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The Standard by Number

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Designation	Title of Standard	Abstract
ISO 13485:2016	Medical devices Quality management systems Requirements for regulatory purposes	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. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization. The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes. If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to ISO 13485:2016 reflect any exclusion of design and development controls. If any requirement in Clauses 6, 7 or 8 of ISO 13485:2016 is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.
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ISO 15223-1:2021 /DAmd 1	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements Amendment 1: Addition of defined term for authorized representative and Modified EC REP symbol to not be country or region specific	No Abstract Available
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Abstract /Description of the Standard

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IEC 80001-1:2021	Application of risk management for IT-networks incorporating medical devices Part 1: Safety effectiveness and security in the implementation and use of connected medical devices or connected health software
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ISO/TR 80001-2-7:2015	Application of risk management for IT-networks incorporating medical devices Application guidance Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1

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Designation	Title of Standard
IEC 62366-1:2015+AMD1:2020 CSV	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
AAMI HIT1000-4(PS):2020	Safety and effectiveness of health IT software and systems Part 4: Application of **human factors engineering**
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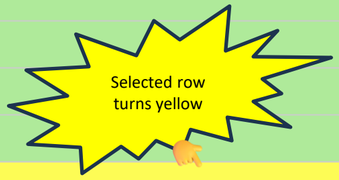

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ANSI/AAMI HE75:2009/(R)2018	**Human factors engineering** Design of medical devices
IEC 62366-1:2015+AMD1:2020 CSV	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
AAMI HIT1000-4(PS):2020	Safety and effectiveness of health IT software and systems Part 4: Application of **human factors engineering**
AAMI TIR51:2014/(R)2017	**Human factors engineering** Guidance for contextual inquiry
AAMI TIR55:2014/(R)2017	**Human factors engineering** for processing medical devices
ISO 13485:2016	Medical devices Quality management systems Requirements for regulatory purposes
ISO 14971:2019	Medical devices Application of risk management to medical devices
ISO 15223-1:2021 /DAmd 1	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements Amendment 1: Addition of defined term for authorized representative and Modified EC REP symbol to not be country or region specific
ISO 15223-2:2010	Medical devices Symbols to be used with medical device labels labelling and information to be supplied Part 2: Symbol development selection and validation
ISO 15378:2017 /Amd 1:2024	Primary packaging materials for medicinal products Particular requirements for the application of ISO 9001:2015 with reference to good manufacturing practice (GMP) Amendment 1: Climate action changes
ISO 16142-1:2016	Medical devices Recognized essential principles of safety and performance of medical devices Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 16142-2:2017	Medical devices Recognized essential principles of safety and performance of medical devices Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
ISO/TS 19218-2:2012	Medical devices Hierarchical coding structure for adverse events Part 2: Evaluation codes
ISO/TR 19244:2014	Guidance on transition periods for standards developed by ISO/TC 84 Devices for administration of medicinal products and catheters
ISO 20069:2019	Guidance for assessment and evaluation of changes to drug delivery systems
ISO/TR 20416:2020	Medical devices Post-market surveillance for manufacturers
ISO 20417:2021	Medical devices Information to be supplied by the manufacturer
ISO/TR 24971:2020	Medical devices Guidance on the application of ISO 14971
IEC 62304:2006 /Amd 1:2015	Medical device software Software life cycle processes Amendment 1

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Human Factors Engineering

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Designation	Title of Standard	Abstract	Link
IEC 62366-1:2015+AMD1:2020 CSV	Medical devices - Part 1: Application of usability engineering to medical devices	IEC 62366-1:2015+A1:2020 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use. This first edition of IEC 62366-1, together with the first edition of IEC 62366-2 (not published yet), cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1:2014. Part 1 has been updated to include contemporary concepts of usability engineering, while also streamlining the process. It strengthens links to ISO 14971:2007 and the related methods of risk management as applied to safety related aspects of medical device user interfaces. Part 2, once published, will contain tutorial information to assist manufactures in complying with Part 1, as well as offering more detailed descriptions of usability engineering methods that can be applied more generally to medical devices that go beyond safety-related aspects of medical device user interfaces. The contents of the corrigendum of July 2016 have been included in this copy. This consolidated version consists of the first edition (2015) and its amendment 1 (2020). Therefore, no need to order amendment in addition to this publication.	https://webstore.iec.ch/en/iec-search/result?q=IEC%2062366-1%3A2015%2BAMD1%3A2020%20CSV
IEC TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	IEC TR 62366-2:2016(E), which is a Technical Report, contains background information and provides guidance that addresses specific areas that experience suggests can be helpful for those implementing a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS both as defined in IEC 62366-1:2015 and as supporting goals other than SAFETY. This technical report is not intended to be used for regulatory purposes. It contains no requirements and only provides guidance and tutorial information. This publication is to be read in conjunction with .	https://webstore.iec.ch/en/iec-search/result?q=IEC%20TR%2062366-2%3A2016
ANSI/AAMI HE75:2009/(R)2018	Human factors engineering Design of medical devices	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).	https://store.aami.org/s/store?_gl=1*1t8pqua*_gcl_au*NzcxMTM3NDg2LjE3MjczMjY5NDI.*_ga*MTQ3NDU1MzMyLjE3MjczMjY5NDI.*_ga_PMV3KJP116*MTcyNzM0MTcyNy4yLjEuMTcyNzM0MTczMi4wLjAuMA..#/store/browse/detail/a152E000006j67OQAQ
	Medical devices Quality management	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. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization. The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed	