comment: Highly relevant for usability engineering of medical devices, essential for designers.
IEC Standards	IEC TR 62366-2 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices	CE	2016	https://www.iso.org/standard/69126.html	> 200 €	Any	
IEC Standards	IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	CE	2020	https://www.vde-verlag.de/iec-normen/249080/iec-60601-1-2005-amd1-2012-amd2-2020-csv.html	> 200 €	Any	Comment: Essential for basic safety and performance, includes usability aspects. Abstract: IEC 60601-1:2005+A1:2012+A2:2020 contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard.
IEC Standards	IEC 60601-1-6 Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	CE	2010	https://webstore.iec.ch/en/publication/2595	< 200 €	Regulatory Affairs	Comment: Collateral standard focused on usability, highly relevant for medical electrical equipment. Abstract: IEC 60601-1-6:2010 specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to basic safety and essential performance of medical electrical equipment.
IEC Standards	IEC 60601-1-8:2006 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	CE	2006	https://www.iso.org/standard/41986.html	> 200 €	Design & Usability	Comment: Important for alarm systems in medical equipment, usability implications for safety. Abstract: Specifies basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent alarm signals and consistent control states and their marking for all alarm systems.
IEC Standards	IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	CE	2015	https://www.iso.org/standard/65529.html	> 200 €	Design & Usability	Comment: Essential for home healthcare devices, significant usability considerations. Abstract: IEC 60601-1-11:2015 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment.
IEC Standards	IEC 62304:2006 + AMD 1:2015 Medical device software - Software life cycle processes	CE	2015	https://www.iso.org/standard/38421.html	> 200 €	Design & Usability	Comment: Essential for SaMD Abstract: Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes.
IEC Standards	IEC 82304-1:2016 Health software -- Part 1: General requirements for product safety	CE	2016	https://www.vde-verlag.de/iec-normen/223971/iec-82304-1-2016.html	< 200 €	Design & Usability	Comment: Critical for health software, including usability and product safety. Abstract: IEC 82304-1:2016 applies to the safety and security of health software products designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for manufacturers. It covers the entire lifecycle including design, development, validation, installation, maintenance, and disposal of health software products.
IEC Standards	IEC TR 60878:2015 Graphical symbols for electrical equipment in medical practice	CE	2022	https://www.vde-verlag.de/iec-normen/251316/iec-tr-60878-2022.html	> 200 €	Design & Usability	Comment: Important for understanding graphical symbols in medical practice, usability relevance. Abstract: IEC TR 60878:2022 provides a compilation, for easy reference, of graphical symbols (graphics, title, description) and safety signs for medical electrical equipment. The graphical symbols are grouped in sections according to their specific field of application (see Clause 4).



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IEC Standards	IEC 80601-2-12+Cor.1:2025 - Particular requirements for basic safety and essential performance of critical care ventilators	CE	2025	https://www.vde-verlag.de/iec-normen/252260/iso-80601-2-12-2023.html	> 200 €	Design & Usability	Comment: Critical for ventilators, includes safety and usability performance requirements. Abstract: ISO 80601-2-12:2023 This document applies to the basic safety and essential performance of a critical care ventilator in combination with its accessories, hereafter referred to as ME equipment
IEC Standards	IEC 80601-2-13 - Particular requirements for basic safety and essential performance of an anaesthetic workstation	CE	2022	https://www.iso.org/standard/76679.html	> 200 €	Design & Usability	Comment: Relevant for anesthetic workstations, safety and usability performance requirements. Abstract: This document is applicable to the basic safety and essential performance of an anaesthetic workstation for administering inhalational anaesthesia whilst continuously attended by a professional operator.
