TUOMI MEDICAL BUSINESS UNIT

Qualified Hard- and Software Development

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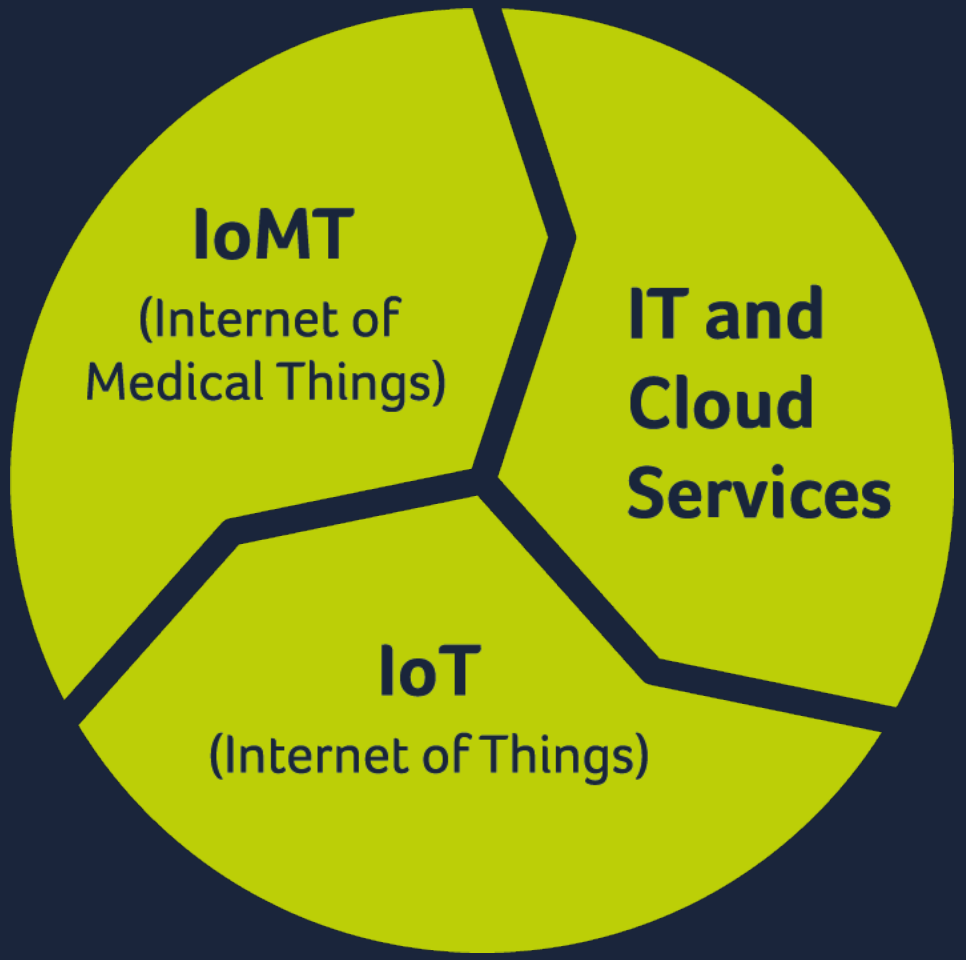
TUOMI BUSINESS PORTFOLIO



TUOMI SOFTWARE DEVELOPMENT AND CONSULTING

2010
decision to invest in software development in the field of NFC applications

2011
Galaxy on Ice with Samsung, Frankfurt

2012 – 2013
EU Project recodura green access funded by EU ECO Innovation

Since 2012
Various local authorities in Germany deploy GPS tracking from TUOMI in partnership with Maxtech Oulu

December 2013
Deployment of NFC technology for the Austrian ÖBB rail network

2014 - 2016
Project for Bayer HealthCare, Switzerland and Guardian in Singapore

2014 March
Deployment of NFC technology for the Stadtmuseum Simeonstift, Trier, Germany

2014 January – November
Access control and NFC consulting project for DOM Sicherheitstechnik (securidev)

2015
Award Top Innovator together with Top-Label

2015 December
book with article about tuomi innovations

Since 2016 August
Projekt mHealth mit SciPharm, Control and monitoring IIP

2015 - 2016
NFC - Multimedia Guides:

- Schleswig Holstein State Museum Foundation Schloss Gottdorf
- Maritime Museum in Kotka Finnland

