Health Apps Quality & Reliability – new Technical Specification EN ISO/IEC TS 82304-2

Your Regulatory Partner

QAdvis

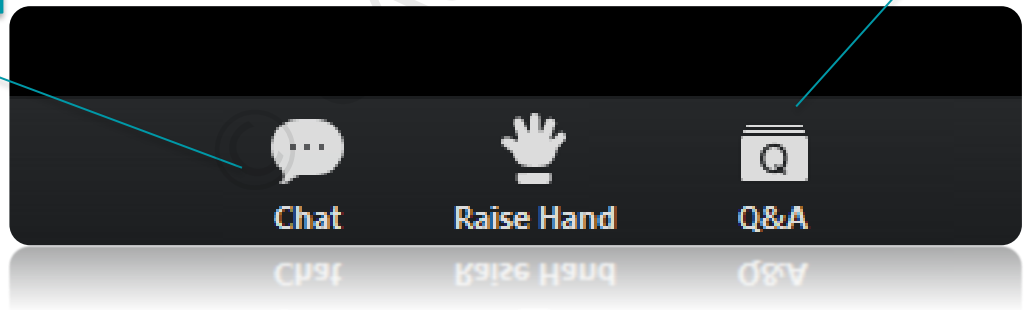
Practical issues

- Presentation will be recorded
- Questions answered after the presentation
- Short evaluation in the end

Zoom webinar

‘Chat’- used to get in touch with the administrator, will not be answered by the presenter.

Ask your questions, via ‘Q&A’.



Agenda

- Presentation (30 min)
  - Intro
  - Background & Purpose
  - Scope
  - Content
  - Status & timeline
- Q&A (15 min)

QAdvis – Key competence areas

QMS In-the-cloud

Turnkey QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management (ISO 14971)
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

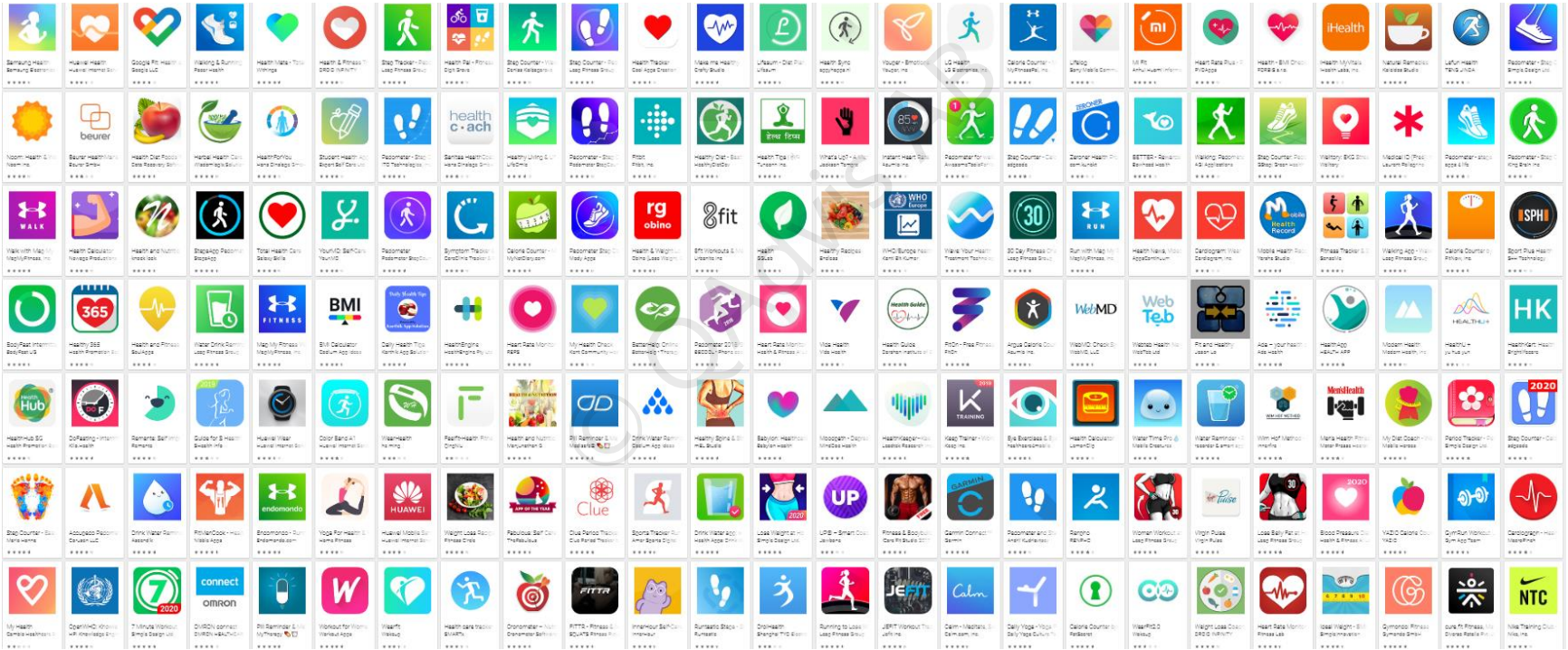
QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