AAMI-Standards	ANSI/AAMI HE75:2009/(R)2013 Human factors engineering – Design of medical devices	FDA	2025	https://webstore.ansi.org/standards/aami/ansiaamihe752009r2018	> 200 €	Design & Usability	Comment: A general introduction to medical design usability. Highly relevant for human factors engineering in medical device design. Abstract: This recommended practice covers general human factors engineering (HFE) principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE (e.g., connectors, controls, visual displays, automation, software–user interfaces, hand tools, workstations, mobile medical devices, home health care devices)
AAMI-Standards	AAMI TIR49: 2013 Design of training and instructional materials for medical devices used in non-clinical environments	FDA	2013	https://webstore.ansi.org/standards/aami/aamitir492013tir49	< 200 €	Design & Usability	Comment: A general introduction medical manuals. Useful for designing instructional materials, important in non-clinical settings. Abstract: The purpose of this technical information report (TIR) is to provide a relevant source of information, design criteria, and guidelines for the instructional and training materials and processes intended to accompany medical devices used in a non-clinical environment, which for the purpose of this document, is defined as an environment other than a facility where a health professional is continually present whenever a patient is present
AAMI-Standards	AAMI TIR50: 2014 Post-market surveillance of use error managementAAMI TIR 51	FDA	2017	https://webstore.ansi.org/standards/aami/aamitir502014r2017	> 200 €	Design & Usability	Comment: Seems to be a general introduction post-release testing. Relevant for post-market surveillance, focused on managing use errors. Abstract: This document will address the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective regarding human factors assessment. The goal is to provide guidance on how clinicians and manufacturers can best collect and leverage post-market use error data to improve product safety and usability.
AAMI-Standards	AAMI TIR51: 2014 Human factors engineering – Guidance for contextual inquiry	FDA	2014	https://webstore.ansi.org/standards/aami/aamitir512014r2017	< 200 €	Design & Usability	Comment: Seems to be a general introduction conducting research in medical design. Guidance on contextual inquiry in human factors, useful for user research. Abstract: Provides guidance on conducting contextual inquiry research that is used to provide information for improving medical procedures, environments, training, and/or devices.
AAMI-Standards	AAMI TIR55: 2014 Human factors engineering for processing medical devices	FDA	2014	https://webstore.ansi.org/standards/aami/aamitir552014r2017	< 200 €	Design & Usability	Comment: General introduction to writing cleaning instructions. Focused on human factors in processing medical devices, relevant for usability. Abstract: Provides guidance on the application of human factors engineering principles to instructions provided by manufacturers for cleaning medical devices.
AAMI-Standards	AAMI TIR61: 2014 Generating reports for human factors design validation results for external cardiac defibrillators	FDA	2014	https://webstore.ansi.org/standards/aami/aamitir612014r2019	< 200 €	Design & Usability	Comment: Critical for reporting human factors validation results, relevant for documentation.
AAMI-Standards	AAMI TIR 12: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	FDA	2020	https://webstore.ansi.org/standards/aami/aamitir122020	> 200 €	Design & Usability	Comment: Guidance for designing reusable devices, important for safety and usability. Abstract: This technical information report (TIR) provides guidance to medical device manufacturers, who are required to provide instructions that detail the processing steps from pre-treatment at the point of use through the terminal process and storage to accompany reusable and single-use medical devices that are processed by a health care facility prior to clinical use.
AAMI-Standards	AAMI TIR30:2011 (R2016), A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.	FDA	2016	https://webstore.ansi.org/standards/aami/AAMITIR302011R2016	< 200 €	Design & Usability	Abstract: This report is intended as a resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. In addition to describing available processes, materials, test methods, and acceptance criteria for cleaning medical devices that are labeled by the manufacturer for reuse and reprocessing, the report also discusses some of the underlying problems and challenges associated with validating a cleaning method. Extensive references and a sample cleaning validation outline and also are included
ISO	ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes	CE	2016	https://www.iso.org/standard/59752.html	< 200 €	Quality Management	Comment: Focus on Quality Management. Essential for quality management systems, including usability as part of regulatory requirements. Abstract: ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.



