Fill the gap!

New product standard: IEC 82304-1

SWEDISH STANDARDS INSTITUTE
STANDARD DEVELOPER 2016

SWEDISH Medtech

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QAdvis team

QAdvis key competence areas

QMS in-the cloud
Turn key quality systems
Sharepoint based
Digital signatures
Efficient and lean
Validated and compliant

System development
Project management
Product software validation
Regulated software validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting
Interim management
Expert advise
Audits/Mock audits/assessments
Warning letter, compliance projects
PMA, 510k, CE-mark, EC-cert
Global regulatory support
Vigilance, recall, post market survy
Clinical evaluation/clinical study

Training/courses
CE-marking
ISO 13485
IEC 62304 & IEC 82304-1
IEC 60601-1
SW life cycle
SW risk management
FDA's QSR
Risk management
Etc

Lean and Six Sigma
Training and Consulting
In cooperation with Oriel
Stat-A-Matrix Inc.

European Authorised Representation
Providing European representation for non-EU MedTech companies

Active member of EAAR: European Association of Authorised Representatives

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Agenda

- Background
- Scope
- Content
- Relations to other standards
- Status

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Background

- IEC 60601 - series of technical standards for the safety and effectiveness of medical electrical equipment
- Covers PEMS Programmable Electrical Medical Systems

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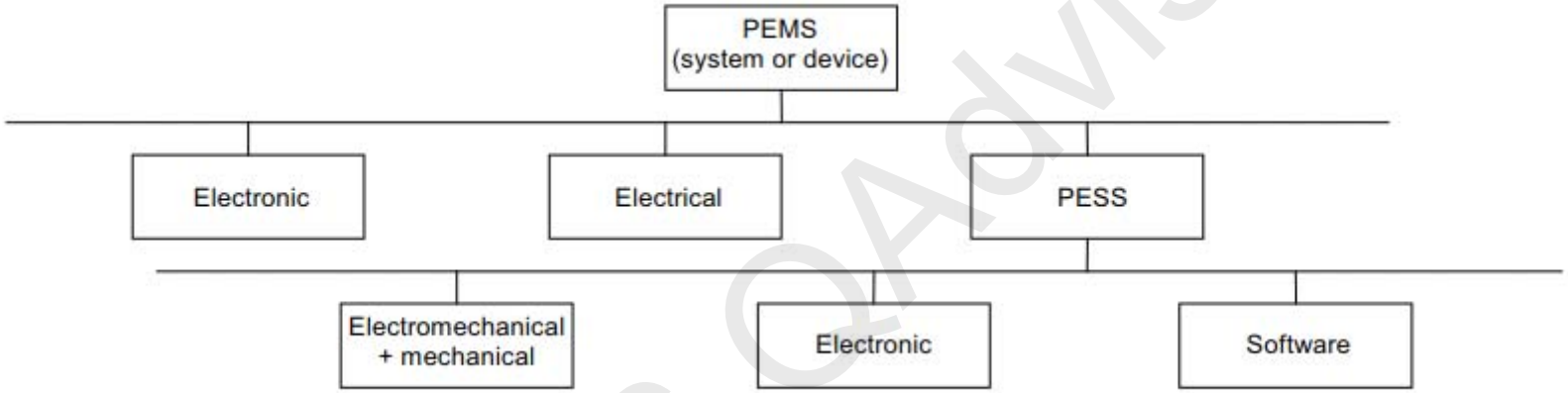
Background



3.90
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM
PEMS
ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

3.91
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS
system based on one or more central processing units, including their software and interfaces

