medical
MDR / IVDR

SERVICE CATALOGUE

2023

QTICS medical

Consulting

Education

Preclinical testing

Productions equipment testing

Clinical investigation

Certification

OUR OFFER

For a full understanding of the MDR, we offer 2 hours of preparatory training (including 15 minutes of consultation)

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.

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.

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 cyber security 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.

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.

QTICS medical

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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)	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.

Cybersecurity		
6.	MDR I. Product-specific requirements	Developing a cybersecurity strategy
7.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 ISO 810001-5-1 AAMI TIR57	Gap analysis
8.	Relevant provisions of MDR I MDCG 2019-16 ISO 14971 AAMI TIR57	Prepare / support the Risk Management File based on Cybersecurity.
9.	AAMI TIR57	Provide expert review of the acceptability of all residual risks for Cybersecurity.
10.	-	Monitoring the state-of-the-art level of Cybersecurity and reporting regularly.

Cybersecurity		
11.	MDR I.	Support and review the Instruction for Use based on Cybersecurity
12.	EN 60601-1 EN 62304 IEC 82304-1 EN 62304 IEC 81001-5-1	Change or create design and development procedures for Cyber Security
13.	EN 62304 (IEC 62304) IEC 81001-5-1	Evaluation of Cyber Security aspects of software requirements: • software architecture security analysis, • safety review of risk analysis.
14.	IEC/TR 60601-4-5 (IEC 62443-4-2)	Safety aspects of medical devices, support for safety level classification
15.	ISO/IEC 27001 ISO/IEC 27002	Development and certification support of Information Security Management System

Conformity assessment support - MDR		
16.	MDR Art. 29. 31.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
17.	MDR Art. 27. VI. B.	UDI design support
18.	MDR Art. 10 (9) IX., XI. A. ISO 13485	Implementation of quality management system: • preparation of documentation, • introductory education, • internal audit, • management review.
19.	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.

Conformity assessment support - MDR		
20.	MDR III.	Preparation of technical documentation on post-market surveillance: • post-market surveillance plan, • Periodic safety update report, • post-market surveillance report.
21.	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.
22.	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.
23.	EN 62366-1	Supporting of the Usability Engineering Process: • compilation of the Usability Engineering File, • associated risk evaluation.
24.	MDR Art. 10 (9) IX., XI. A. ISO 13485	Perform audits: • CE (MDR) internal audit, • ISO 13485 internal audit, • supplier audit.

