



BAYOOMED GmbH

Service Portfolio

BAYOOMED

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Software Development Lifecycle / mHealth & eHealth

- ☐ User centered design & requirements engineering
- ☐ Prototyping & feasibility studies
- ☐ Software architecture & detailed design
- ☐ Software development of critical modules & entire solutions according to IEC 62304
 - Web based applications & responsive web apps
 - Cloud-based solutions
 - Mobile medical apps (native & cross-platform) incl. DiGA
 - Desktop applications
 - Embedded software & firmware
 - Hardware connectivity (BLE, NFC, WIFI)
 - Algorithm development, Data Science & AI
- ☐ Verification & testing
 - Unit, software & system integration
 - Automated UI testing
- ☐ Software validation according to GAMP5
- ☐ App Store releases



Accompanying Processes & Activities

- ☐ Due diligence services for medical devices, mobile medical apps & medical software
- ☐ Quality Management System according to ISO 13485 & MDSAP
 - Creation of entire QMS
 - Regulatory consulting & mentoring
 - External QMR service
 - Accredited Authority / Notified Body selection & communication
 - Internal Audits
 - Audit preparation & participation
- ☐ Risk management according to ISO 14971
- ☐ Usability / Human factors engineering
- ☐ Clinical evaluation
- ☐ Cybersecurity risk analysis according to FDA and MDCG guidelines
- ☐ Creation, maintenance & review services for Technical Documentation, DHF, DMR & DHR
- ☐ Controlling, quality assurance & coordination of external soft- and hardware vendors (onsite, near & off-shore)



Legal Manufacturer Services (BAYOOCARE) – ISO 13485 and MDSAP

- ☐ Coordination of hardware and software development
- ☐ Supplier & contract management
- ☐ Creation and maintenance of declarations of conformity for medical devices & medical software
- ☐ Conformity assessments with national authorities or Notified Bodies
- ☐ International Launching, e.g. USA, Canada, Australia, Brazil, Japan, Israel
- ☐ Distribution of medical devices & medical software
- ☐ FDA approval, CE marking, international launch & distribution
- ☐ Support (1st, 2nd & 3rd level)
- ☐ Post-market surveillance
- ☐ Vigilance
- ☐ Post-market clinical follow-up
- ☐ Pharmacovigilance support



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—  — MEDICAL SOFTWARE