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Background

- 60601-1, ed. 3, 2005 => 60601-1, ed. 3.1, 2012

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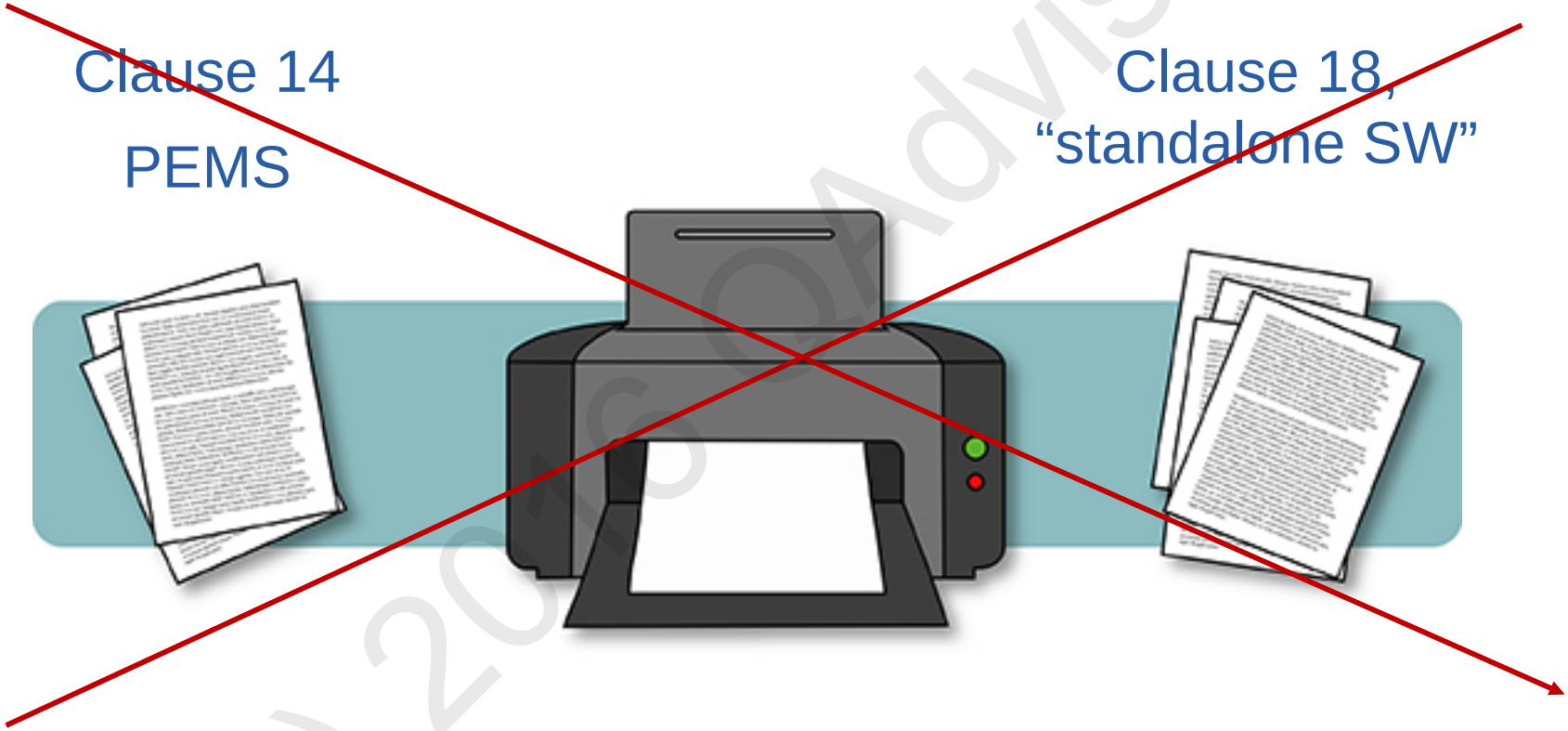
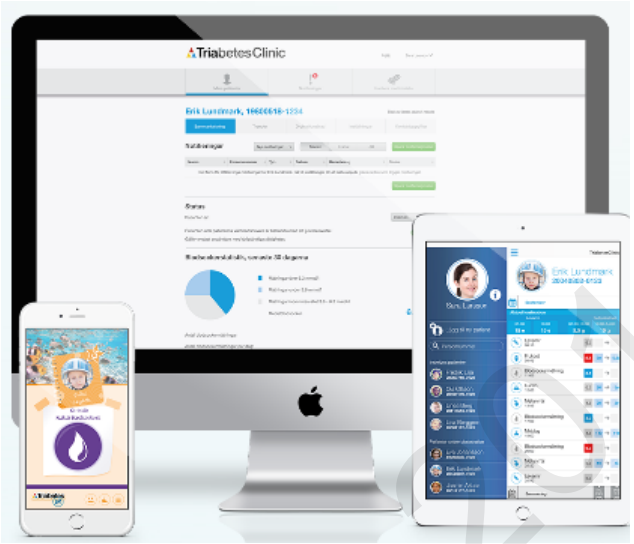
Background



- **New standard needed! => IEC 82304-1**

Scope



1. SW for general computing platforms
2. Health software products
3. Safety & security
4. Manufacturers
5. Entire lifecycle

