medical
SERVICE CATALOGUE

MDR / IVDR / FDA

2023 - 2024

QTICS medical

- Consulting
- Education
- Product Development
- Software Development and Testing
- Preclinical Testing
- Productions Equipment Testing
- Clinical investigation
- Certification

OUR SERVICE PORTFOLIO BY MEDICAL SEGMENTS

Consulting

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.

Product development

Thanks to our professional engineering team we have an extensive experience in the design of custom PCBs, electronic devices and complete product development.

Software development and testing

We build reliable custom software solutions for our customers from concept to FDA approval. Our team of experts supports every step of the development process, including UX/UI design, software development, testing, quality assurance and support services.

Preclinical testing

Verification of medical devices safety is mandatory for all manufacturers. We provide biocompatibility, safety and usability testing services to verify the safety of active and IVD devices.

Cybersecurity evaluation

Active and IVD devices which are connected, store any data, include any computing, control analogue or digital functionality are subject of mandatory assessment and validation of cybersecurity risk. We execute cybersecurity evaluations based on strictest accreditations and standards.

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

synthesis NET

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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SEARCH
CONSULTING

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.
5.	EN 60601-1 EN 61010-2-101	Technical advice for the safe, standard design of devices
Software Development and Testing		
6.	TMMi framework ISO 13485	Thorough evaluation of team capabilities, goals and skill sets
7.	ISO 13485	Process improvement recommendations to optimize efficiency and quality
8.	ISO 13485	Ensuring outputs meet regulatory requirements and industry standards
9.	ISO 13485	Facilitating compliance with relevant regulations during the development lifecycle
10.	-	Consulting related to Artificial Intelligence Machine Learning and Data Science

Cybersecurity

11.	MDR I. Product-specific requirements	Developing a cybersecurity strategy
12.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 ISO 810001-5-1 AAMI TIR57	Gap analysis
13.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 AAMI TIR57	Prepare / support the Risk Management File based on Cybersecurity
14.	AAMI TIR57	Provide expert review of the acceptability of all residual risks for Cybersecurity
15.	-	Monitoring the state-of-the-art level of Cybersecurity and reporting regularly
16.	MDR I.	Support and review the Instruction for Use based on Cybersecurity

Cybersecurity

17.	EN 60601-1 EN 62304 IEC 82304-1 EN 62304 IEC 81001-5-1	Change or create design and development procedures for Cybersecurity
18.	EN 62304 (IEC 62304) IEC 81001-5-1	Evaluation of Cybersecurity aspects of software requirements: ▪ Software architecture security analysis ▪ Safety review of risk analysis
19.	IEC/TR 60601-4-5 (IEC 62443-4-2)	Safety aspects of medical devices, support for safety level classification
20.	ISO/IEC 27001 ISO/IEC 27002	Development and certification support of Information Security Management System

Conformity assessment support - MDR		
21.	MDR Art. 29. 31.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
22.	MDR Art. 27. VI. B.	UDI design support
23.	MDR Art. 10 (9) IX., XI. A. ISO 13485	Implementation of quality management system: ▪ Preparation of documentation ▪ Introductory education ▪ Internal audit ▪ Management review
24.	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
25.	MDR III.	Preparation of technical documentation on post-market surveillance: ▪ Post-market surveillance plan ▪ Periodic safety update report ▪ Post-market surveillance report
26.	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
27.	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

Conformity assessment support - MDR		
28.	IEC 62366-1	Supporting of the Usability Engineering Process: ▪ Compilation of the Usability Engineering File ▪ Associated risk evaluation.
29.	MDR Art. 10 (9) IX., XI. A. ISO 13485	Perform audits: ▪ CE (MDR) internal audit ▪ ISO 13485 internal audit ▪ Supplier audit
Conformity assessment support - IVDR		
30.	IVDR Art. 26. 28.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
31.	IVDR Art. 24. VI. B.	UDI design support
32.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	Implementation of quality management system: ▪ Preparation of documentation ▪ Introductory education ▪ Internal audit ▪ Management review
33.	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
34.	IVDR III.	Preparation of technical documentation on post-market surveillance: ▪ Post-market surveillance plan ▪ Periodic safety update report ▪ Post-market surveillance report