Since 2017
NFC-Finder by SiNNUP Onetouchlabel and other NFC applications online

Since 2018
NFC - Multimedia Guides:

- Hoffmann Akademie für junge Forscher Gießen,
- Schiffahrtsmuseum Mainz
- Pfalzmuseum Bad Dürkheim

Since 2019

- Digital Fair Assitant PAV Card / f-mp
- CityGuide Saalfeld and Neuwied
- Bitburger Braugruppe VKF 10+1
- Multimedia Guide Brockenhaus
- Take2ei progressive WebApp

Starting February 2020
ISO Certiification process with TÜV Süd for ISO 13485 of soft- und hardware development

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 103794 0001 Rev. 00

Holder of Certificate: **Tuomi S.A.**
7, Fausermillen
6689 Mertert
LUXEMBOURG

Facility(ies): Tuomi S.A.
7, Fausermillen, 6689 Mertert, LUXEMBOURG

see Scope of Certificate

Certification Mark:

Scope of Certificate: **Design and development, production, distribution and service of software and hardware for active implantable devices delivering drugs and active non-implantable devices for circulation and administration or removal of substances**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 103794 0001 Rev. 00

Report No.: 713168629

Valid from: 2021-03-19
Valid until: 2024-03-18

Date, 2021-03-19

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICA

CERTIFICATE ISO 13485:2016

Qualified Hard- and Software Development

- Medical Device Regulation 2017/745/EU
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- EN 62304:2006 + Cor.:2008 + A1:2015 Medical device software – Software life-cycle processes
- IEC 62366-1:2015 + AC:2015 Medical devices
- IEC 82304-1 Health software

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SOFTWARE FOR AND AS MEDICAL DEVICE