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Scope

SW for general computing platforms

- Standalone software
- Software medical device
- Software-only products
- SaMD, Software as a Medical Device
- SaaS, Software as a Service

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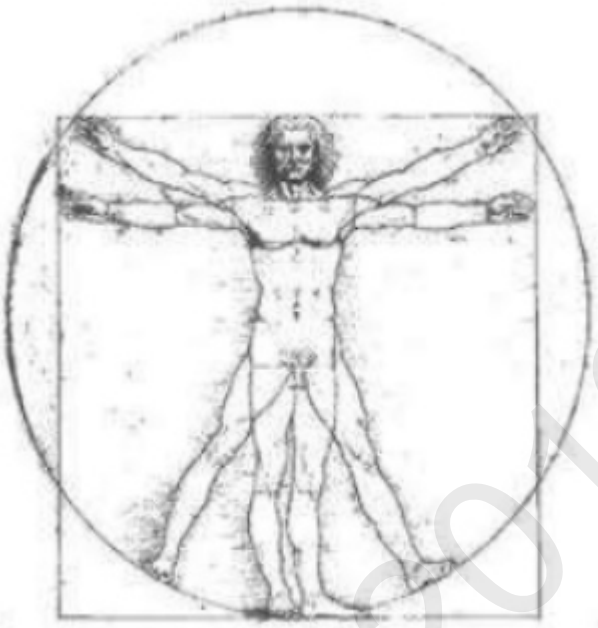
Scope



Health

WHO definition: “Health is a
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 1946)

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Scope

Health software

Software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

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Scope

Safety

Freedom from unacceptable risk

Security

Protection of information and data so that unauthorized persons or systems cannot read or modify them and authorized persons or systems are not denied access to them

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Scope

Manufacturer

Natural or legal person with responsibility for the design, development, packaging, or labelling of a health software product, or adapting a health software product before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

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Scope

Entire lifecycle

- Design
- Development
- Validation
- Installation
- Maintenance
- Disposal

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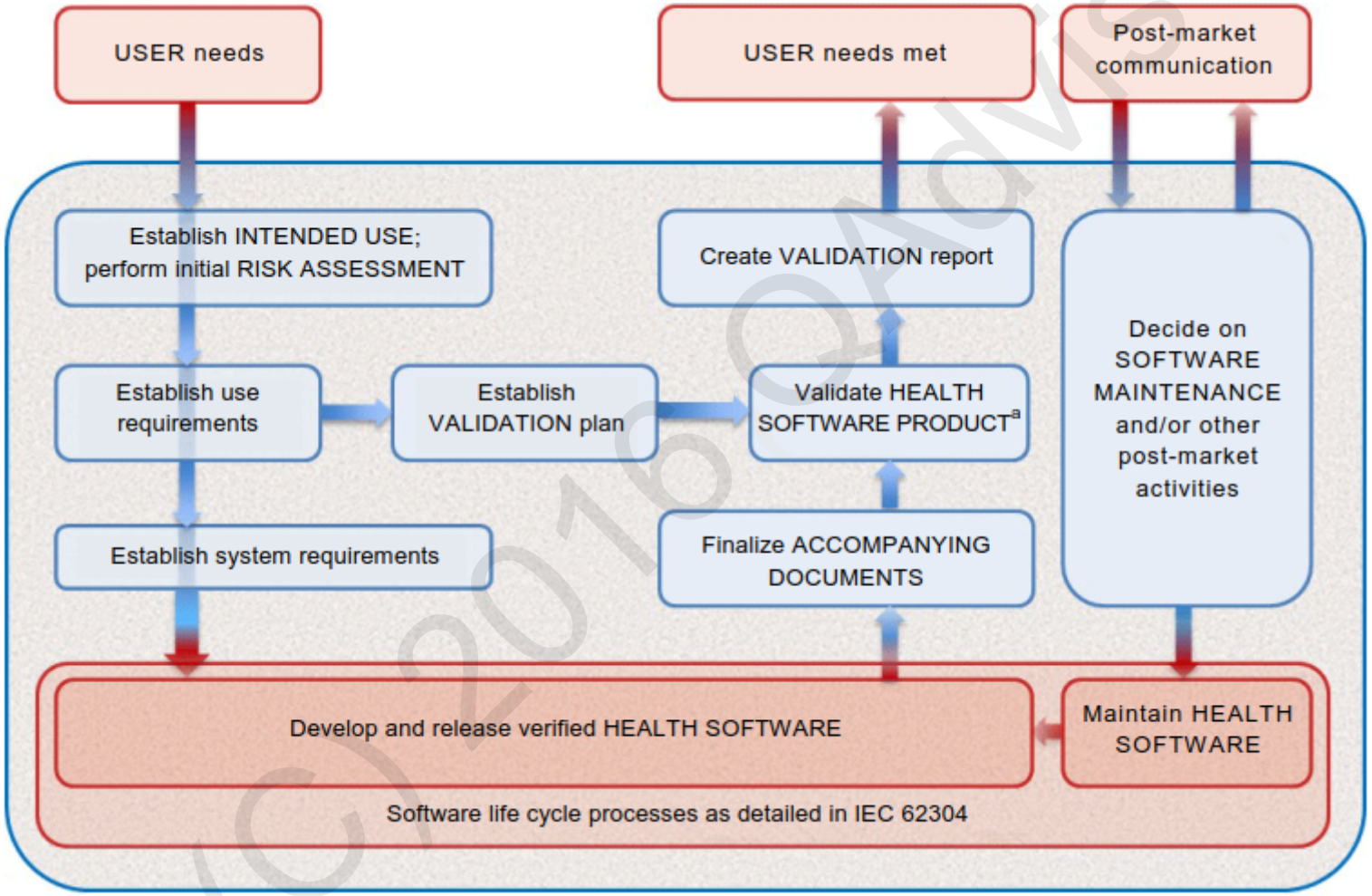
Content