Conformity assessment support - IVDR		
35.	IVDR XIII.	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
36.	IEC 62366-1	Supporting of the Usability Engineering Process: ▪ Compilation of the Usability Engineering File ▪ Associated risk evaluation
37.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	Perform audits: ▪ CE (IVDR) internal audit ▪ ISO 13485 internal audit ▪ Supplier audit
Conformity assessment support – FDA		
38.	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
39.	21 CFR Part 11	▪ Consulting on Electronic Records and Electronic Signatures
40.	IEC 62366-1	Supporting of the Usability Engineering Process: ▪ Compilation of the Usability Engineering File ▪ Associated risk evaluation
41.	21 CFR Part 820 ISO 13485	Perform audits: ▪ 21 CFR Part 820 internal audit ▪ ISO 13485 internal audit ▪ Supplier audit

Conformity assessment support - RoHS		
42.	RoHS Article 7. b)	Support for internal production control procedure: ▪ Development of technical documentation ▪ Supplementing the quality management system with RoHS requirements
Conformity assessment support – production equipment (machines)		
43.	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
44.	(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

EDUCATION

Management system trainings		
45.	ISO 13485	Standard introductory training
46.	ISO 9001, ISO 14001	Standard introductory training
47.	ISO 13485	Internal Auditor Training
48.	ISO 9001, ISO 14001	Internal Auditor Training
49.	ISO/IEC 17025	Internal Auditor Training
50.	21 CFR Part 820	Introductory training
51.	21 CFR Subchapter H	Regulatory training covering FDA regulations
MDR, IVDR trainings		
52.	MDR II., III.	Technical documentation
53.	MDR 15.	Person Responsible for Regulatory Compliance (PRRC)
54.	MDR XIV.	Clinical Evaluation
55.	MDR III.	Post-market surveillance system (PMS)
56.	MDR XIV. B.	Post-market clinical follow-up (PMCF)
57.	MDR, /IVDR	Cybersecurity
MDR, IVDR related standards trainings		
58.	ISO 14971	Risk management
59.	EN 62366-1	Usability Engineering
60.	EN 60601-1	Safety test of medical electrical equipment
61.	EN 61010-1	Electrical equipment for measurement, control, and laboratory use
62.	EN 61010-2-101	In vitro diagnostics (IVD) medical equipment

MD and related standards training		
63.	2006/42/EC	CE marking of machines
64.	2006/42/EC EN ISO 10218-X ISO/TS 15066	CE marking of industrial robot and collaborative robot systems
65.	EN ISO 12100	Risk evaluation of industrial machines
66.	(relevant standards)	Safety and technical requirements of machines
67.		Training related to Artificial Intelligence Machine Learning and Data Science

PRODUCT DEVELOPMENT

PCB Design		
68.	ISO 9001 AS/EN9100 DO254 ISO 13485	System design: ▪ Healthcare and Medical devices ▪ Space, Aerospace ▪ Industrial, Automotive, ICT/IoT
69.	ISO 9001 AS/EN9100 DO254 ISO 13485	Schematics: ▪ Altium, Mentor, Cadence and Zuken tools
70.	ISO 9001 AS/EN9100 DO254 ISO 13485	Schematics: ▪ Altium, Mentor, Cadence and Zuken tools
71.	ISO 9001	▪ Simulation
72.	AS/EN9100 DO254 ISO 13485	Spice and IBIS AMI
Embedded Software Development		
73.	ISO 9001 AS/EN9100 DO178 ISO 13485	MCU, microcontroller: ▪ Major MCUs: STM32, Nordic Semiconductor, Silabs, ESP32
74.	ISO 9001, AS/EN9100 DO178 ISO 13485	FPGA development: ▪ Chips: Intel, AMD, System on SOC ▪ SOM: Trenz, Kria
75.	ISO 9001, AS/EN9100 DO178 ISO 13485	Linux: Major MCUs: NXP, Broadcom, RPI, Qualcomm Allwinner Custom BSP
Turnkey product development		
76.	IPC 600 IPC610 Class 3	Prototype manufacturing
77.		Functional Test System Development