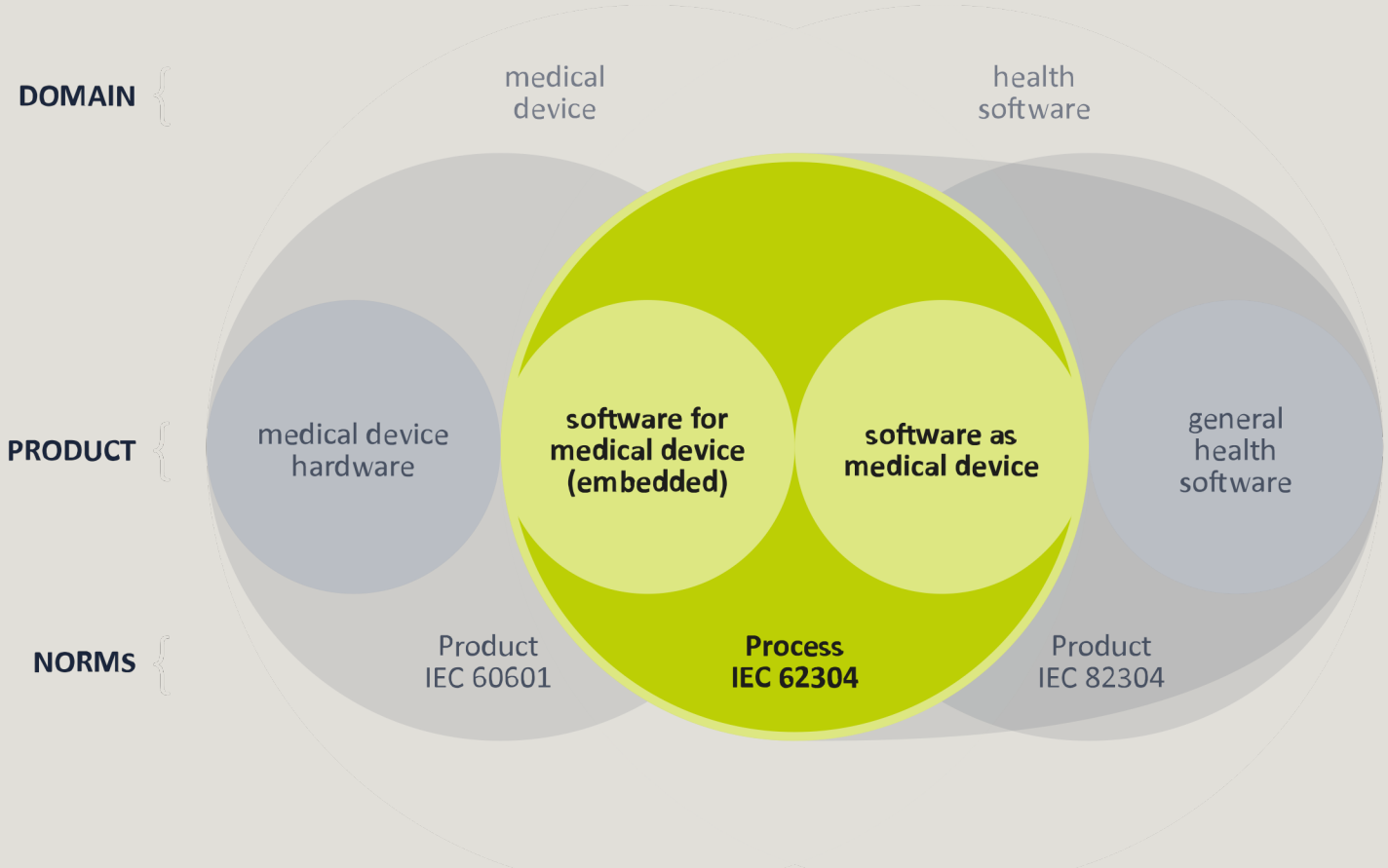
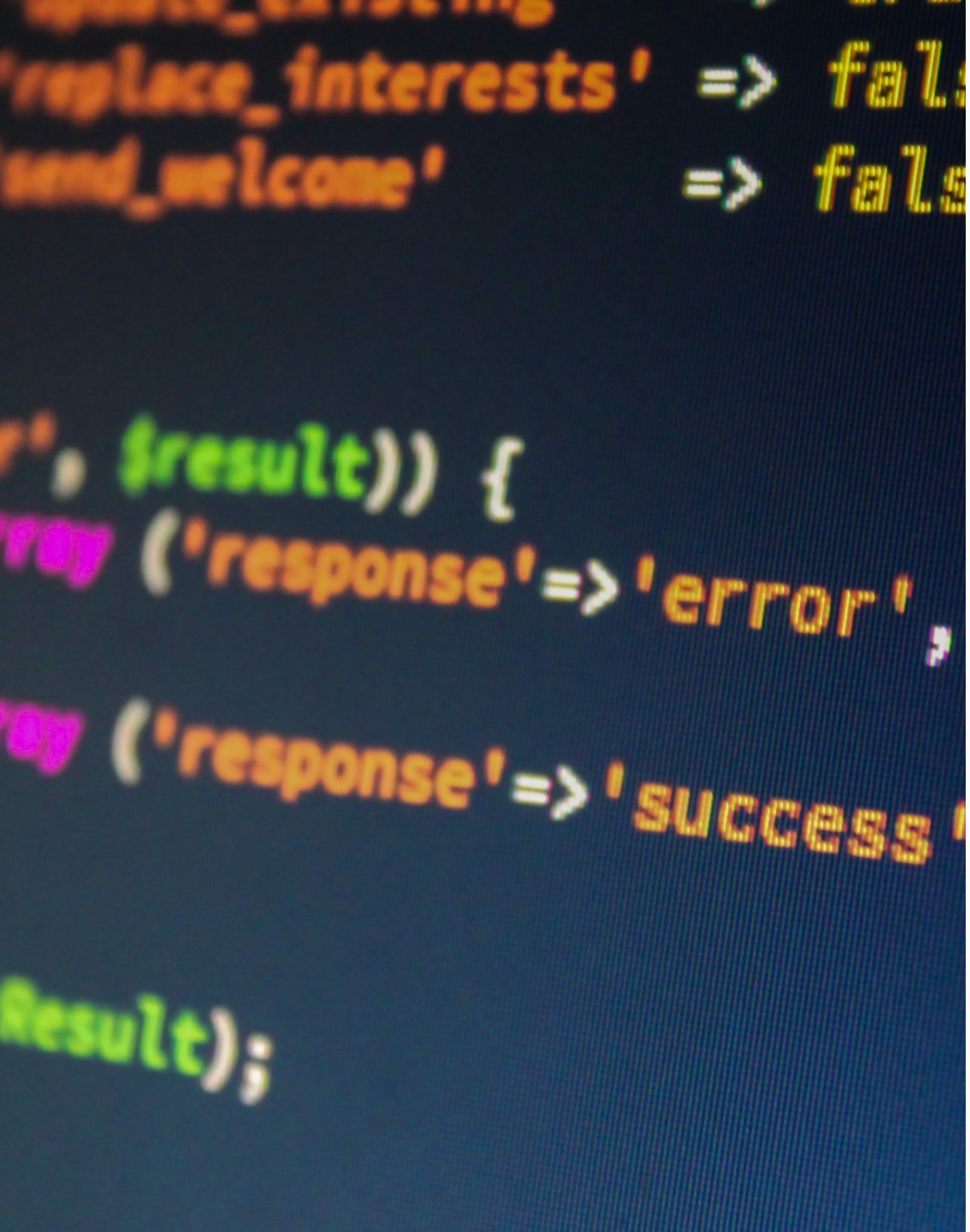