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standard - intl.	ISO 14971:2019 Medical devices — Application of risk management to medical devices	Any	2019	https://www.iso.org/standard/72704.html	< 200 €	Any	Abstract: This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
guidance - intl.	ISO TR 204971-1:2020 Medical devices — Guidance on the application of ISO 14971	Any	2020	https://www.iso.org/standard/74437.html	> 200 €	Risk Management, Regulatory Affairs, Design & Usability	Comment: guidance on the development, implementation and maintenance of a risk management system for medical devices according to ISO 14971:2019.
guidance - intl.	ISO/TS 24971-2:2026(?) Medical devices — Guidance on the application of ISO 14971 Part 2: Machine learning in artificial intelligence	Any	under publication	https://www.iso.org/standard/87600.html	n/a	Risk Management, Design & Usability	Comment: Guidance on how to apply the risk management process of ISO 14971:2019 to ML-enabled medical devices (MLMD). This document is intended to be used in conjunction with ISO 14971 and does not alter the risk management requirements specified in ISO 14971.
guidance - intl.	ISO /AWI TS 24971-3:2027(?) Medical devices - Guidance on the application of ISO 14971 Part 3: Combination products	Any	under development	https://www.iso.org/standard/91186.html	n/a	Design & Usability, Risk Management	Comment: Recommendations on the concurrent application of ISO 14971 and ICH Q9 risk management principles and processes during development and marketing of combination products that include a device constituent part (eg, drug-device, biological drug-device, or drug-device-biologic). These recommendations are intended to inform the adoption and application of established risk management processes during all phases of the lifecycle of combination products.
ISO	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer	CE	2021	https://www.iso.org/standard/77326.html	< 100 €	Design & Usability	Comment: Important for understanding symbols used in device labeling, relevant for usability. Abstract: This document specifies symbols used to express information supplied for a medical device. This document is applicable to symbols used in a broad spectrum of medical devices, that are available globally and need to meet different regulatory requirements.
ISO	ISO 15223-2:2010 Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 2: Symbol development, selection and validation	CE	2010	https://www.iso.org/standard/42343.html	< 100 €	Design & Usability	Abstract: ISO 15223-2:2010 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.
ISO	ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008)	CE	2008	https://www.iso.org/standard/45611.html	< 100 €	Design & Usability	Abstract: ISO 3826-2:2008 addresses symbols that may be used to convey certain items of information related to medical devices dedicated to blood collection processes and storage. The information may be required on the device itself, as part of the label, or provided with the device. Many countries require that their own language be used to display textual information with medical devices. This raises problems to device manufacturers and users.
ISO	ISO 23908:2011 Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	CE	2011	/	< 100 €	Design & Usability	Comment: Withdrawn Abstract: ISO 23908:2011 gives requirements and test methods for evaluating the performance parameters of sharps injury protection features, whether active or passive in design, for medical devices containing (sharp) hypodermic needles for single use, introducers for catheters and lancets, and other needles used in blood sampling. The sharps injury protection devices it covers may be provided integral to the device or combined with the device prior to use to achieve the sharps injury protection.
ISO	ISO 80369 series on small-bore connectors for liquids and gases in healthcare applications with its applicable sub-parts	CE	2018	https://www.iso.org/standard/64419.html	< 200 €	Design & Usability	Abstract: This document specifies general requirements for small-bore connectors, which convey liquids or gases in healthcare applications. These small-bore connectors are used in medical devices or accessories intended for use with a patient.
