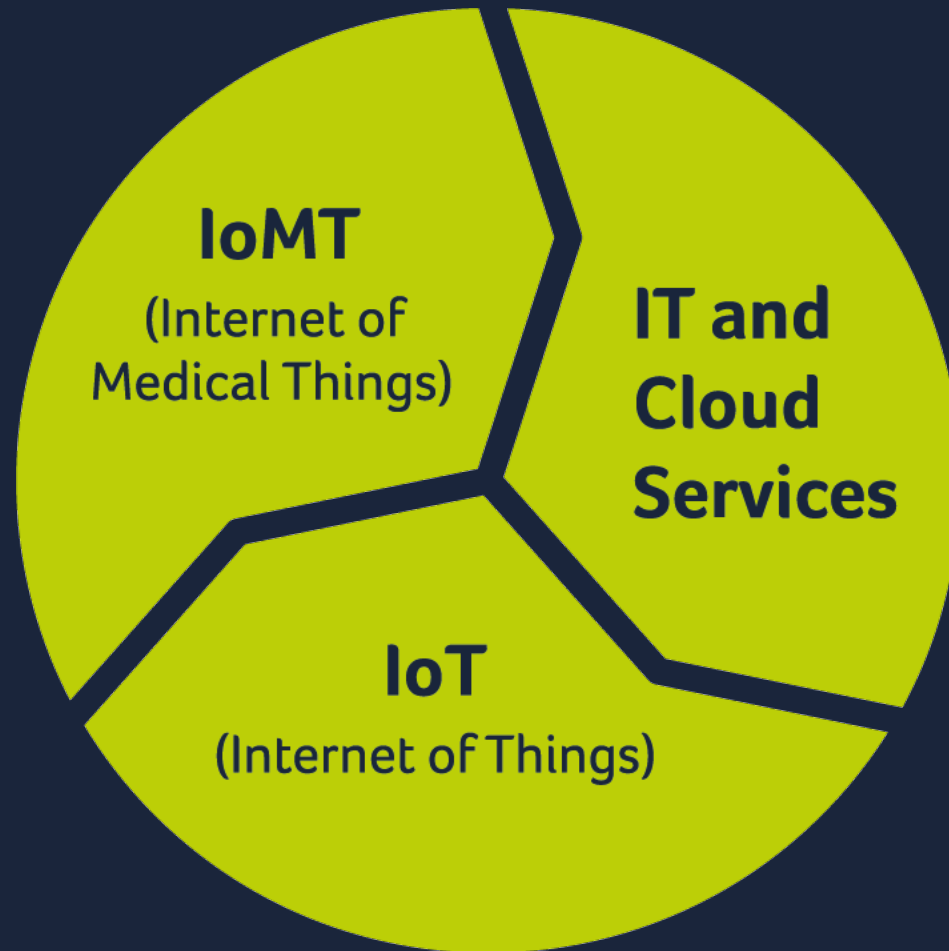




TUOMI MEDICAL BUSINESS UNIT

Qualified Hard- and Software Development

TUOMI BUSINESS PORTFOLIO



TUOMI SOFTWARE DEVELOPMENT AND CONSULTING





Certificate

No. Q5 103794

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

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

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](http://www.tuvsud.com/ps-cert?q=cert:Q5_103794)

