MDR FROM PRIVATE HEALTH CARE SERVICE PROVIDER PERSPECTIVE

AHMED PROJECT FINAL SEMINAR

22.11.2022 JANI HOPIA

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The New Era of Health

Medical device definition by MDR (Medical Device Regulation 2017/745)

‘medical device’ means 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.

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Rule 11 in MDR (Medical Device Regulation 2017/745)

"Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

Death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.
All other software are classified as class I."

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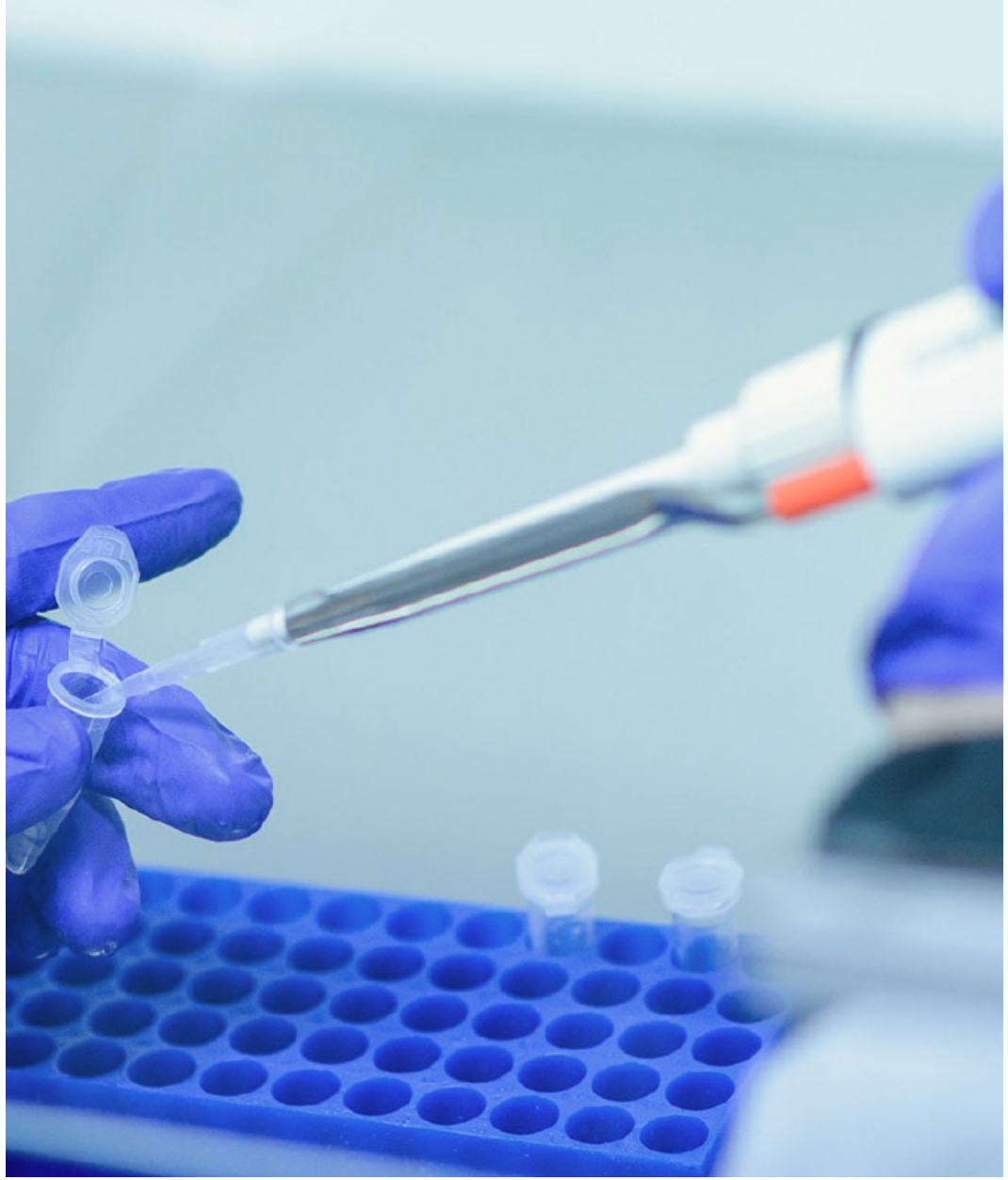
WHAT IT MEANS TO TERVEYSTALO?