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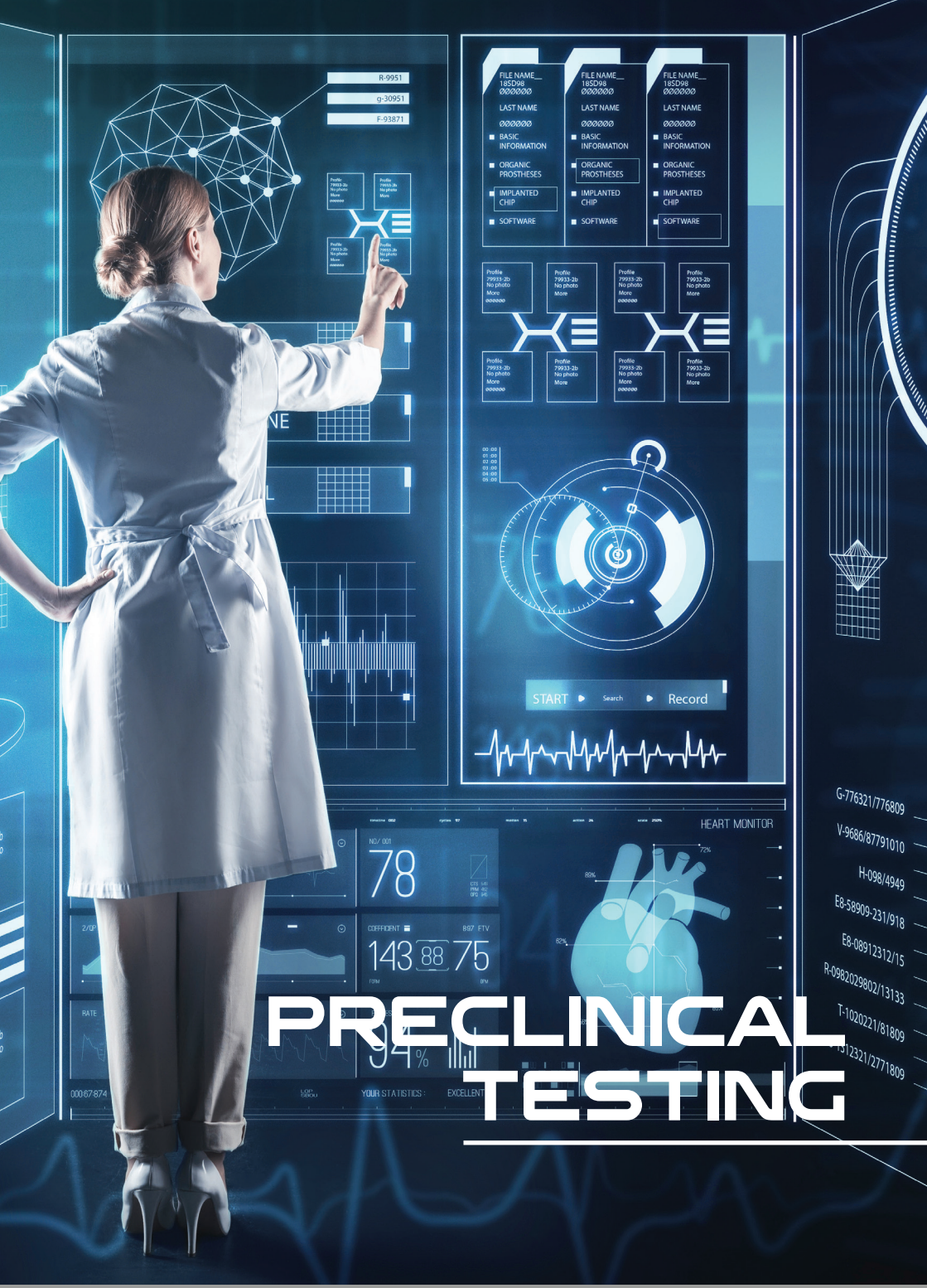
78.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Software Development - Mobile Applications (Native Android, iOS and Cross Platform)
79.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Software Development - Web Applications
80.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Software Development - Desktop Applications
81.	21 CFR Part 820	Developing comprehensive test plans aligned with regulatory requirements
82.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Executing compliance and functional tests to assess product quality
83.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Assessment and validation of cybersecurity risks (QTICS competency)
84.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Identifying and addressing any non-conformances or areas of improvement

85.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Establishing a robust testing framework to support ongoing compliance
86.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Creating comprehensive records to demonstrate compliance with QA processes
87.	21 CFR Part 820 MDR ISO 13485 IEC 62304 IEC 82304-1	Conducting documentation audits to identify gaps and improve documentation practices
88.		Solutions and system integration related to Artificial Intelligence, Machine Learning and Data Science



