medical

Service Catalogue

2024 - 2025

QTICS medical

CONFORMITY ASSESSMENT SUPPORT

EDUCATION

PRECLINICAL TESTING

CLINICAL INVESTIGATION

PRODUCT AND SOFTWARE DEVELOPMENT

CERTIFICATION

OUR SERVICE PORTFOLIO BY MEDICAL SEGMENTS

Conformity assesment support
(MDR/IVDR/FDA)

Compliance with the regulation of medical devices poses an increasingly difficult task for economic operators. In order to reduce the burden on economic operators, we provide full support for the CE marking of medical devices, from regulatory strategy to post-market surveillance.

Education

Fulfilling the requirements of the CE marking is inconceivable without acquiring the appropriate knowledge. We provide training in all relevant areas related to the CE marking of medical devices in the form that best suits your needs: open and outsourced or customized training.

Preclinical and production equipment testing

Verification of medical device safety is mandatory. We provide biocompatibility, safety, and usability testing for active and IVD devices. Devices that are connected, store data, or include computing and control functions require cybersecurity risk assessment, which we perform according to strict standards and accreditations.

Product and software development

Our expert engineering team designs custom PCBs, electronic devices, and complete products. We develop reliable software solutions, supporting the entire process from concept to FDA approval, including UX/UI design, development, testing, and quality assurance.

Clinical investigation

The key to CE marking of medical devices is validation of clinical safety and performance. With our team of doctors and biologists, we provide a full range of services from the design of clinical investigations, through licensing, to the preparation of a clinical investigation report.

Certification

The entrance ticket to the international medical device market is ISO 13485 certification. With our accredited ISO 13485 and ISO 27001 certification service, we provide internationally recognized certificates. In addition, we provide effective support for the selection of a notified body.

QTICS medical

QTICS MEDICAL DIVISION

SAASCO Tanácsadó és Mérnöki Iroda Kft.

PCB DESIGN

brighthills

TAM CERT

QTICS medical

CONFORMITICS LAB

TOXI-COOP Toxicological Research Center

DRUG RESEARCH CENTER

CCLAB

ONE STOP SHOP MODEL

One stop shop
for MedTech companies

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CONFORMITY ASSESSMENT SUPPORT

DESIGN AND DEVELOPMENT OF MEDICAL DEVICES

1.	-	**Product qualification support:** • Applicable legislation • Definition of relevant categories / classes
2.	National Guideline on HTE Evaluation	Preparation of Health Technology Assessment
3.	MDR 10. (9) a) IVDR 10. (8) a)	**Preparation of strategy for regulatory compliance:** • Key players in the target market • Conformity assessment procedure • The content of required documentation • Applicable standards and guidance
4.	MDR I.	Preparation of test plan: identification of tests to verify the general safety and performance requirements of MDR Annex I.

Services related to MDR		
5.	-	General Consultation on MDR Requirements
6.	MDR Art. 29. 31.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
7.	MDR Art. 27. VI. B.	UDI design support
8.	MDR Art. 10 (9) IX., XI. A. ISO 13485	**Implementation of quality management system:** • Preparation of documentation • Introductory education • Internal audit • Management review
9.	MDR II.	**Preparation of the Technical Documentation:** • Device description • Information to be supplied by the manufacturer • Design and manufacturing information • General safety and performance requirements checklist • Benefit-risk analysis and risk management • Product verification and validation support