Terveystalo will become a medical device manufacturer

- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- Terveystalo is ISO 13485:2016 certified since August 2021
- All medical device software development activities must the MDR compliant
- Other regulations and legislation



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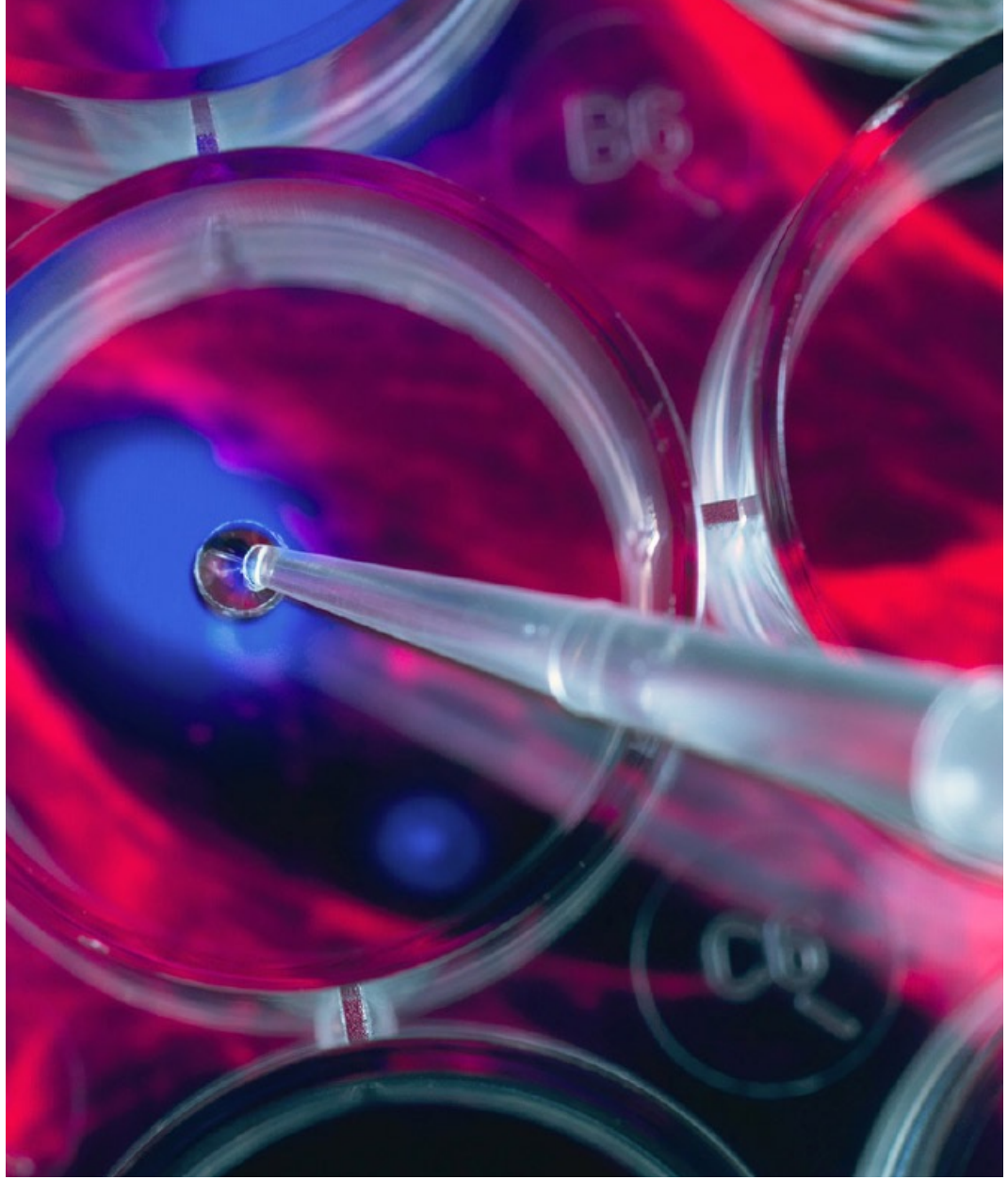
FOUNDATIONS FOR SaMD DEVELOPMENT