ISO	ISO 11607-1:2019 Packaging of terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	CE	2019	https://www.iso.org/standard/70799.html	> 200 €	Any	
ISO	ISO 11608-1:2022 Needle-based injection systems for medical use — Requirements and test methods	CE	2022	https://www.iso.org/standard/70733.html#:~:text=This%20document%20specifies%20requirements%20and%20or%20intramuscular%20delivery%2C%20incorporating%20pre	> 200 €	Any	
ISO	ISO/TR 7250-2:2024 Basic human body measurements for technological design - Part 2: Statistical summaries of body measurements from individual ISO populations	CE	2024	https://www.iso.org/standard/84822.html	> 200 €	Any	Abstract: ISO/TR 7250-2: 2024 Basic human body measurements for technological design - Part 2: Statistical summaries of body measurements from individual ISO populations
ISO	ISO 9241-210:2019 Ergonomics of human-system interaction - Part 210: Human-centered design for interactive systems	CE	2019	https://www.iso.org/standard/77520.html	< 200 €	Any	
ISO	ISO 25062:2025 System and software engineering - System and software Quality Requirements and Evaluation (SQuaRe) - Common Industry Format (CIF) for reporting usability evaluations	CE	2025	https://www.iso.org/standard/84255.html	< 200 €	Any	
ISO	ISO 9186-1:2014 Graphical symbols -- Test methods -- Part 1: Method for testing comprehensibility	CE	2014	https://www.iso.org/standard/59226.html#:~:text=ISO%209186%2D1%3A2014%20specifies%20graphical%20symbols%20are%20readily%20understood.	< 100 €	Design & Usability	Abstract: ISO 9186-1:2014 specifies a method for testing the comprehensibility of graphical symbols. It provides a measure of the extent to which a variant of a graphical symbol communicates its intended message. The purpose is to ensure that graphical symbols and signs using graphical symbols are readily understood.
ISO	ISO 9241-11 Ergonomic requirements for office work with visual display terminals (VDTs) -- Part 11: Guidance on usability	CE	2018	https://www.iso.org/standard/63500.html	< 200 €	Design & Usability	Abstract: ISO 9241-11:2018 provides a framework for understanding the concept of usability and applying it to situations where people use interactive systems, and other types of systems (including built environments), and products (including industrial and consumer products) and services (including technical and personal services).



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ISO	ISO 9241-110 Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems	CE	2019	https://www.iso.org/standard/77520.html	< 200 €	Design & Usability	Abstract: This document provides requirements and recommendations for human-centred design principles and activities throughout the life cycle of computer-based interactive systems. It is intended to be used by those managing design processes, and is concerned with ways in which both hardware and software components of interactive systems can enhance human-system interaction.
ISO	ISO 9241-171 Ergonomics of human-system interaction -- Part 171: Guidance on software accessibility	CE	2008	https://www.iso.org/standard/39080.html	> 200 €	Design & Usability	Abstract: ISO 9241-171:2008 provides ergonomics guidance and specifications for the design of accessible software for use at work, in the home, in education and in public places. It covers issues associated with designing accessible software for people with the widest range of physical, sensory and cognitive abilities, including those who are temporarily disabled, and the elderly. It addresses software considerations for accessibility that complement general design for usability as addressed by ISO 9241-110, ISO 9241-11 to ISO 9241-17, ISO 14915 and ISO 13407.
ISO	ISO 9241-210 Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems	CE	2019	https://www.iso.org/standard/77520.html	< 200 €	Design & Usability	Abstract: This document provides requirements and recommendations for human-centred design principles and activities throughout the life cycle of computer-based interactive systems. It is intended to be used by those managing design processes, and is concerned with ways in which both hardware and software components of interactive systems can enhance human-system interaction.
ISO	ISO/IEC 25062:2006 Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability test reports	CE	2006	https://www.iso.org/standard/43046.html	< 200 €	Design & Usability	Abstract: ISO/IEC 25062:2006 provides a standard method for reporting usability test findings. The format is designed for reporting results of formal usability tests in which quantitative measurements were collected, and is particularly appropriate for summative/comparative testing. The CIF does not indicate how to perform a usability test but provides guidance on how to report the results of a usability test. The CIF targets two audiences: usability professionals and stakeholders in an organization. Stakeholders can use the usability data to help make informed decisions concerning the release of software products or the procurement of such products.
ISO	ISO/IEC 25064:2013 Systems and software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability: User needs report	CE	2013	https://www.iso.org/standard/35790.html	< 200 €	Design & Usability	Abstract: ISO/IEC 25064:2013 describes the Common Industry Format (CIF) for user needs reports, and provides specifications for their contents and format, including the content elements to be provided. User needs reports include both the collection and documentation of information from various sources relevant to user needs, and the analysis and integration of this information into consolidated user needs.