Presentation of the speaker Maria Rickardsson

- >20 years experience in regulatory frameworks, quality assurance and risk management in medical device, software and telecom
- Extensive experience from ISO 13485, ISO 14971 and IEC 62304
- Member of standardization committees for medical device software and medical device IT networks

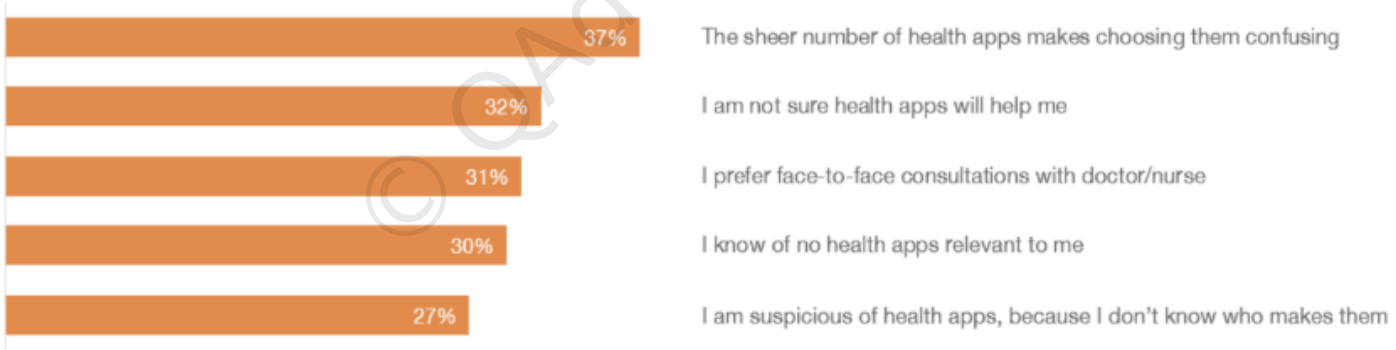
Why health apps need a new Technical Specification



Patient perspective

- Unclear what is the right App

Chart 9: Significant barriers to health app use exist from the patient perspective: too many apps to choose from, not enough certainty that they offer any value, and concern that they will replace face-to-face consultations with doctors or nurses.



EU Single Market Strategy

https://ec.europa.eu/growth/single-market/european-standards/ict-standardisation

National App Quality Frameworks

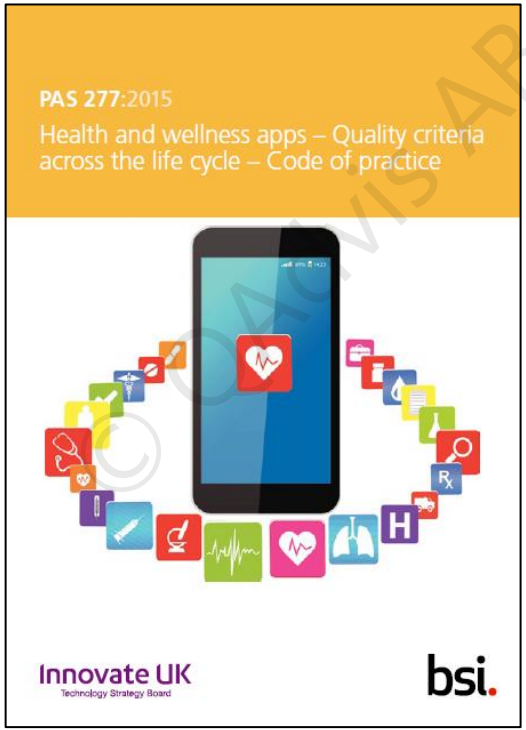
GIG CYMRU NHS WALES
Iechyd Cyhoeddus Cymru
Public Health Wales
Recommended by Public Health Wales