Bild 5.7 Anwendungsbereiche internationaler Software-Standards, in: Entwicklung und Herstellung medizinischer Software: Normen in der Medizintechnik (VDE-Schriftenreihe -Normen verständlich Bd. 171), S. 191



WHAT WE ARE OFFERING

1. **GAP Analysis**
2. **Proof of concept**
3. **Design and Software Development**
   - Privacy by design
   - Security by design
4. **Prototyping and Testing**
5. **Consulting and realization certification**
   - ISO 13485
   - EU – Medical Device Regulation

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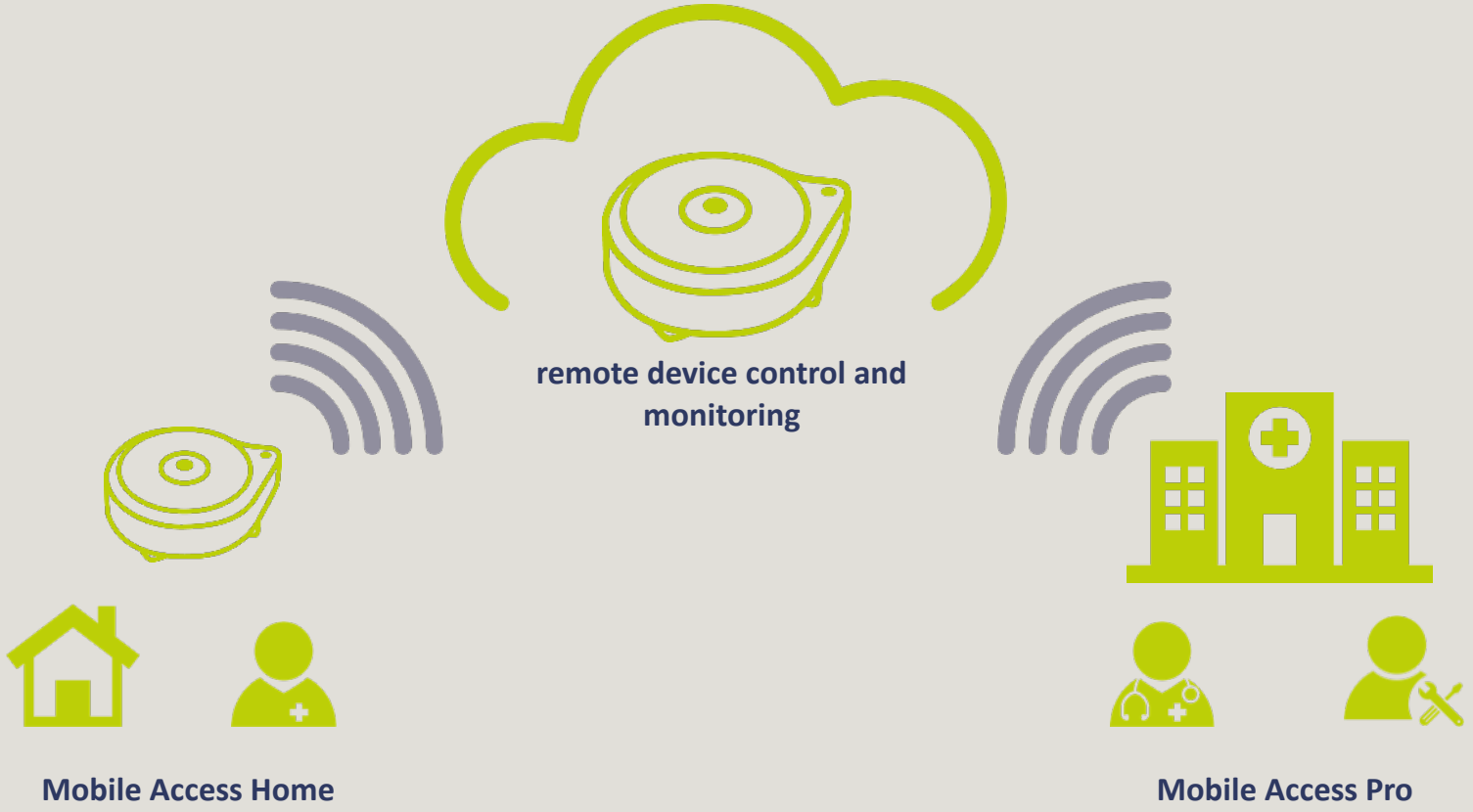
SHOWCASE: SCIPHARM

