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+AMD1:2014 Medical 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 management
• 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 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

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

• FDA Guidance: Mobile Medical Applications