Distintivo AppSaludable
Reconocimiento de aplicaciones de salud para su uso de forma fiable, minimizando riesgos.
Agencia de Calidad Sanitaria de Andalucía
CONSEJERÍA DE SALUD Y FAMILIAS

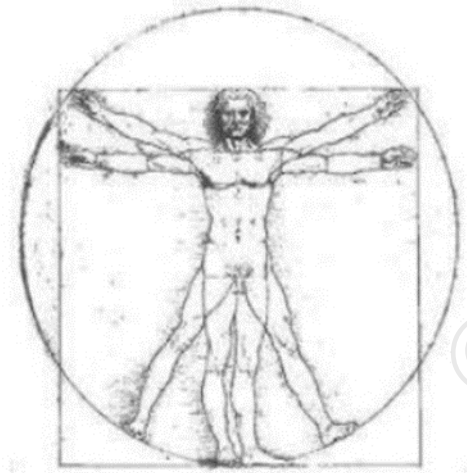
knmg voor verantwoorde medische zorg

Medical App Checker:
Evaluation of Mobile Medical Apps

Starting point - EN ISO/IEC TS 82304-2



Definition of HEALTH



health

- state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

www.who.int/about/who-we-are/constitution

Definition of HEALTH SOFTWARE

health software

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

IEC 82304-1:2016

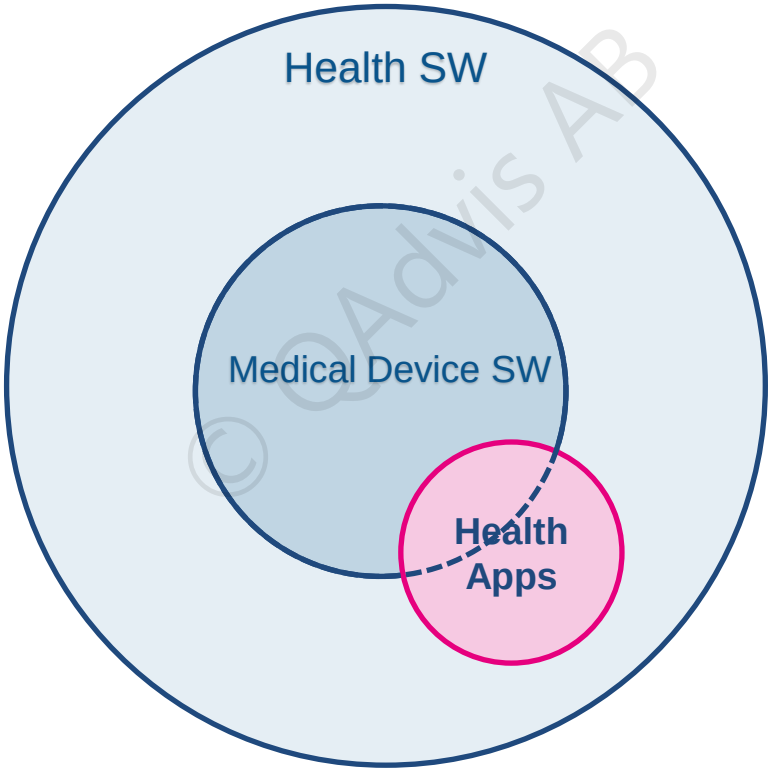
Definition of App

App

- software application that can be executed (run) on a computing platform, and is typically a small application run or accessed on mobile devices

BSI PAS 277:2015, 3.1.1

Scope of EN ISO/IEC TS 82304-2



Definition of MEDICAL DEVICE

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

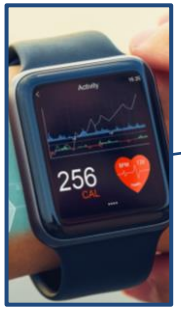
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