Services related to MDR		
10.	-	**Gap analysis:** • On technical documentation • On quality management system • On risk management system • On list of non-conformities by NB
11.	MDR III.	**Preparation of Technical Documentation on Post-market Surveillance:** • Post-market surveillance plan • Periodic safety update report • Post-market surveillance report
12.	MDR XIV.	**Preparation of the Clinical Evaluation:** • Clinical evaluation plan • Clinical evaluation report • Post Market Clinical Follow-up (PMCF) plan, • Post Market Clinical Follow-up (PMCF) report
13.	ISO 10993-1 ISO 10993-18	**Preparation of the Biological Evaluation Plan & Report:** • Preparation of the biological evaluation strategy • Characterization of materials • Selection of studies or justification for omitting studies • Toxicological risk assessment • Summary evaluation of biocompatibility
14.	IEC 62366-1	**Supporting of the Usability Engineering Process:** • Compilation of the Usability Engineering File • Associated risk evaluation
15.	MDR Art. 10 (9) IX., XI. A. ISO 13485	**Perform audits:** • CE (MDR) internal audit • ISO 13485 internal audit • Supplier audit
16.	MDR IX., XI. A.	Support to identifying the right NB partner

Services related to IVDR		
17.	-	General Consultation on IVDR Requirements
18.	IVDR Art. 26. 28.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
19.	IVDR Art. 24. VI. B.	UDI design support
20.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	**Implementation of quality management system:** • Preparation of documentation • Introductory education • Internal audit • Management review
21.	-	**Gap analysis:** • On technical documentation • On quality management system • On risk management system • On list of non-conformities by NB

Services related to IVDR		
22.	IVDR II.	**Preparation of the Technical Documentation:** • Device description • Information to be supplied by the manufacturer • Design and manufacturing information • General safety and performance requirements checklist • Benefit-risk analysis and risk management • Product verification and validation support
23.	IVDR III.	**Preparation of Technical Documentation on Post-market Surveillance:** • Post-market surveillance plan • Periodic safety update report • Post-market surveillance report
24.	IVDR XIII.	**Preparation of the Performance Evaluation:** • Perfomance evaluation plan • Performance evaluation report • Post Market Performance Follow-up (PMPF) plan • Post Market Performance Follow-up (PMPF) report
25.	IEC 62366-1	**Supporting of the Usability Engineering Process:** • Compilation of the Usability Engineering File • Associated risk evaluation
26.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	**Perform audits:** • CE (IVDR) internal audit • ISO 13485 internal audit • Supplier audit
27.	IVDR IX., X., XI.	Support to identifying the right NB partner

Services related to FDA		
28.	21 CFR Part 820	**Implementation of Quality Management System:** • Designing and implementing QMS processes and procedures • Ensuring documentation aligns with relevant regulations and standards • Developing documentation templates and tools for efficient management • Conducting internal audits and assessments to identify areas for improvement • Providing training and support to ensure successful QMS implementation
29.	21 CFR Part 11	Consulting on Electronic Records and Electronic Signatures
30.	IEC 62366-1	**Supporting of the Usability Engineering Process:** • Compilation of the Usability Engineering File • Associated risk evaluation
31.	21 CFR Part 820 ISO 13485	**Perform audits:** • 21 CFR Part 820 internal audit • ISO 13485 internal audit • Supplier audit

Consultation on Preclinical tests		
32.	EN 60601-1 EN 61010-2-101	Technical advice for the safe, standard design of devices
33.	ISO 10993-1 ISO 10993-18	**Preparation of the Biological Evaluation Report:** • Preparation of the biological evaluation strategy • Characterization of materials • Selection of studies or justification for omitting studies • Toxicological risk assessment • Summary evaluation of biocompatibility
34.	MDR 10. (9) a) IVDR 10. (8) a)	**Preparation of strategy for regulatory compliance:** • Key players in the target market • Conformity assessment procedure • The content of required documentation • Applicable standards and guidance
Consultation on Cybersecurity		
35.	MDR I. Product-specific requirements	Developing a cybersecurity strategy
36.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 ISO 810001-5-1 AAMI TIR57	Gap analysis