Internet of medical Things



SHOWCASE: SCIMEDES PUMP REMOTE CONTROL PLATFORM

IIP

Contactless interface

COMMsUnit

NFC/Bluetooth interface

MobileApp

Pump Monitoring App

Control Application

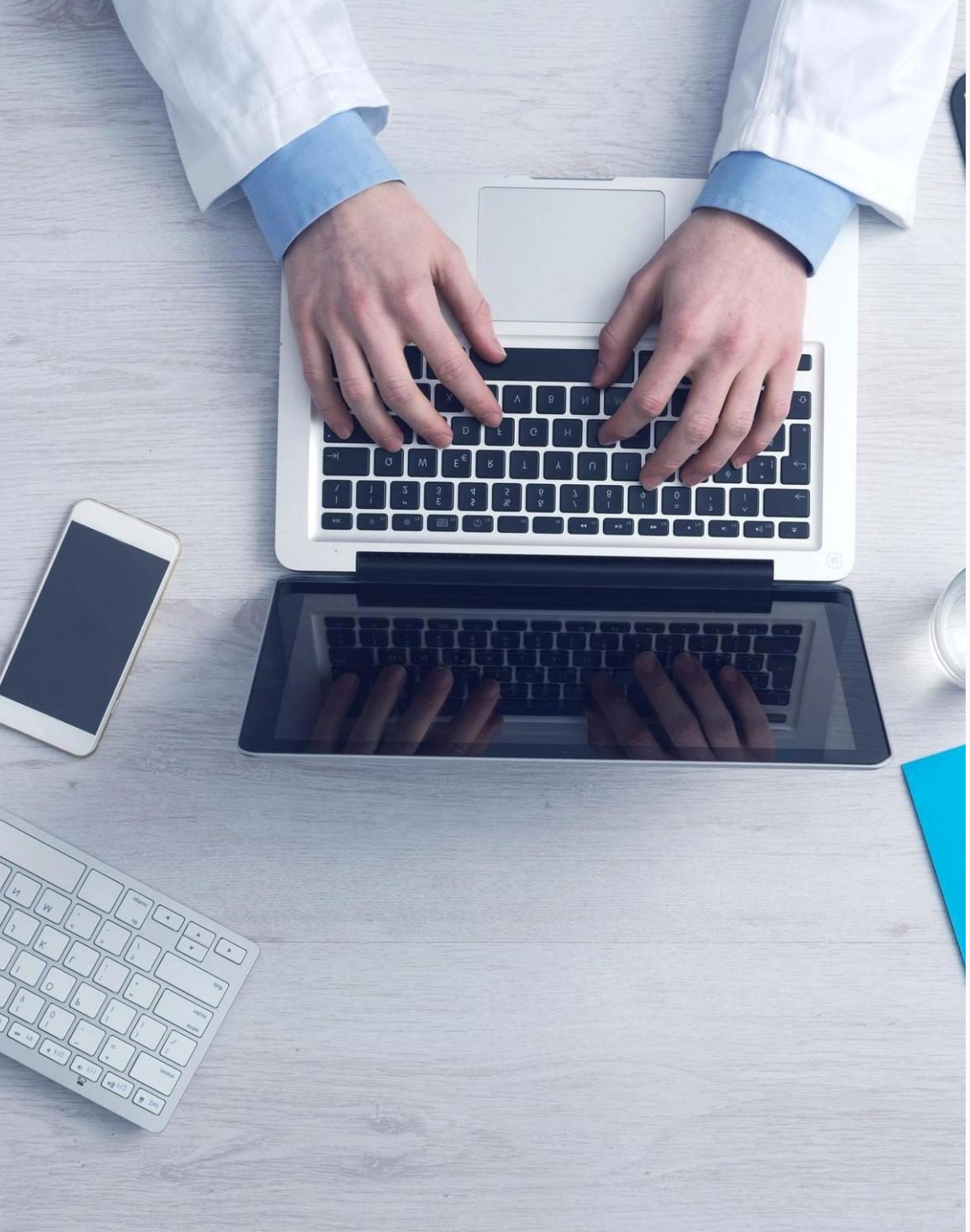
Remote Pump

Monitoring and Control

Medical Staff

Data analysis

Evaluation



CLOUD CONTROL APPLICATION

1. **More comfort through Remote Control**