REGULATION (EU) 2017/745 on medical devices

Scope of EN ISO/IEC TS 82304-2



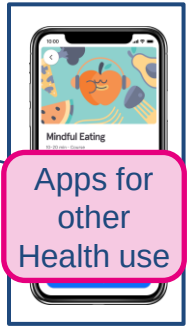
Health SW

SW part of HW products

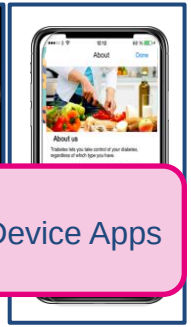
SW only products

Medical Device SW

Health Apps

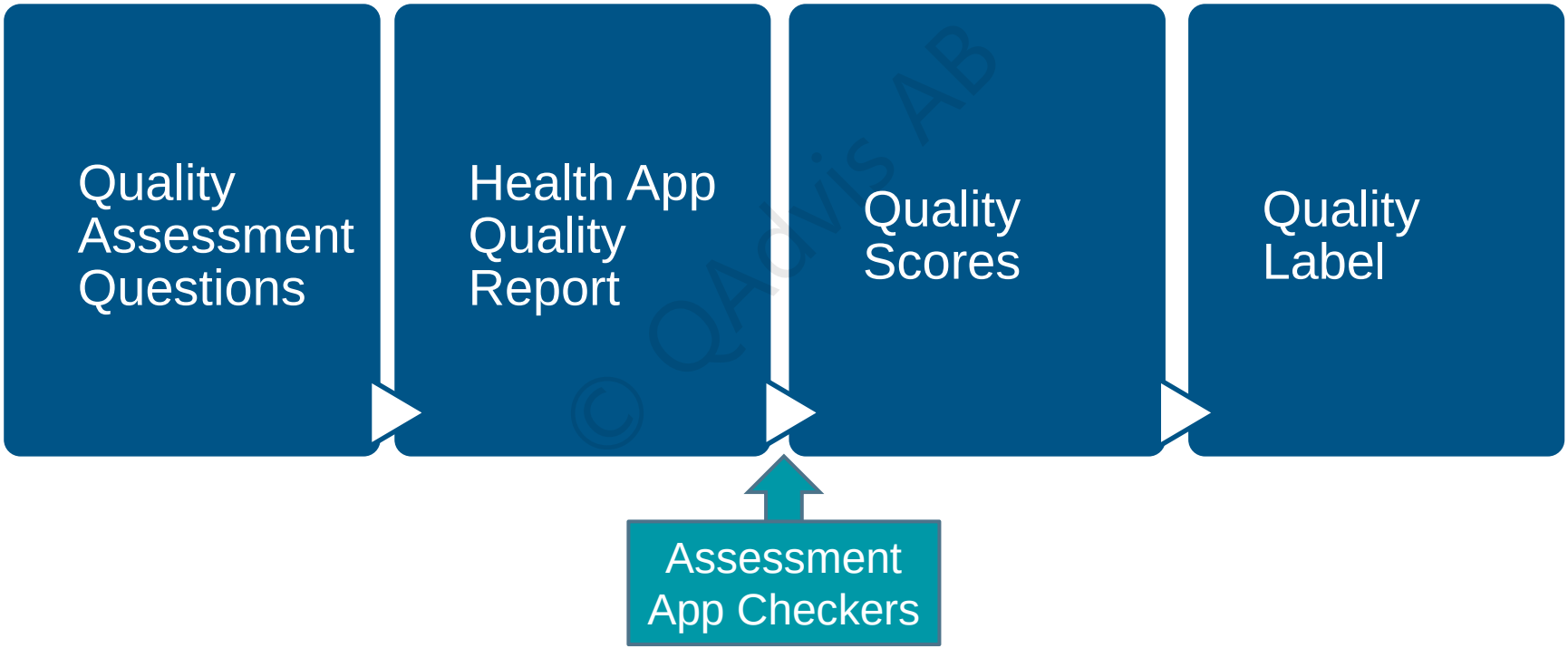


Apps for other Health use



Medical Device Apps

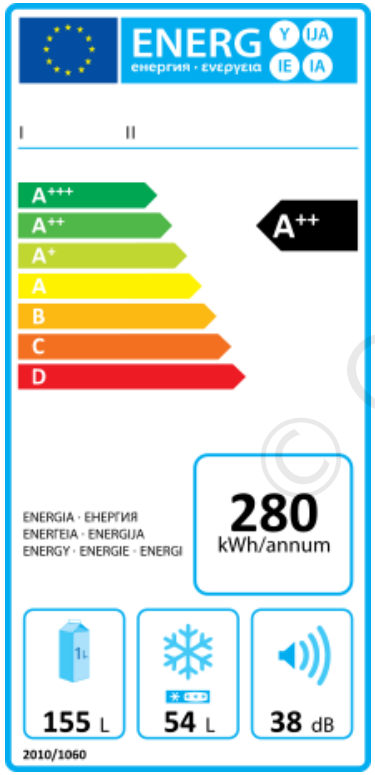
Content – Quality Criteria



Quality Assessment Questions

A	• Product information
B	• Clinical benefit and safety
C	• Accessibility and usability
D	• Privacy and security
E	• Technical performance and interoperability

