Regulation and standards

Patient Safety

- 2017/745/EC: Medical Devices Regulation
- 93/42/EEC: Medical Devices Directive

Privacy

- 2016/679/EC: General Data Protection Regulation

Accessibility

- 2016/2102/EC: Directive on accessibility of websites and mobile applications of governmental bodies.

Usability

- ISO/IEC 40500:2012: W3C Guidelines; WCAG 2.0 https://www.w3.org/WAI/intro/wcag
- ISO 9241-210: 2010: Ergonomics of human-system interaction   -- Part 210: Human-centred design for interactive systems

Quality

- ISO/IEEE 11073:2009 Health Informatics - Point of Care medical device communication
- ISO 13485: 2016 Medical devices – Quality management systems: requirements for regulatory purposes
- ISO 14155:2011 – Clinical investigation of medical devices for human subjects – Good clinical practice
- ISO/TR14969:2004 Medical devices – Quality management systems: Guidance on the application of ISO 13485
- ISO 14971:2007 Medical Devices: Application of Risk management to Medical Devices. And IEC/TR80002-1 Guidance on ISO 14971 for medical device software.
- ISO/IEC 25010:2011: Systems and software engineering – Systems and software quality requirements and evaluation

Security

- ISO/IEC 27000 Information technology – Security techniques – information security management systems – overview and vocabulary
- ISO/IEC 27001:2013: Information Security Management Systems
- ISO/IEC 27002:2013: Security Techniques – Code of practice for information security controls
- OWASP https://www.owasp.org/index.php/Category:OWASP_Application_Security_Verification_Standard_Project

Other

- IEC 60601-1: Basic safety and performance
- IEC 62304:2006 Health Software – Software lifecycle Processes
- IEC 62366 – Medical Devices: Application of Usability engineering to medical devices.
- AAMI TIR45:2012 Guidance on the use of AGILE practices in the development of medical device software
- CEN/TS 15260 Health Informatics – Classification of safety risks from health informatics products.
- 2011/83/EC: Consumers' rights Directive
- 2000/31/EC: eCommerce Directive
- 2005/29/EC Unfair Commercial Practices Directive