CLINICAL KNOWHOW

- **Intended purpose**
- MEDDEV 2.7.1 rev 4 Clinical evaluation - Guide for manufacturers and notified bodies
- MEDDEV 2.7.1. rev chapter 6: Who should perform the clinical evaluation?
- MDCG 2020-1 Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software



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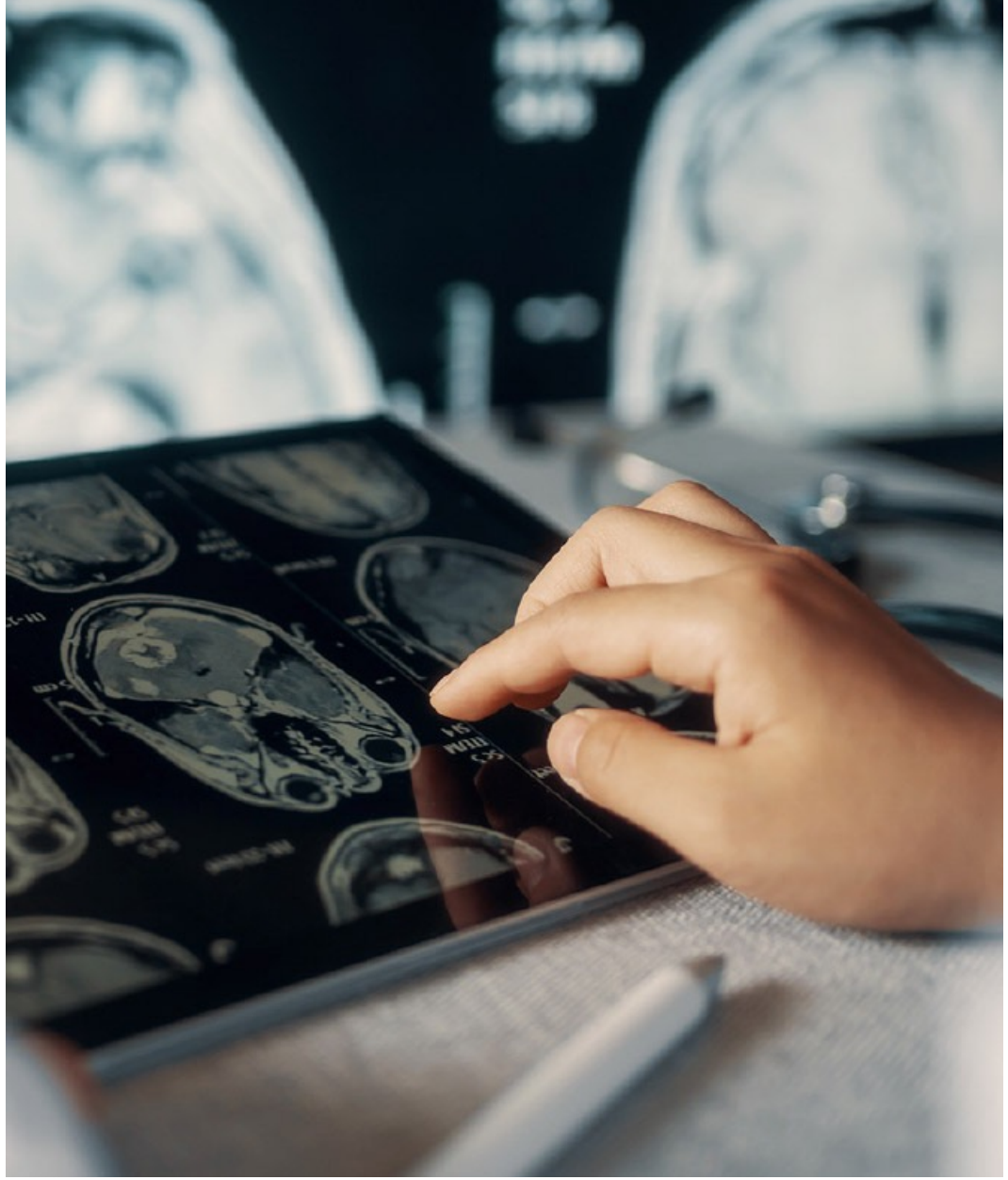
FOUNDATIONS FOR SaMD DEVELOPMENT