Product standard

Content



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Content

- Requirements specification
- Software life cycle processes
- Validation
- Identification
- Accompanying documents
- Post-market activities

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Content

§ 4 Health software product requirements

- Intended use
- Product risk assessment
- Use requirements
- System requirements

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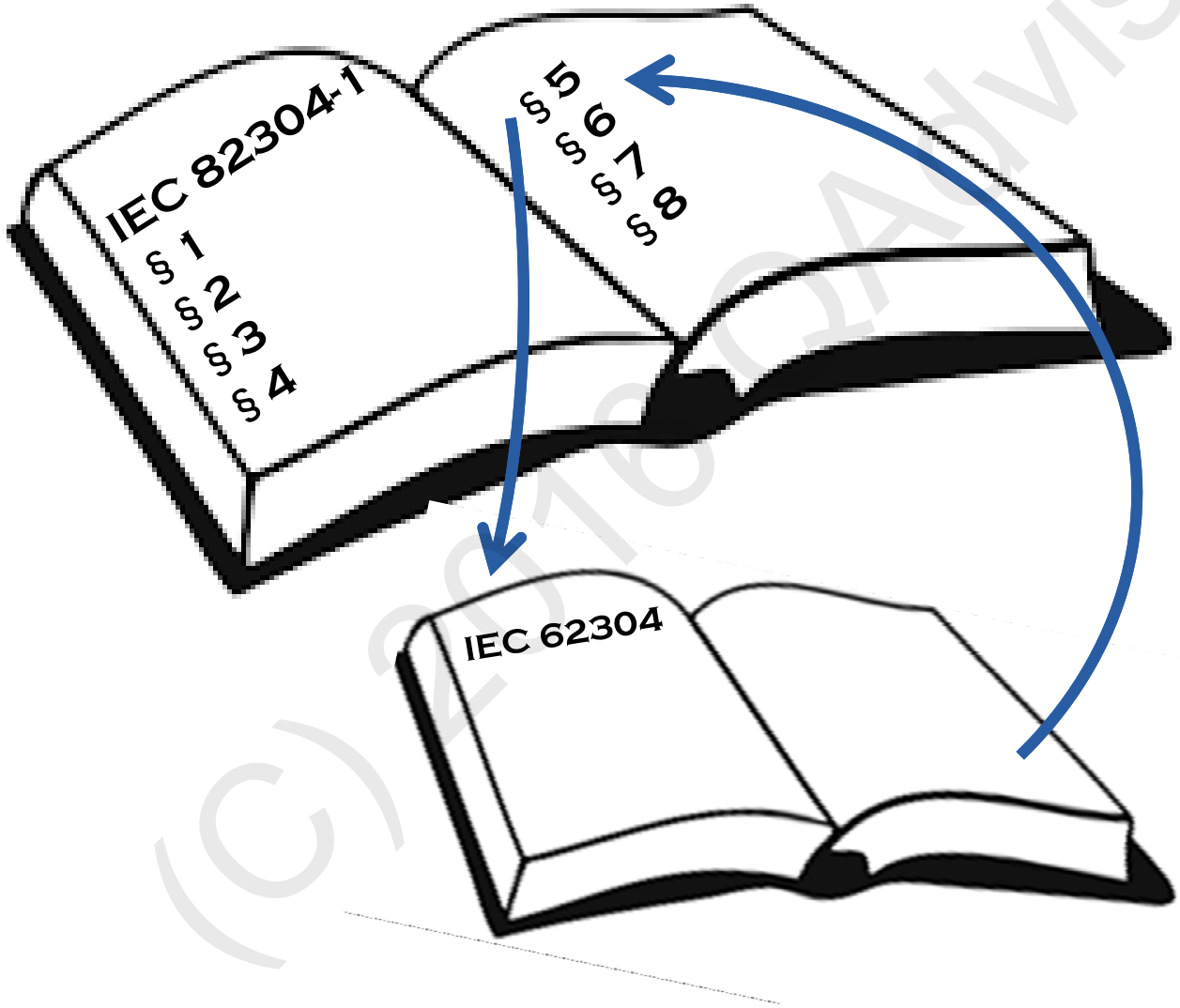
Content