   Physician can read and program the implantable and external devices at anytime and anyplace

2. **Enhancement through Remote Patient Monitoring**
   Capturing of other health related parameters through mHealth devices & self report

3. **Improvement of therapy quality**
   Reliable and continuous patient & device monitoring

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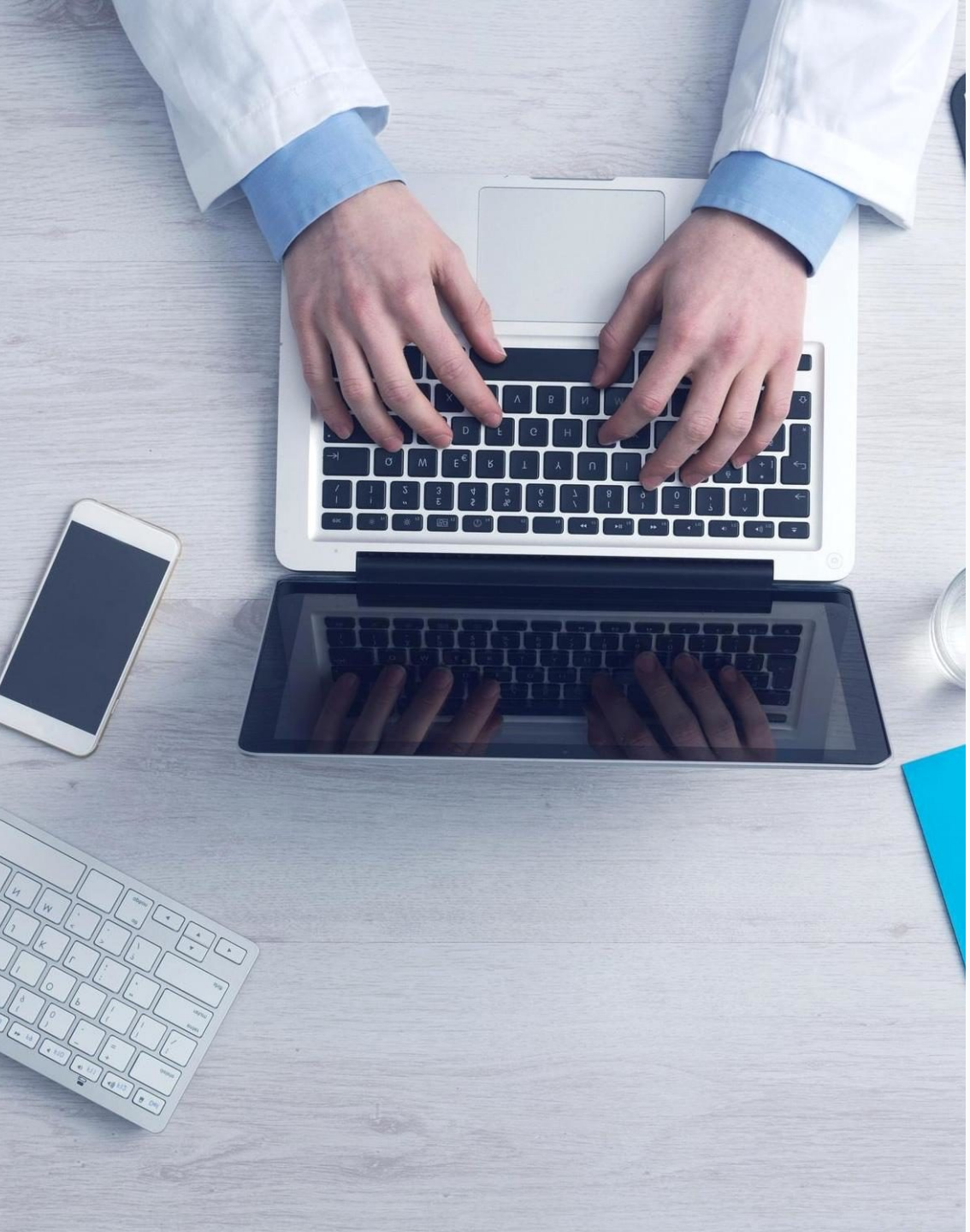