Consultation on Cybersecurity		
37.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 AAMI TIR57	Prepare / support the Risk Management File based on Cybersecurity
38.	AAMI TIR57	Provide expert review of the acceptability of all residual risks for Cybersecurity
39.	-	Monitoring the state-of-the-art level of Cybersecurity and reporting regularly
40.	MDR I.	Support and review the Instruction for Use based on Cybersecurity
41.	EN 60601-1 EN 62304 IEC 82304-1 EN 62304 IEC 81001-5-1	Change or create design and development procedures for Cybersecurity
42.	EN 62304 (IEC 62304) IEC 81001-5-1	**Evaluation of Cybersecurity aspects of software requirements:** • Software architecture security analysis • Safety review of risk analysis
43.	IEC/TR 60601-4-5 (IEC 62443-4-2)	Safety aspects of medical devices, support for safety level classification
44.	ISO/IEC 27001 ISO/IEC 27002	Development and certification support of Information Security Management System

Consultation on Clinical Investigation		
45.	MDR 10. (9) a) IVDR 10. (8) a)	**Preparation of Clinical Strategy for regulatory compliance:** • Key players in the target market • Conformity assessment procedure • The content of required documentation • Applicable standards and guidance
Consultation on Software Development		
46.	TMMi framework ISO 13485	Thorough evaluation of team capabilities, goals and skill sets
47.	ISO 13485	Process improvement recommendations to optimize efficiency and quality
48.	ISO 13485	Ensuring outputs meet regulatory requirements and industry standards Facilitating compliance with relevant regulations during the development lifecycle
49.	AI Act ISO / IEC 22989 ISO / IEC 23053 ISO / IEC 24029-1, 24029-2	Consulting related to Artificial Intelligence, Machine Learning and Data Science

Services related to RoHS		
50.	RoHS Article 7. b)	**Support for internal production control procedure:** • Development of technical documentation • Supplementing the quality management system with RoHS requirements
Services related to production equipment (machines)		
51.	RoHS Article 7. b)	**Defining the requirements for the placing on the market or putting into service of production equipment:** • Legislations • Harmonized standards • Conformity assessment procedure • Manufacturers or operator tasks
52.	(MD, LVD, EMC, ATEX)	**Compilation of Technical Documentation in accordance with the relevant legislations:** • List of applicable harmonized and other standards • Risk evaluation documentation • Drawings, wiring diagrams • User documentation • EU declaration of conformity
53.	MD, EN ISO 14159	Hygienic inspection of production equipment

EDUCATION

Trainings on Management Systems		
54.	ISO 13485	Standard introductory training
55.	ISO 9001, ISO 14001	Standard introductory training
56.	ISO 13485	Internal Auditor Training
57.	ISO 9001, ISO 14001	Internal Auditor Training
58.	ISO/IEC 17025	Internal Auditor Training
59.	21 CFR Part 820	Introductory training
60.	21 CFR Subchapter H	Regulatory training covering FDA regulations
MDR, IVDR training		
61.	MDR II., III.	Technical Documentation
62.	MDR 15.	Person Responsible for Regulatory Compliance (PRRC)
63.	MDR XIV.	Clinical Evaluation
64.	MDR III.	Post-market Surveillance System (PMS)
65.	MDR XIV. B.	Post-market clinical follow-up (PMCF)
66.	MDR, IVDR	Cybersecurity
MDR, IVDR related standards training		
67.	ISO 14971	Risk management
68.	EN 62366-1	Usability Engineering
69.	EN 60601-1	Safety test of medical electrical equipment
70.	EN 61010-1	Electrical equipment for measurement, control, and laboratory use
71.	EN 61010-2-101	In vitro diagnostics (IVD) medical equipment

MD and related standards training		
72.	2006/42/EC	CE marking of machines
73.	2006/42/EC EN ISO 10218-X ISO/TS 15066	CE marking of industrial robot and collaborative robot systems
74.	EN ISO 12100	Risk evaluation of industrial machines
75.	(relevant standards)	Safety and technical requirements of machines
76.	AI Act ISO / IEC 22989 ISO / IEC 23053 ISO / IEC 24029-1, 24029-2	Training related to Artificial Intelligence, Machine Learning and Data Science