Report No.: 713168629

Valid from: 2020-11-10
Valid until: 2023-11-09

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

SOFTWARE FOR AND AS MEDICAL DEVICE

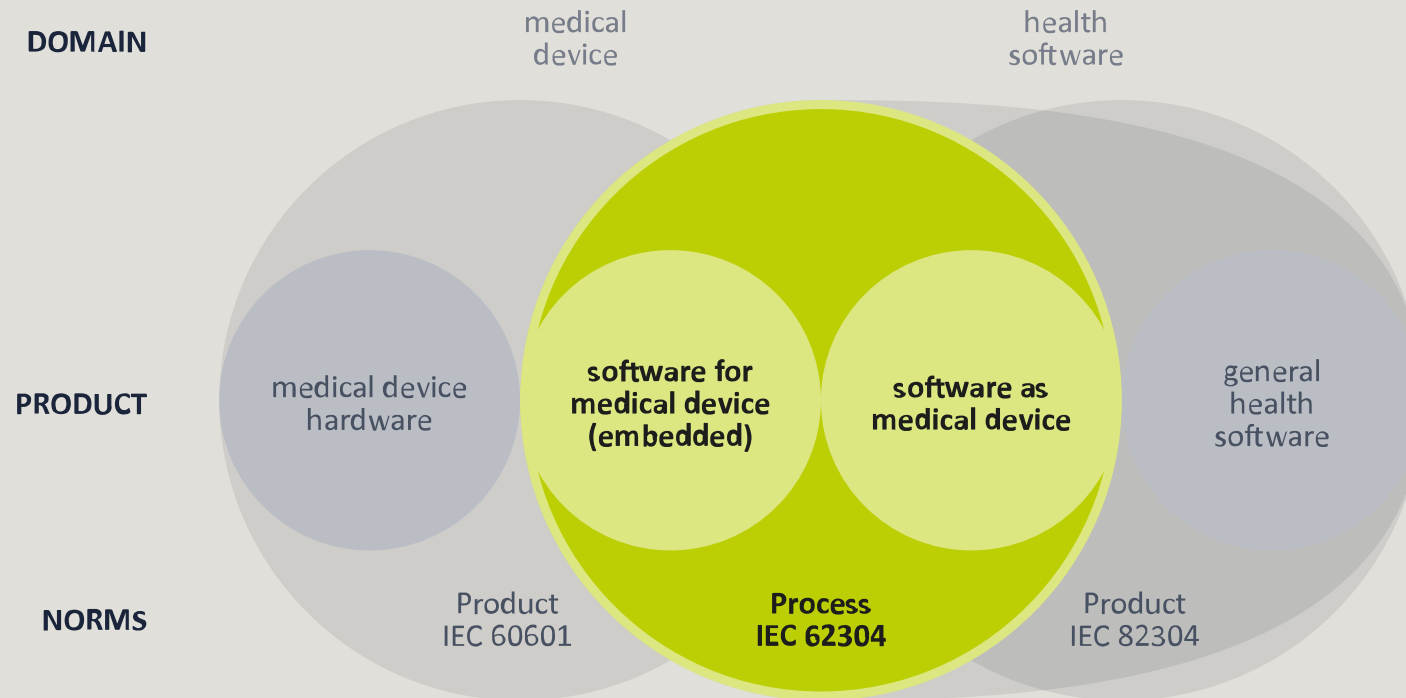
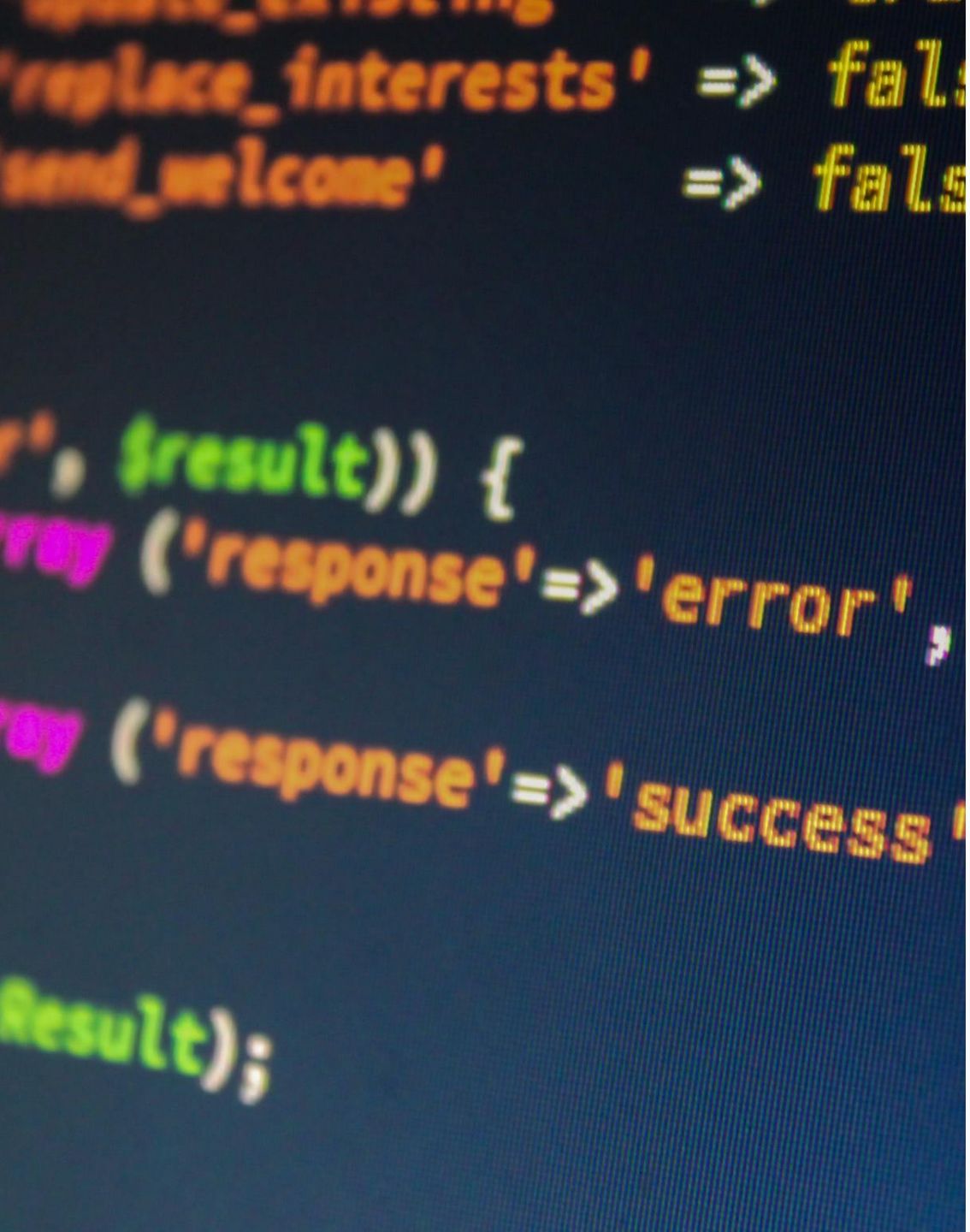