CLOUD CONTROL APPLICATION

4. **Increased safety**
   Fast notification and response in emergency situations

5. **Increased user friendliness**
   Simplified display and more efficient operation

6. **Data protection**
   Secure transmission and storage of patient data

7. **Improved tracebility of medical devices**
   Supporting the European Regulation of the UDI System

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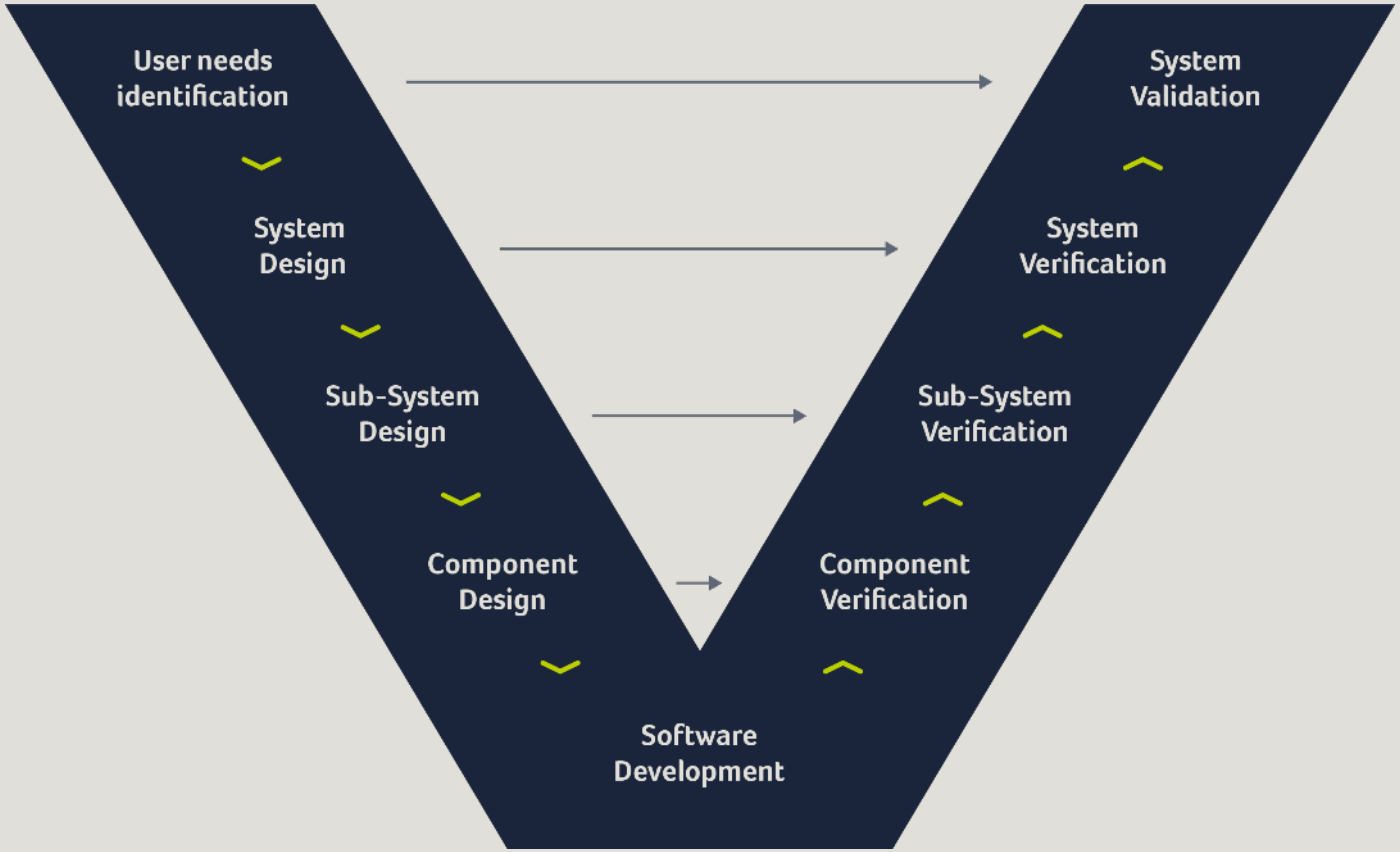
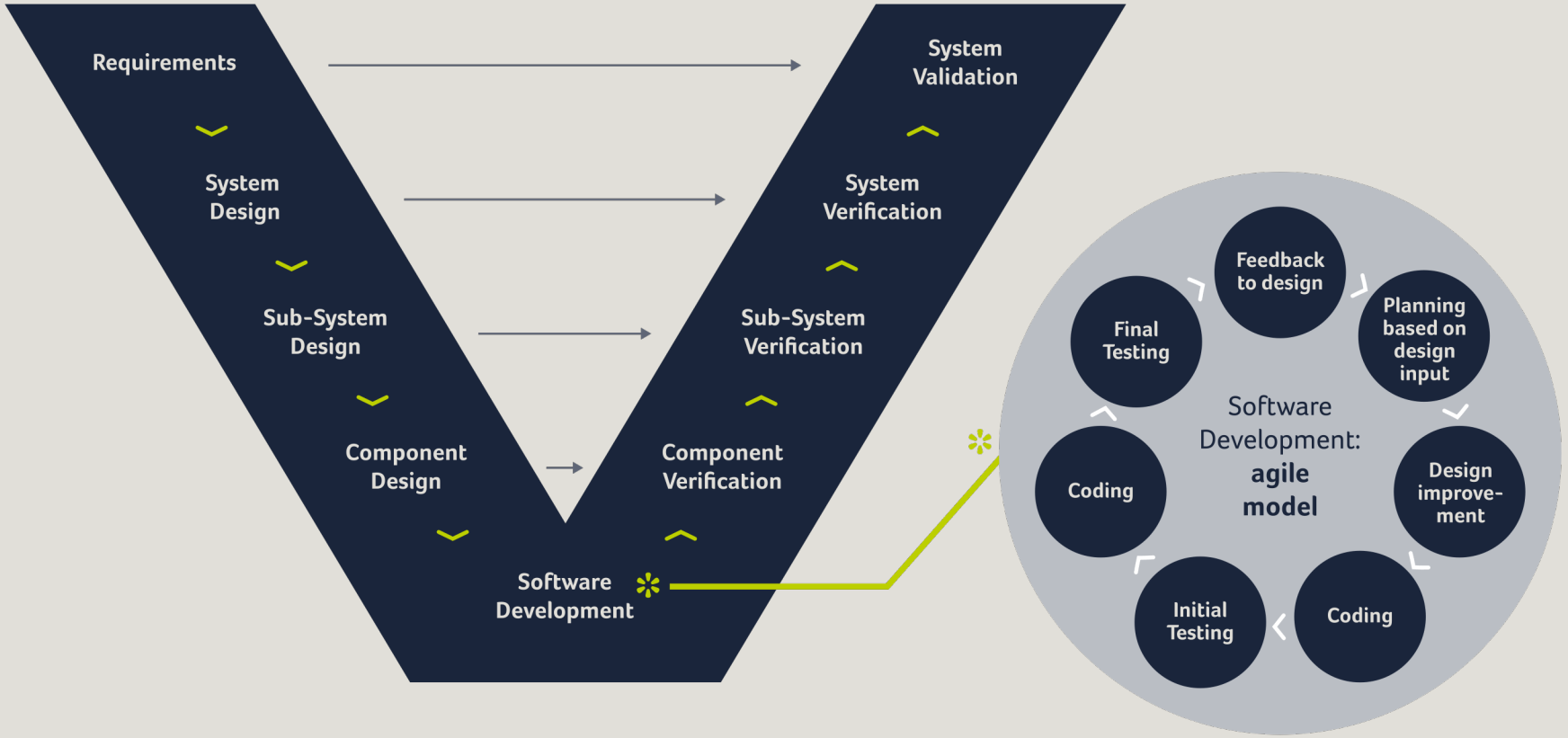
SOFTWARE DEVELOPMENT

V-Model as required by ISO 13485, MDR and FDA



WHAT WE ARE DOING

Agile-V Model



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