PRECLINICAL TESTING

Biocompatibility testing		
77.	ISO 10993-3	Tests for genotoxicity, carcinogenicity and reproductive toxicity
78.	ISO 10993-4	Selection of tests for interactions with blood
79.	ISO 10993-5	Tests for in vitro cytotoxicity
80.	ISO 10993-10	Tests for irritation and skin sensitization
81.	ISO 10993-11	Tests for systemic toxicity
82.	ISO 10993-18	Chemical characterization of materials (UV, MS, IR)
Safety testing		
83.	EN 60601-1 (IEC 60601-1)	Medical electrical equipment
84.	EN 60601-1-6 (IEC 60601-1-6)	Medical electrical equipment – Usability
85.	EN 60601-1-8 (IEC 6060-1-8)	Alarm systems in medical electrical equipment and medical electrical systems
86.	EN 60601-2-10 (IEC 60601-2-10)	Nerve and muscle stimulators
87.	EN 60601-2-25 (IEC 60601-2-25)	Electrocardiographs
88.	EN 60601-2-26 (IEC 60601-2-26)	Electroencephalographs
89.	EN 60601-2-27 (IEC 60601-2-27)	Electrocardiographic monitoring equipment
90.	EN 60601-2-47 (IEC 60601-2-47)	Ambulatory electrocardiographic systems
91.	EN 60601-2-4 (IEC 60601-2-4)	Cardiac defibrillators

Safety testing		
92.	EN 80601-2-30 (IEC 80601-2-30)	Automatic cycling non- invasive blood pressure monitoring equipment
93.	EN 61010-1) (IEC 61010-1)	Electrical equipment for measurement, control, and laboratory use
94.	2EN 61010-2-101 (IEC 61010-2-101)	Particular requirements for in vitro diagnostic (IVD) medical equipment
95.	(MD, LVD, EMC, ATEX)	**CE conformity testing:** • Documentation evaluation • Visual inspection • Functional examination • Instrumental measurements (on-site or laboratory)
96.	(relevant occupational safety and health regulations)	**Safety tests:** • Preliminary • Periodic • Extraordinary
97.	(specified standards or other specifications)	**Other conformity tests, acceptance checks:** • according to standards • according to customer or other specifications • according to a customized system of criteria

Usability testing		
98.	IEC 62366-1	Formative evaluation (expert review, standard review)
99.	IEC 62336-1	Summative evaluation (Usability test)
Cybersecurity testing		
100.	IEC 81001-5-1 ISO 14971 AAMI TIR 57	Risk Assessment
101.	IEC 81001-5-1	Secure requirements testing
102.	IEC 81001-5-1	Threat mitigation testing
103.	IEC 81001-5-1 MDR I. MDCG 2019-16 ISO 14971 AAMI TIR 57	**Vulnerability testing** • Threat modelling-based vulnerability assessment • Security Testing / Penetration Test
RoHS testing		
104.	RoHS Annex II	Determination of the concentration of hazardous substances

CLINICAL INVESTIGATION

105.	MDR XV. Chapter II. 3.	Preparation of the Clinical Investigation Plan; data collection, literature search
106.	MDR XV. Chapter II. 1-2.	Preparation of the documentation regarding the application for clinical investigation
107.	MDR Art. 70	Preparation of the Clinical Investigation authorization (submitting the application, communication with the authority)
108.	MDR Art. 72	**Conduct of the Clinical Investigation, including:** • Article 77. Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination • Article 80. Recording and reporting of adverse events that occur during clinical investigations
109.	MDR Art. 87	Supporting the reporting of serious incidents and field safety corrective actions
110.	MDR XV. Chapter III. 4-6.	Follow the Clinical Investigation (monitoring, data management, project management)
111.	MDR XV. Chapter III. 7.	Preparation of Clinical Investigation Report