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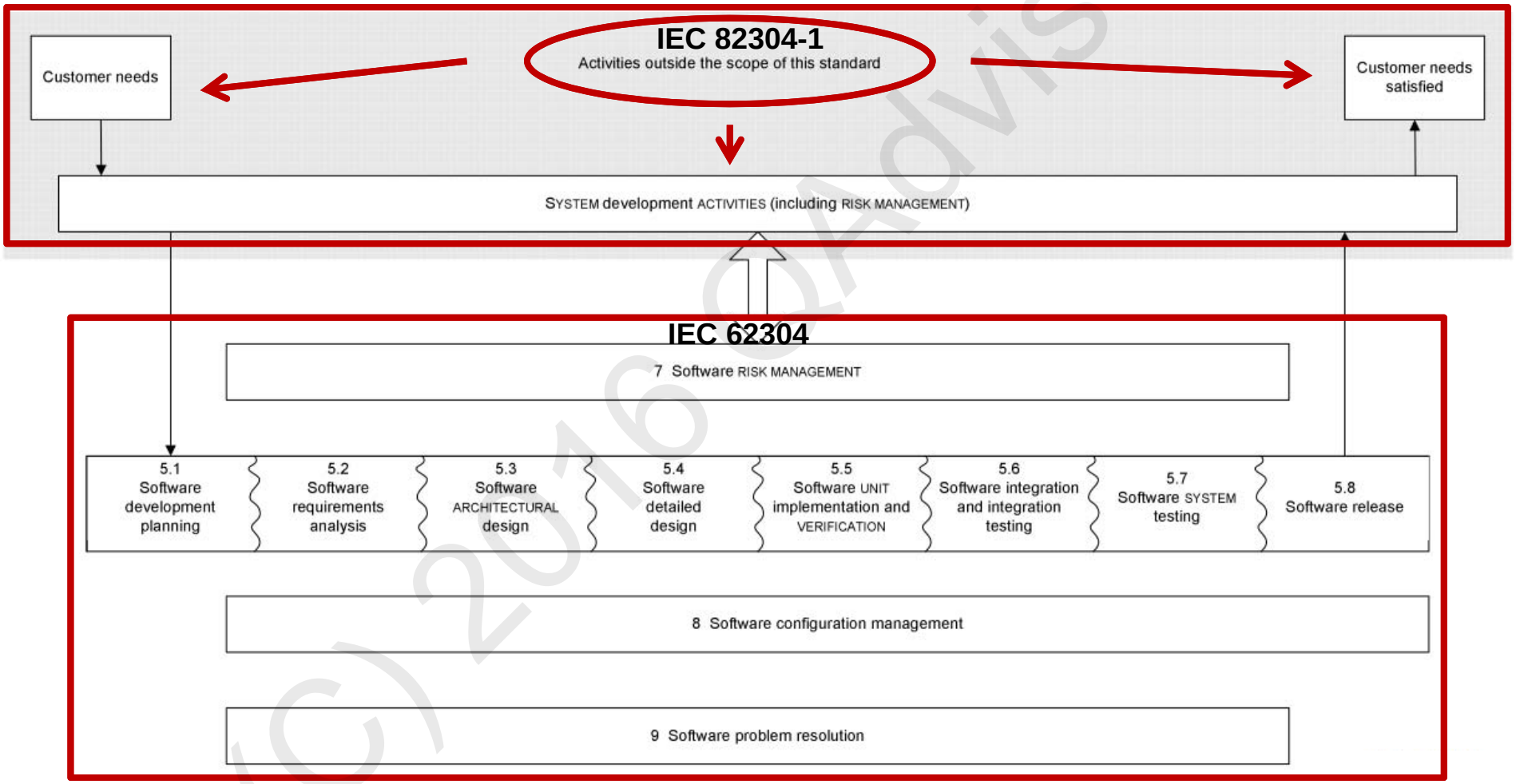
Content