DATA HANDLING AND MANAGEMENT

- GDPR (General Data Protection Regulation)
- Act on the Secondary Use of Health and Social Data
- Other relevant legislation and regulation



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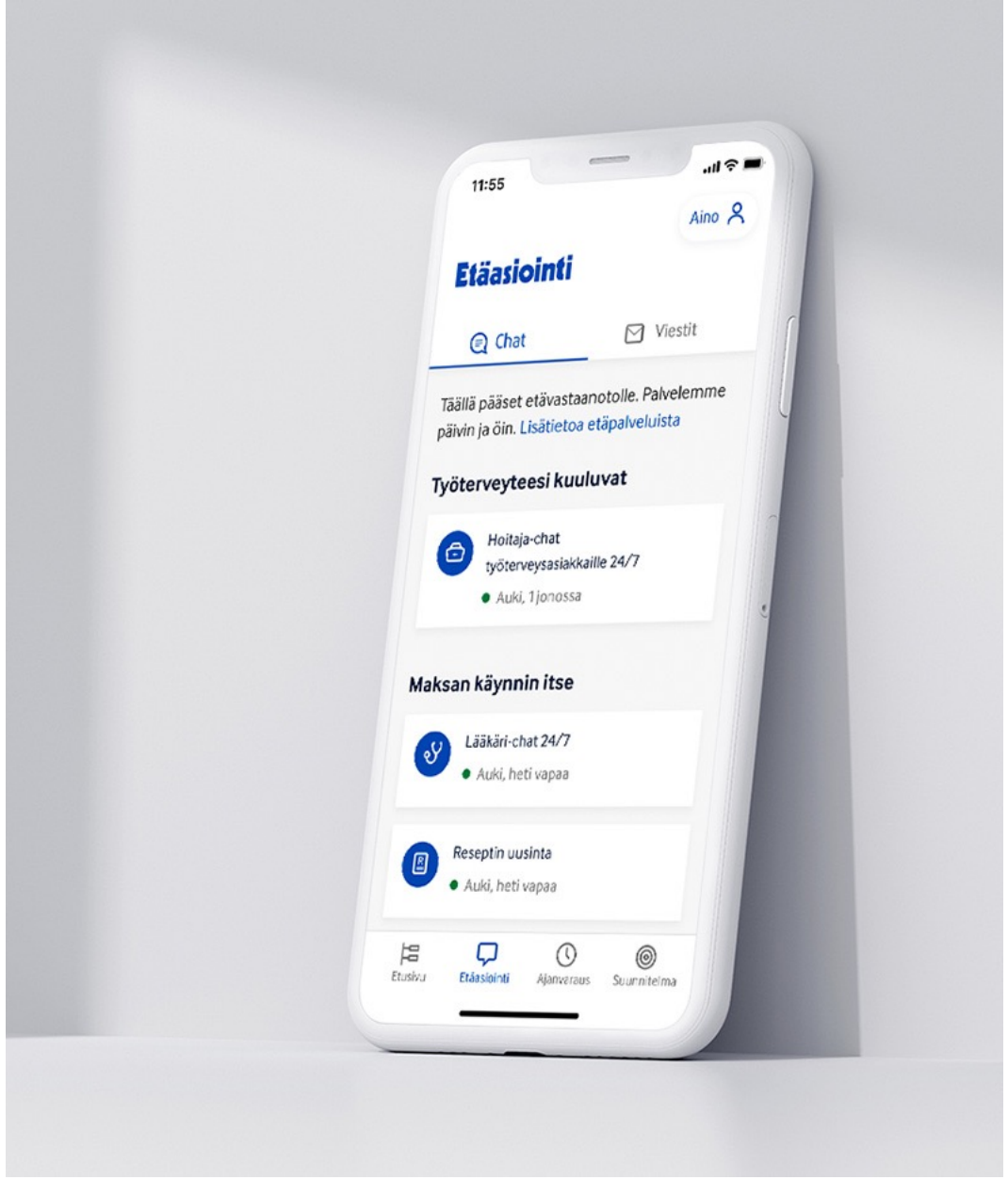
FOUNDATIONS FOR SaMD DEVELOPMENT