Score & Label



App identification

Benefit

Score

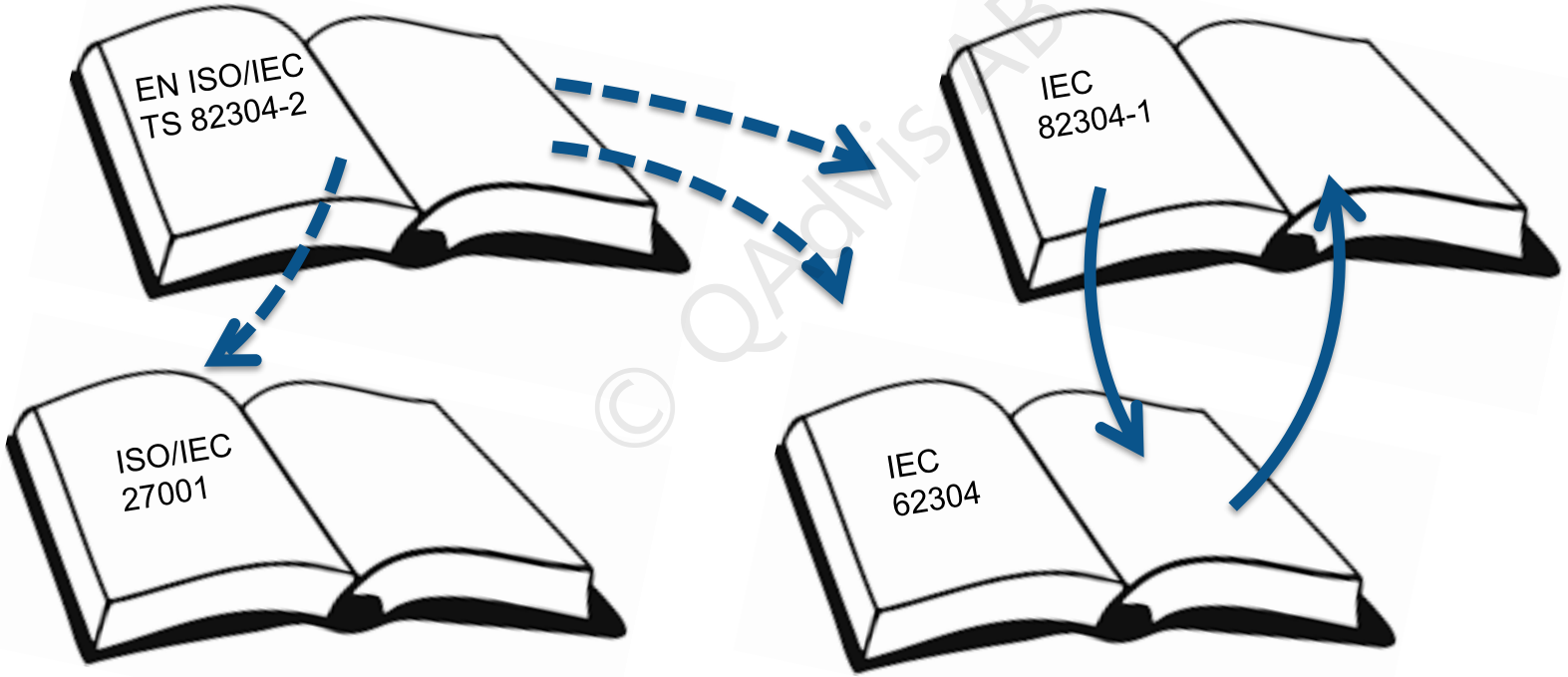
Contact

Referenced standards

Referenced standards

- **IEC 82304-1**
  Health software — Part 1: General requirements for product safety
- **IEC 62304**
  Medical device software — Software life cycle processes — Amendment 1
- **ISO/IEC 27001**
  Information technology — Security techniques — Information security management systems
- **cMHAFF**
  HL7 Consumer Mobile Health Application Functional Framework

Standards relations



IEC 82304-1 Health software — Part 1: General requirements for product safety

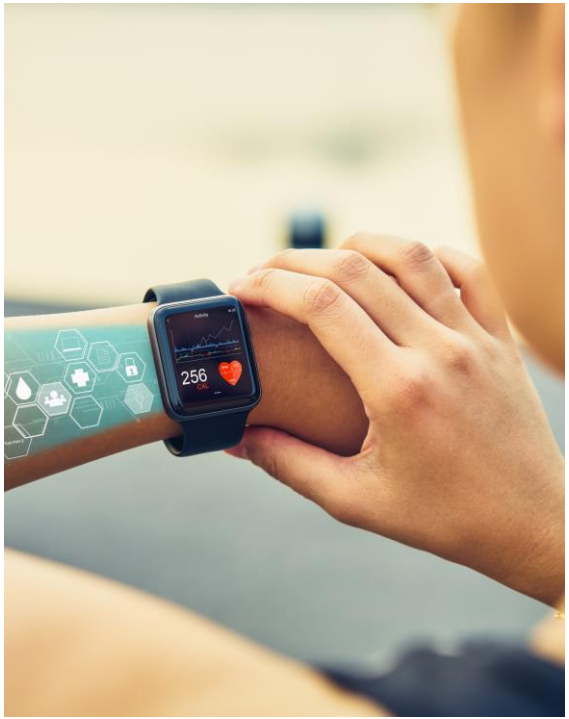
- Requirements specification
- Software life cycle processes
- Validation
- Identification
- Accompanying documents
- Post-market activities

Timeline