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Content

§ 6 Health software product validation

- Address Use requirements
- Plan
- Perform
- Report

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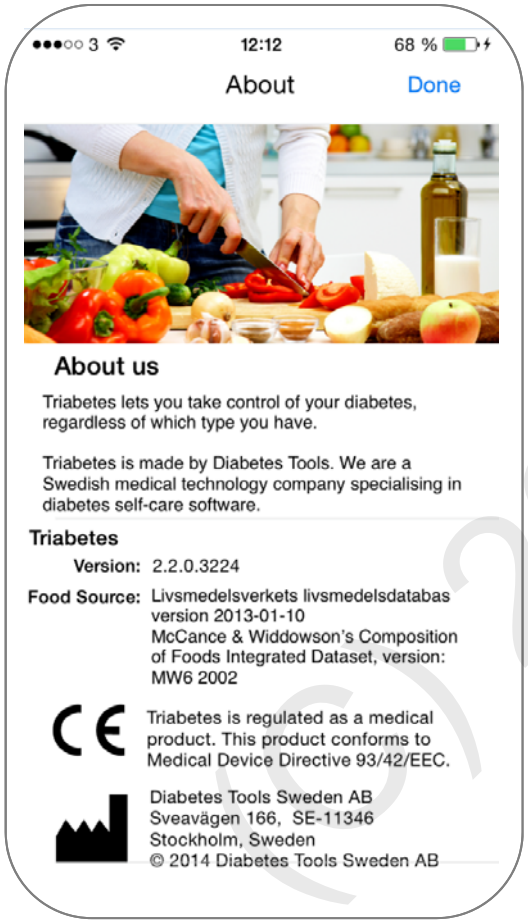
Content

§ 7.1 Health software product identification



- Manufacturer name / trademark
- Product name / type reference
- Version identifier

Content

§ 7.2 Health software product accompanying documents

- Manufacturer contact information
- Product identification
- Version
- Instructions for use
- Technical description

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Content

§ 7.2.2 Instructions for use

- Health software description
- Warnings and notices
- Installation
- Start-up procedure
- Shut-down procedure
- Operating instructions
- Messages
- Decommissioning and disposal
- Technical description

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Content

§ 7.2.3 Technical description

- System requirements
- Details of the supported SW platforms
- Environmental conditions transport/storage
- Characteristics
- Installation requirements/restrictions
- Maintenance
- Technical security options
- Detection of security breach

Content

§ 7.2.3.2 Use in non controlled IT network

- Technical specification, characteristics & configuration
- Information flow
- Hazardous situations
- Risk information

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Content

§ 8 Post-market activities

- Maintenance
- Re-validation
- Post-market communication
- Decommissioning and disposal

Content

§ 8.2 Maintenance

- Errors impacting safety and/or security
- Modifications

IEC 62304

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Content

§ 8.3 Re-validation

- Affected parts
- Update Validation plan
- Supported HW/SW platforms

Content

§ 8.4 Post-market communication

- Security vulnerabilities
- New releases
- Upgrade or not

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Content

§ 8.5 Decommissioning and disposal

- Safeguarding personal and health-related data
- Use requirements

Relations to other standards

- IEC 60601, IEC 61010, ISO 14708
- IEC 62304
- ISO 14971
- IEC 80001-1, IEC 80001-2-2
- IEC 62366-1

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Status

Next step

- FDIS, Sep 02, 2016
- Voting ends Oct 14, 2016
- Publication, Dec 2016

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Status

Next step

- Harmonized standard?

QAdvis can support you as needed

IEC 82304-1

- Gap analysis
- Implementation
- Compliance assessment
- Training
- Performing specific activities e.g. software risk management

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Thank you

Questions & Answers

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