MEDICAL DEVICE SOFTWARE DEVELOPMENT

- IEC 62304:2006/Amd 1:2015 Medical device software — Software life cycle processes
- ISO 14971:2019 Medical devices — Application of risk management to medical devices
- IEC 62366:1-2015 Medical devices — Part 1: Application of usability engineering to medical devices
- Other relevant regulation



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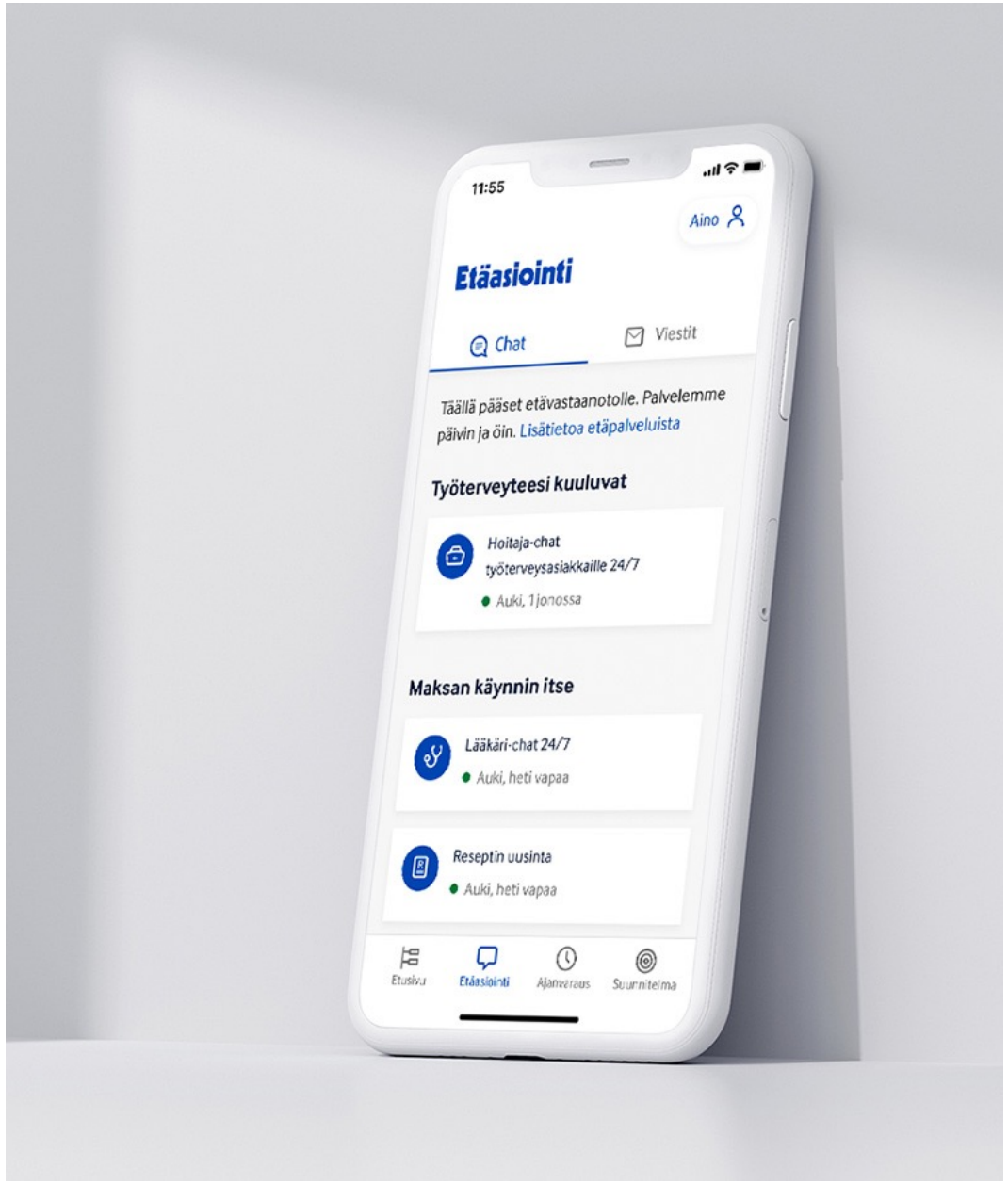
CHALLENGES aka REALITY

