List of regulatory applicable documents for medical devices

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This is a list of regulatory relevant documents applying to usability engineering for medical devices. This list was compiled by the Working Group Usability for Medical Devices of the German UPA.

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ATTENTION: This list does not claim to be exhaustive and include all applicable documents for applying usability engineering to medical devices.

European directive and regulations

- Medical Device Directive (93/42/EWG)

- Active Implantable Medical Devices (90/385/EEC)
- In-Vitro Diagnostica (98/79/EG)

Ratified since May 2017 with three to five years of transition period are:

- Medical Device Regulation (2017/745)
- In-vitro Diagnostic Regulation (2017/746)

IEC Standards

- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- IEC TR 62366-2 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
- IEC 62366:2007+AMD1:2014Medical devices – Application of usability engineering to medical devices
- IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- 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
- 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
- IEC 62304:2005/Amd 1:2015 Medical device software –Software life cycle processes
- IEC 82304-1:2016 Health software -- Part 1: General requirements for product safety
- IEC TR 60878:2015 Graphical symbols for electrical equipment in medical practice
- IEC 80601-2-12 - Particular requirements for basic safety and essential performance of critical care ventilators
- IEC 80601-2-13 - Particular requirements for basic safety and essential performance of an anaesthetic workstation

AAMI-Standards

- ANSI/AAMI HE75:2009/(R)2013 Human factors engineering – Design of medical devices
- AAMI TIR49: 2013 Design of training and instructional materials for medical devices used in non-clinical environments
- AAMI TIR50: 2014 Post-market surveillance of use error managementAAMI TIR 51
- AAMI TIR51: 2014 Human factors engineering – Guidance for contextual inquiry
- AAMI TIR55: 2014 Human factors engineering for processing medical devices

- AAMI TIR59:2017 Integrating human factors into design controls
- AAMI TIR61: 2014 Generating reports for human factors design validation results for external cardiac defibrillators
- AAMI TIR 12: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

ISO Standards

- ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices
- ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements
- 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
- 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)
- 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
- ISO 80369 series on small-bore connectors for liquids and gases in healthcare applications with its applicable sub-parts
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CEN

- CEN EN 980:2008 Symbols for use in the labelling of medical devices

Codes of Federal Regulation (U.S.)

- 21 CFR Part 820 Quality System Regulation
- 50.1 CFR Part C

FDA Guidance papers

- Guidance: Applying Human Factors and Usability Engineering to Medical Devices
- Guidance: Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation
- Guidance: Design Control Guidance for Medical Device Manufactures
- Guidance: Design Considerations for Devices Intended for Home Use
- Guidance: Design Human Factors Principles for Medical Device Labeling
- Guidance: Self-Monitoring Blood Glucose Test Systems for Over the Counter Use

- Guidance: Blood Glucose Monitoring Test System for Prescription Point-of-Care Use
- Guidance: Safety Considerations for Product Design to Minimize Medication Errors
- Guidance: Human Factors Points to Consider for IDE Devices
- Guidance: Guidance on Medical Device Patient Labeling
- Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Guidance: Medical Devices with Sharps Injury Prevention Features
- Guidance: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices
- Draft Guidance: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development
- Draft guidance: List of Highest Priority Devices for Human Factors Review
- Draft guidance: Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA

Medicines and Healthcare products regulatory agency (MHRA, United Kingdom)

- Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products Version 1.0 September 2017

Further helpful standards and guidances

- ISO 9186-1:2014 Graphical symbols -- Test methods -- Part 1: Method for testing comprehensibility
- ISO 9241-11 Ergonomic requirements for office work with visual display terminals (VDTs) -- Part 11: Guidance on usability
- ISO 9241-110 Ergonomics of human-system interaction -- Part 110: Dialogue principles
- ISO 9241-171 Ergonomics of human-system interaction -- Part 171: Guidance on software accessibility
- ISO 9241-210 Ergonomics of human-system interaction -- Part 210: Human-centred design for interactive systems
- Further standards in the ISO 9241 series might be helpful to apply.

- ISO/IEC 25062:2006 Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability test reports
- ISO/IEC 25064:2013 Systems and software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability: User needs report

- 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
- Further standards of 25000 series might be helpful to apply.

- FDA Guidance: Mobile Medical Applications