PRODUCT AND SOFTWARE DEVELOPMENT

PCB Design		
112.	ISO 9001 AS/EN9100 DO254 ISO 13485	**System design:** • Healthcare and Medical devices • Space, Aerospace • Industrial, Automotive, ICT/IoT
113.	ISO 9001 AS/EN9100 DO254 ISO 13485	**Schematics:** • Altium, Mentor, Cadence and Zuken tools
114.	ISO 9001 AS/EN9100 DO254 ISO 13485	**PCB layout:** • Altium, Mentor, Cadence and Zuken tools
115.	ISO 9001 AS/EN9100 DO254 ISO 13485	**Simulation:** • Spice and IBIS AMI
Embedded Software Development		
116.	ISO 9001 AS/EN9100 DO178 ISO 13485	**MCU, microcontroller:** • Major MCUs: STM32, Nordic Semiconductor, Silabs, ESP32
117.	ISO 9001, AS/EN9100 DO178 ISO 13485	**FPGA development:** • Chips: Intel, AMD, System on SOC • SOM: Trenz, Kria
118.	ISO 9001, AS/EN9100 DO178 ISO 13485	**Linux:** • Major MCUs: NXP, Broadcom, RPI, Qualcomm, Allwinner • Custom BSP
Turnkey product development		
119.	IPC 600 IPC610 Class 3	Prototype manufacturing
120.	-	Functional Test System Development

Software as a medical device development		
121.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Software Development - Mobile Applications (Native Android, iOS and Cross Platform)
122.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Software Development - Web Applications
123.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Software Development - Desktop Applications
123.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Developing comprehensive test plans aligned with regulatory requirements
124.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Executing compliance and functional tests to assess product quality
125.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Identifying and addressing any non-conformances or areas of improvement
126.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Establishing a robust testing framework to support ongoing compliance
127.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Creating comprehensive records to demonstrate software compliance with QA processes
129.	21 CFR Part 820 MDR ISO 13485 IEC 62304, IEC 82304-1	Conducting documentation audits to identify gaps and improve software documentation practices
130.	AI Act ISO / IEC 22989 ISO / IEC 23053 ISO / IEC 24029-1, 24029-2	Solutions and system integration related to Artificial Intelligence, Machine Learning and Data Science

CERTIFICATION

Management Systems Certification		
132.	ISO 13485	Quality Management Systems for Medical devices
132.	ISO / IEC 27001	Information Security Management Systems
133.	ISO 9001	Quality Management Systems
134.	ISO 45001	Occupational Health and Safety Management Systems
135.	ISO 50001	Energy Management Systems
136.	ISO 14001	Environmental Management Systems
137.	ISO 37001	Anti-bribery Management Systems
138.	ISO 56001	Innovation Management Systems
139.	ISO/IEC 42001	AI Management Systems
EC Type – Examination		
140.	MD	EC type - examination or certificate of conformity (CoC) of production equipment
141.	LVD	Certificate of conformity (CoC) of production equipment
142.	EMC	EC type - examination or certificate of conformity (CoC)
143.	RED	EC type - examination or certificate of conformity (CoC)
144.	ATEX	EC type - examination or certificate of conformity (CoC)
Certificate of Conformity (CoC)		
145.	RoHS	Certificate of conformity (CoC)
GDPR Certificate and Data Protection Seal		
146.	GDPR	Europrivacy™/® GDPR - Accredited data protection certificate and data protection seal under Article 42 GDPR

ABBREVIATIONS

ATEX - Equipment and protective systems intended for use in potentially explosive atmosphere (2014/34/EU)
CFR - Code of Federal Regulations (USA)
EMC - Electromagnetic Compatibility Directive (2014/30/EU)
FDA - US Food and Drug Administration
GDPR - General Data Protection Regulation (2016/679)
HTA - Health Technology Assessment
IVDR - In Vitro Diagnostic Medical Devices Regulation ((EU 2017/746)
LVD - Low Voltage Directive (2014/35/EU)
MD - Machine Directive (2006/42/EC)
MDR - Medical Device Regulation (2017/745/EU)
RoHS - Restriction of the use of certain Hazardous Substances in electrical and electronic equipment Directive (2011/65/EU)
TMMi - Test Maturity Model Integration

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