- SaMD development is very front heavy
- Strict requirements for SW development
  - SW tool validation
  - Safety classification
  - Architecture
  - Risk management
  - Traceability
  - Usability
  - Verification and validation
  - SW maintenance
  - Etc.
- Post market surveillance activities
- Timelines are very challenging
  - Notified Bodies needed for CE registration



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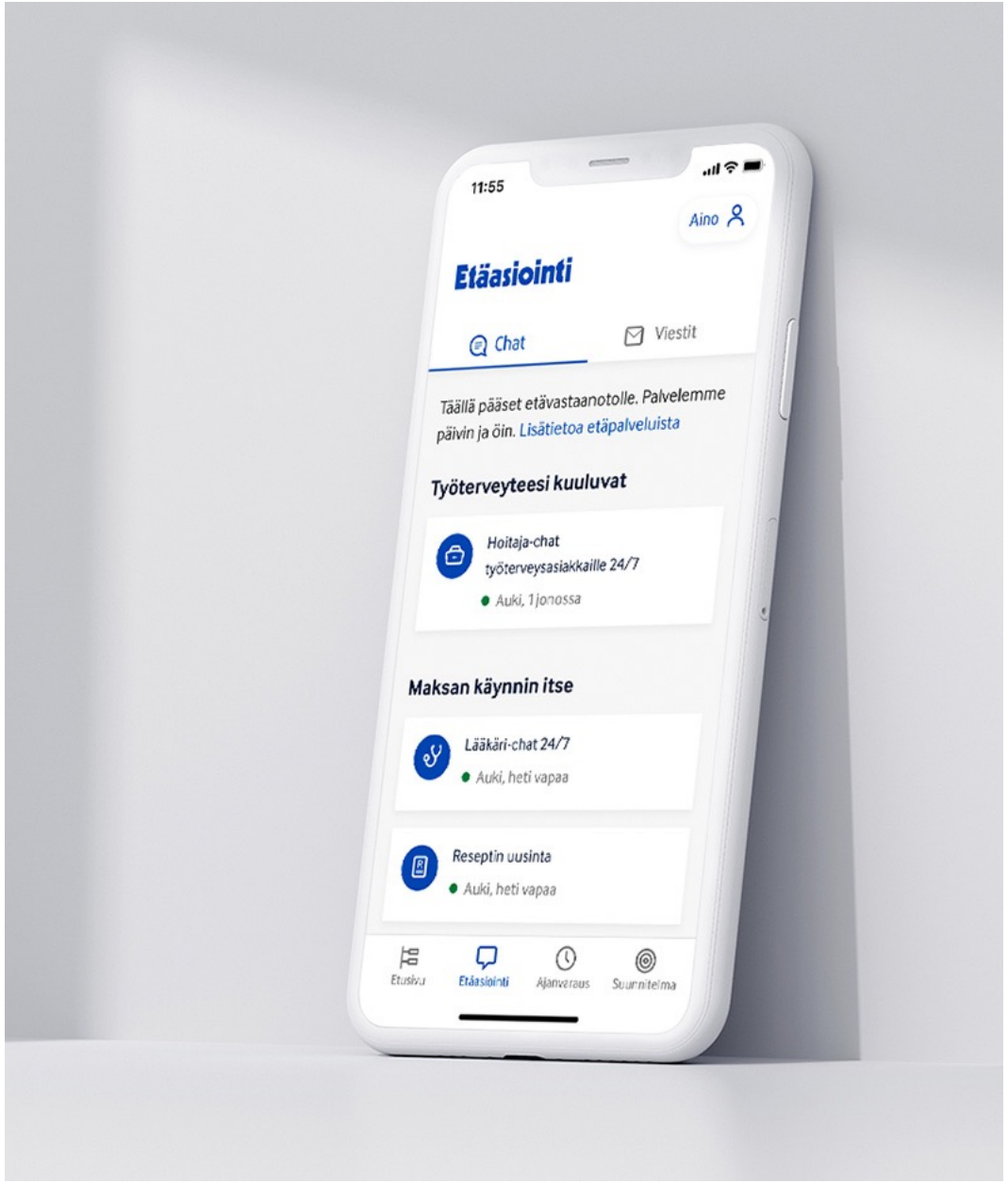
SOLUTIONS

- Agile methodologies
  - Still need to document
- DevOps
- ReqOps
- Harness the SW tools
- Omboard all the stakeholders
- Work smarter, not harder!



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