Bild 5.7 Anwendungsbereiche internationaler Software-Standards, in: Entwicklung und Herstellung medizinischer Software: Normen in der Medizintechnik (VDE-Schriftenreihe -Normen verständlich Bd. 171), S. 191

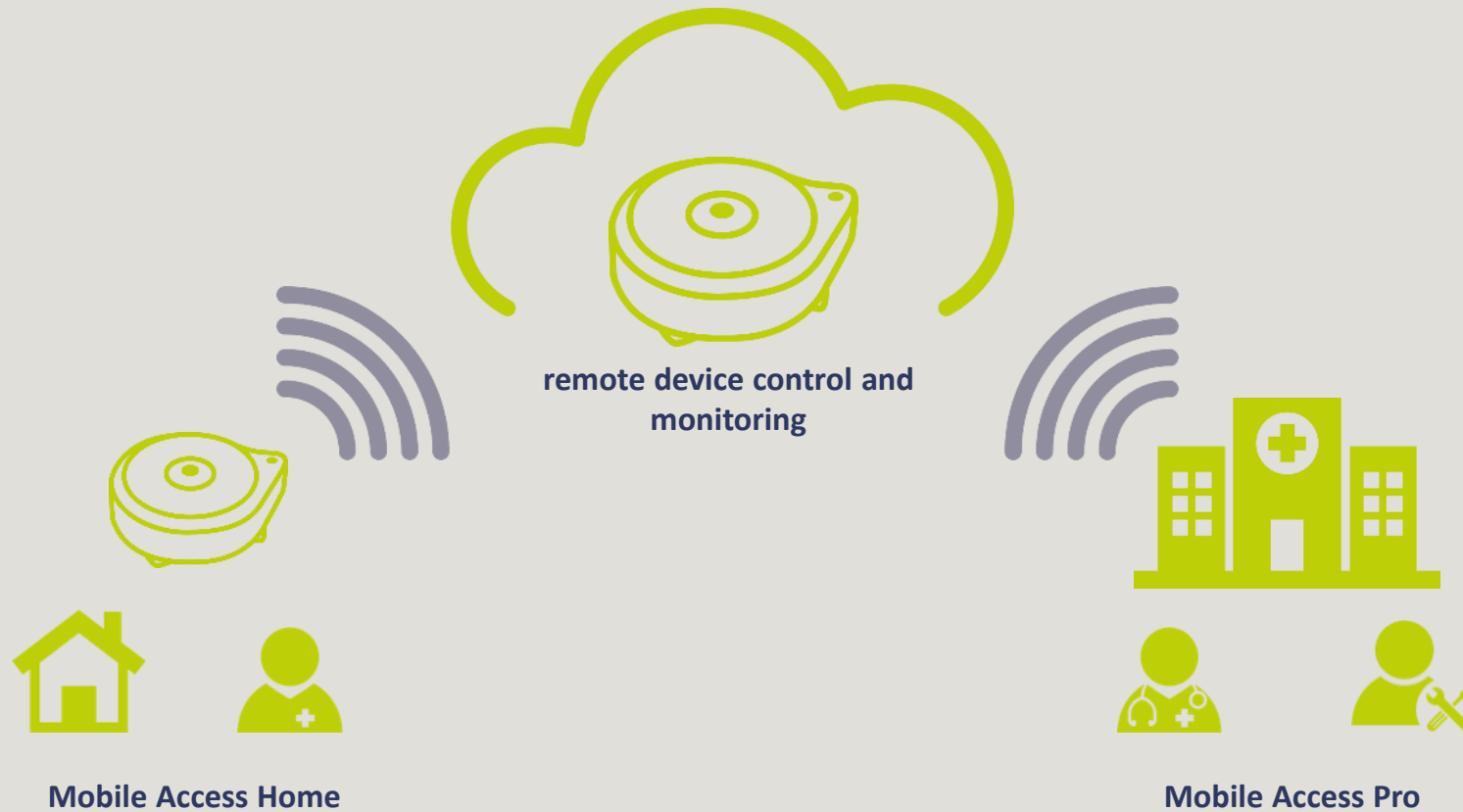


WHAT WE ARE OFFERING

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

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 SOLUTION

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



CLOUD SOLUTION

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



tuomi S.A.

7, Fausermillen
6689 Mertert
Luxembourg

mail@tuomi.eu
www.tuomi.eu