- August 2020 – DTS voting starts
- October 2020 – voting closed
- December 2020 – TS published
- Next edition?

DTS – Draft Technical Specification TS – Technical Specification

Summary



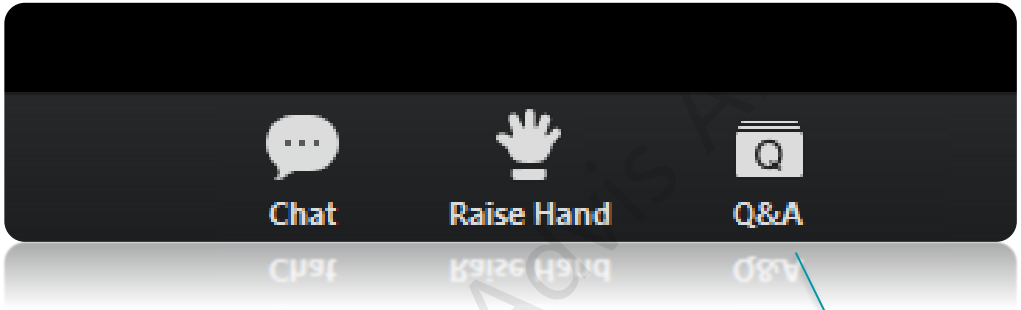
- New Technical Specification by end of this year
- Common Quality Assessment Framework
- Help users
- Help App Developers

QAdvis services

- Courses
  - Medica Device SW process design (IEC 62304)
  - CE - marking
  - Technical Documentation
  - IVDR / MDR
  - Risk management,
  - ISO 13485:2016
- Product specific workshop
- Internal trainings
- GAP analysis and implementation plan
- Quality Management System
- Auditing
- Risk management
- Clinical evaluation

www.qadvis.com/courses-and-seminars/

Thank you for your attention!
Questions & Answers



Ask your questions now, via ‘Q&A’.

Evaluation