ISO	ISO/IEC 25063 :2014 Systems and software engineering -- Systems and software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability: Context of use description	CE	2014	https://www.iso.org/standard/35789.html	< 200 €	Design & Usability	Abstract: ISO/IEC 25063:2014 describes the Common Industry Format (CIF) for context of use descriptions and specifies the contents of both high-level and detailed descriptions of the context of use for an existing, intended, implemented or deployed system. A context-of-use description includes information about the users and other stakeholder groups, the characteristics of each user group, the goals of the users, the tasks of the users, and the environment(s) in which the system is used.
ISO	ISO 7000:2019 Graphical symbols for use on equipment — Registered symbols	CE	2019	https://www.iso.org/standard/78717.html	Free	Any	Abstract: The ISO 7000 database provides a collection of graphical symbols which are placed on equipment or parts of equipment of any kind in order to instruct the person(s) using the equipment as to its operation.
FDA Guidance papers	Guidance: Applying Human Factors and Usability Engineering to Medical Devices	FDA	2016	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices	Free	Design & Usability	Comment: Very broad overview on definitions and testing standards Abstract: The document outlines nonbinding recommendations for industry and FDA staff, aiming to assist in making medical devices safe and effective for intended users, uses, and use environments.
FDA Guidance papers	Guidance: Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation	FDA	2017	https://www.fda.gov/medical-devices/human-factors-and-medical-devices/human-factors-implications-new-gmp-rule-overall-requirements-new-quality-system-regulation	Free	Design & Usability	Comment: Very general overview
FDA Guidance papers	Guidance: Design Control Guidance for Medical Device Manufactures	FDA	1997	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers	Free	Design & Usability	Comment: Very generic Abstract: This document is intended to provide guidance to those involved in designing clinical studies intended to support pre-market submissions for medical devices and FDA staff who review those submissions.
FDA Guidance papers	Guidance: Design Considerations for Devices Intended for Home Use	FDA	2014	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use	Free	Design & Usability	Comment: Very generic Abstract: This guidance is intended to assist manufacturers in designing and developing home use devices that comply with applicable standards of safety and effectiveness and other regulatory requirements.
FDA Guidance papers	Guidance: Design Human Factors Principles for Medical Device Labeling	FDA	1997	https://www.gmp-navigator.com/files/guidemgr/227-a.pdf	Free	Any	Comment: Dated
FDA Guidance papers	Guidance: Self-Monitoring Blood Glucose Test Systems for Over the Counter Use	FDA	2020	https://www.fda.gov/media/87721/download	Free	Design & Usability	Comment: Very generic Abstract: This guidance document describes studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for self-monitoring blood glucose test systems (SMBGs) which are for over-the-counter (OTC) home use by lay-users. This guidance document is intended to guide manufacturers in conducting appropriate performance studies and preparing 510(k) submissions for these device types and replaces the final guidance entitled "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on October 11, 2016.
FDA Guidance papers	Guidance: Blood Glucose Monitoring Test System for Prescription Point-of-Care Use	FDA	2020	https://www.fda.gov/media/119829/download	Free	Any	Comment: Contains recommendations for user study participant numbers

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FDA Guidance papers	Guidance: Safety Considerations for Product Design to Minimize Medication Errors	FDA	2016	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-product-design-minimize-medication-errors-guidance-industry	Free	Any	Comment: Very generic testing advices Abstract: The recommendations in this guidance apply broadly to the development of drug and biologic products. Accordingly, this guidance is intended for sponsors of investigational new drug applications (INDs); applicants of new drug applications (NDAs), biologics licensing applications (BLAs), abbreviated new drug applications (ANDAs); and manufacturers of prescription drugs marketed without an approved application or over-the-counter (OTC) monograph drugs. This guidance provides a set of principles for using a systems approach to minimize medication errors relating to product design and container closure design and thus enhance patient safety.