PRECLINICAL TESTING

Biocompatibility testing		
89.	ISO 10993-3	Tests for genotoxicity, carcinogenicity and reproductive toxicity
90.	ISO 10993-4	Selection of tests for interactions with blood
91.	ISO 10993-5	Tests for in vitro cytotoxicity
92.	ISO 10993-10	Tests for irritation and skin sensitization
93.	ISO 10993-11	Tests for systemic toxicity
94.	ISO 10993-18	Chemical characterization of materials (UV, MS, IR)
Safety testing		
95.	EN 60601-1 (IEC 60601-1)	Medical electrical equipment
96.	EN 60601-1-6 (IEC 60601-1-6)	Medical electrical equipment – Usability
97.	EN 60601-1-8 (IEC 6060-1-8)	Alarm systems in medical electrical equipment and medical electrical systems
98.	EN 60601-2-10 (IEC 60601-2-10)	Nerve and muscle stimulators
99.	EN 60601-2-25 (IEC 60601-2-25)	Electrocardiographs
100.	EN 60601-2-26 (IEC 60601-2-26)	Electroencephalographs
101.	EN 60601-2-27 (IEC 60601-2-27)	Electrocardiographic monitoring equipment
102.	EN 60601-2-47 (IEC 60601-2-47)	Ambulatory electrocardiographic systems
103.	EN 60601-2-4 (IEC 60601-2-4)	Cardiac defibrillators
104.	EN 80601-2-30 (IEC 80601-2-30)	Automatic cycling non- invasive blood pressure monitoring equipment

Safety testing		
105.	EN 61010-1) (IEC 61010-1)	Electrical equipment for measurement, control, and laboratory use
106.	EN 61010-2-101 (IEC 61010-2-101)	Particular requirements for in vitro diagnostic (IVD) medical equipment
Usability testing		
107.	IEC 62366-1	Formative evaluation (expert review, standard review)
108.	IEC 62336-1	Summative evaluation (Usability test)
Cybersecurity testing		
109.	EC 81001-5-1 ISO 14971 AAMI TIR 57	Risk Assessment
110.	EC 81001-5-1	Secure requirements testing
111.	EC 81001-5-1	Threat mitigation testing
112.	EC 81001-5-1 MDR I. MDCG 2019-16 ISO 14971 AAMI TIR 57	Vulnerability testing A. Threat modeling based vulnerability assessment B. Security Testing / Penetration Test
RoHS testing		
113.	RoHS Annex II	Determination of the concentration of hazardous substances

PRODUCTIONS EQUIPMENT TESTING

114.	(MD, LVD, EMC, ATEX)	CE conformity testing: ▪ Documentation evaluation ▪ Visual inspection ▪ Functional examination ▪ Instrumental measurements (on-site or laboratory)
115.	(relevant occupational safety and health regulations)	Safety tests: ▪ Preliminary ▪ Periodic ▪ Extraordinary
116.	MD, EN ISO 14159	Hygienic inspection of production equipment
117.	(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

CLINICAL INVESTIGATION

118.	MDR XV. Chapter II. 3.	Preparation of the Clinical Investigation Plan; data collection, literature search
119.	MDR XV. Chapter II. 1-2.	Preparation of the documentation regarding the application for clinical investigation
120.	MDR Art. 70	Prepare the Clinical Investigation authorization (submitting the application, communication with the authority)
121.	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
122.	MDR Art. 87	Supporting the reporting of serious incidents and field safety corrective actions
123.	MDR XV. Chapter III. 4-6.	Follow the Clinical Investigation (monitoring, data management, project management)
124.	MDR XV. Chapter III. 7.	Prepare a clinical investigation report


CERTIFICATION

125.	ISO 13485	Quality Management System
126.	ISO 27001	Information security management system
127.	ISO 9001, ISO 14001 ISO 50001, ISO 45001	Management Systems
128.	MDR IX., XI. A.	Conformity assessment Upon completion of above compulsory conformity assurance services the application for Conformity Assessment Procedure has to be placed at an independent Notified Body
129.	MD	EC type - examination or certificate of conformity (CoC) of production equipment
130.	LVD	Certificate of conformity (CoC) of production equipment
131.	EMC	EC type - examination or certificate of conformity (CoC)
132.	RED	EC type - examination or certificate of conformity (CoC)
133.	RoHS	Certificate of conformity (CoC)
134.	ATEX	EC type - examination or certificate of conformity (CoC)

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*

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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