FDA Guidance papers	Guidance: Guidance on Medical Device Patient Labeling	FDA	2001	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling	Free	Design & Usability	Comment: Advice on writing style Abstract: This guidance serves a dual purpose: (1) to assist manufacturers in their development, and (2) to assist Center reviewers in their review and evaluation of medical device patient labeling to help make it understandable to and usable by patients (or family members or other lay persons caring for patients).
FDA Guidance papers	Guidance: Instructions for use – Patient Labeling for Human Prescription Drug and Biological Products	FDA	2022	https://www.fda.gov/media/128446/download	Free	Design & Usability	Comment: Relevant for DDC IFU development, provides recommendations
FDA Guidance papers	Guidance: Medical Devices with Sharps Injury Prevention Features	FDA	2005	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-sharps-injury-prevention-features-guidance-industry-and-fda-staff	Free	Design & Usability	
FDA Guidance papers	Draft Guidance: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development	FDA	2016	https://www.fda.gov/files/about%20fda/published/Human-Factors-Studies-and-Related-Clinical-Study-Considerations-in-Combination-Product-Design-and-Development.pdf	Free	Design & Usability	
FDA Guidance papers	Draft guidance: List of Highest Priority Devices for Human Factors Review	FDA	2016	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/list-highest-priority-devices-human-factors-review	Free	Design & Usability	Abstract: FDA is issuing this guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions (i.e., for PMA, 510(k)). FDA believes these device types have clear potential for serious harm resulting from use error, and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices.
FDA Guidance papers	Draft guidance: Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA	FDA	2017	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/comparative-analyses-and-related-comparative-use-human-factors-studies-drug-device-combination	Free	Design & Usability	Abstract: This guidance is intended to assist potential applicants who plan to develop and submit an abbreviated new drug application (ANDA) to seek approval of a proposed combination product that includes both a drug constituent part and a delivery device constituent part.
FDA Guidance papers	Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling	FDA	2015	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling	Free	Design & Usability	Comment: Testing instructions for devices Abstract: This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices.
FDA Guidance papers	Draft guidance: Content of Human Factors Information in Medical Device Marketing Submissions	FDA	2022	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions	Free	Any	
FDA Guidance papers	Guidance: Application of Human Factors Engineering Principles for Combination Products: Questions and Answers	FDA	2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/application-human-factors-engineering-principles-combination-products-questions-and-answers	Free	Any	
FDA Guidance papers	Guidance: Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications	FDA	2018	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contents-complete-submission-threshold-analyses-and-human-factors-submissions-drug-and-biologic	Free	Any	
FDA Guidance papers	Draft guidance: Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products	FDA	2024	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products	Free	Any	
FDA Guidance papers	Guidance: Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management	FDA	2000	/	n/a	Any	
FDA Guidance papers	Guidance: Policy for Device Software Functions and Mobile Medical Applications	FDA	2022	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications	Free	Legal	
Paper	Beyond the five-user assumption: benefits of increased sample sizes in usability testing (Faulkner, 2003)	Any	2003	https://link.springer.com/article/10.3758/BF03195514	Free	Design & Usability	
Training Curricula	CPUX-Curricula of the UXQB	Any	/	https://www.uxqb.org/de/ux-training-und-zertifizierung/	n/a	Any	Comment: Different ones with different focus available
Newsletter	Institutsjournal - Newsletter by Johner Institute	Any	/	https://www.johner-institut.de/gratis-angebote/instituts-journal/	Free	Design & Usability	Comment: Useful. For readers with basic understanding of the MedTech world, professionals looking to stay up to date



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Category	Title	Regulatory Region	Latest Version	Link	Fee	Audience	Comment
Newsletter	Talking points - Human Factors Newsletter by Emergo UL	Any	/	https://www.emergobyul.com/news/newsletters/talkingpoints	Free	Any	
Database	Manufacturer and User Facility Device Experience (MAUDE) Database	FDA	/	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	Free	Design & Usability	Comment: Useful. Database to find field data and critical incidents with existing products
Webinar Series	Human Factors webinars by Emergo UL	Any	/	https://www.emergobyul.com/events/on-demand-webinars	Free	Design & Usability	
Blog	Blog by Johner Institute	Any	/	https://www.johner-institut.de/blog/	Free	Design & Usability, Legal	
Book	Usability Engineering als Erfolgsfaktor (Geis & Johner, 2015)	Any	2015	https://www.dinmedia.de/de/publikation/usability-engineering-als-erfolgsfaktor/305720340	< 100 €	Any	
Book	Basiswissen Usability und User Experience (Geis & Tesch, 2019)	Any	2019	https://dpunkt.de/produkt/basiswissen-usability-und-user-experience-2/	< 50 €	Design & Usability	
Book	Praxiswissen User Requirements (Geis & Polkehr, 2018)	Any	2018	https://dpunkt.de/produkt/basiswissen-usability-und-user-experience-2/	< 50 €	Any	
Book	Software als Medizinprodukt (Hastenteufel & Renaud, 2019)	Any	2019	https://link.springer.com/book/10.1007/978-3-658-26488-8	< 50 €	Design & Usability	
Book	Human Factors Design Handbook (Woodson, 1992)	Any	1992	https://www.amazon.de/Human-Factors-Design-Handbook-Information/dp/B00XX9TPKQ/ref=sr_1_2?__mk_de_DE=%C3%85M%C3%85%C5%BD%C3%95%C3%91&dib=eyJ2ljoIMSJ9.gDO9WS_c6RBGITmDELdYv4kCS88aq_SrmgldBi0-J86qXAIL-G5EGw3EpxhBJDhNlYmvEfsul8aMEEYRAVvRb19mceslNrqXWolhRbMFzUeMNPjRjOcbvbtff0XyQouEmrSf7PhiAo5xsfNhpVxGUB08Kmj0lo8NjvgCpVTNmBfnrD2pGOnqUUPt5NwbfYFztUpi_Jg42OepNAUo6ihLasDWDXxuttUv5u87YeOltgtQ.VNS0IUY0nSXSublc0nn67RqsNzYyzK5VPsG4QonYkqM&dib_tag=se&keywords=Human+Factors+Design+Handbook+%28Woodson%2C+1992%29&qid=1757347642&s=books&sr=1-2	< 100 €	Design & Usability	
Book	Human Engineering MIL-STD-1472H (2020)	Any	2020	https://www.amazon.de/-/en/Human-Engineering-MIL-STD-1472H-Sept-2020/dp/B0BJYJPLLY	> 200 €	Design & Usability	
Book	Introduction to Human Factors Engineering (Wickens, Lee, Gordon-Becker & Liu, 2013)	Any	2013	https://www.amazon.de/-/en/Introduction-Human-Factors-Engineering/dp/0131837362	< 100 €	Any	
Book	Medical Device Use Error: Root Cause Analysis (Wiklund, Dwyer & David, 2016)	Any	2016	https://www.amazon.de/Medical-Device-Use-Error-Analysis/dp/1498705790	< 200 €	Design & Usability	
Book	Usability Testing of Medical Devices (Wiklund, Kendler & Strohlic, 2015)	Any	2015	https://www.amazon.com/Usability-Testing-Medical-Devices-Michael/dp/1466595884	< 200 €	Any	
Book	Basiswissen Medizinische Software (Johner, Hölzer-Klöpffel & Wittorf, 2020)	Any	2020	https://www.amazon.de/Basiswissen-Medizinische-Software-Weiterbildung-Professional/dp/3864907438	< 50 €	Any	
Podcast	Der Medizinproduktetalk (Deutsch)	Any	/	https://open.spotify.com/show/1H9MS4y7RmDQsDxM4DfDow	Free	Any	
Podcast	Safe and Effective (English)	Any	/	https://open.spotify.com/show/0DeekzwpPZF1KyBi07ZWlk	Free	Any	
Podcast	Medical Device Insights	Any	/	https://open.spotify.com/show/3Exi0pXePITiac4TYoeAwF	Free	Any	
Website	designwith.care	Any	/	designwith.care	Free	Design & Usability	Comment: Community to exchaneg about design pricniples in MedTech