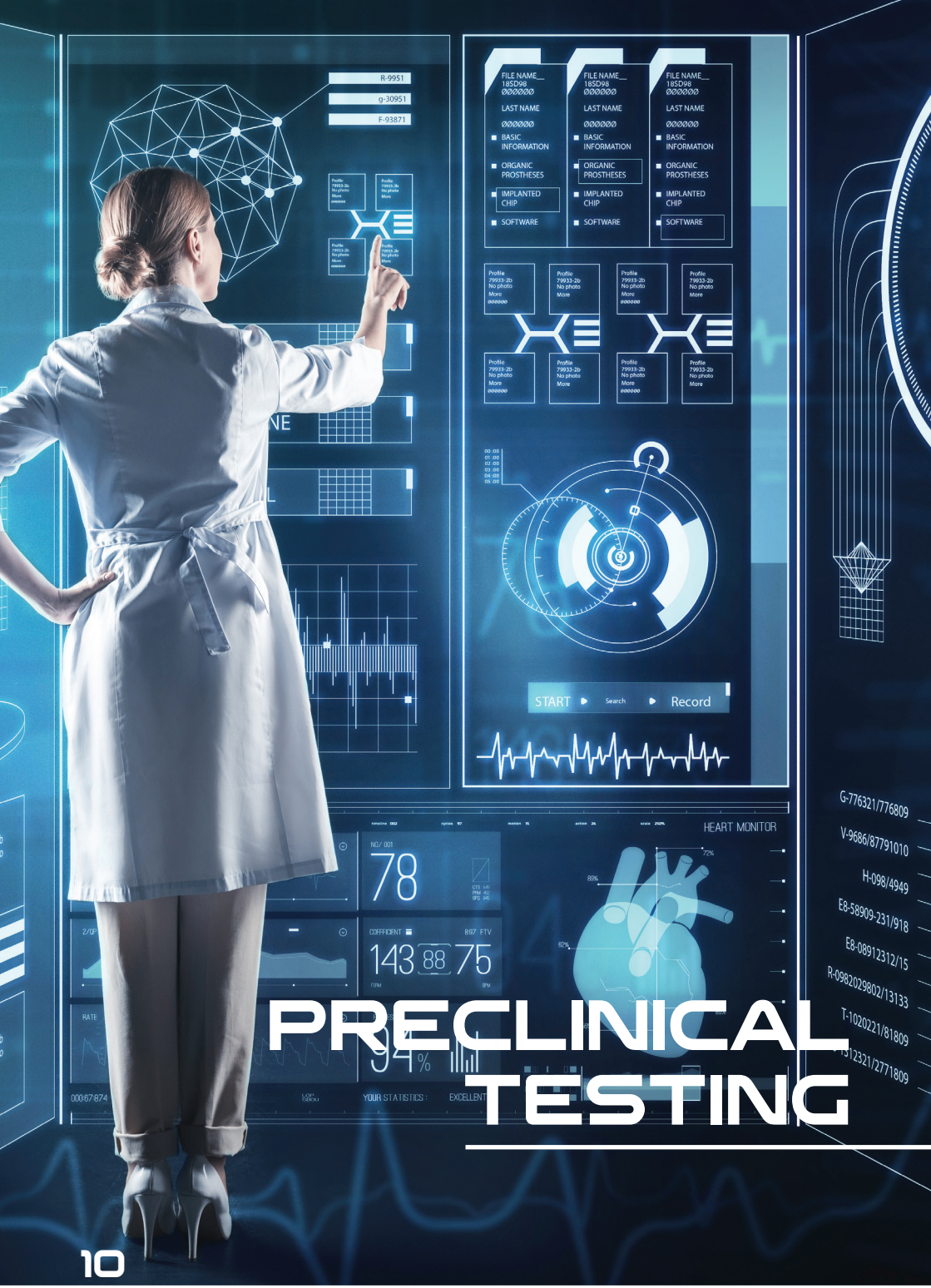
Conformity assessment support - IVDR		
25.	IVDR Art. 26. 28.	Support the registration of medical devices and economic operators (EUDAMED, NOR)
26.	IVDR Art. 24. VI. B.	UDI design support
27.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	IImplementation of quality management system: • preparation of documentation, • introductory education, • internal audit, • management review.
28.	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.
29.	IVDR III.	Preparation of technical documentation on post-market surveillance: • post-market surveillance plan, • Periodic safety update report, • post-market surveillance report.
30.	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.
31.	EN 62366-1	Supporting of the Usability Engineering Process: • compilation of the Usability Engineering File, • associated risk evaluation.
32.	IVDR Art. 10 (8) IX., XI. A. ISO 13485	Perform audits: • CE (MDR) internal audit, • ISO 13485 internal audit, • supplier audit.

Conformity assessment support - RoHS		
33.	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)		
34.	RoHS Article 7. b)	SDefining 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.
35.	(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

36.	ISO 13485	Standard introductory training
37.	ISO 9001, ISO 14001	Standard introductory training
38.	ISO 13485	Internal Auditor Training
39.	ISO 9001, ISO 14001	Internal Auditor Training
40.	ISO/IEC 17025	Internal Auditor Training
41.	MDR II., III.	Technical documentation
42.	MDR 15.	Person Responsible for Regulatory Compliance (PRRC)
43.	MDR XIV.	Clinical Evaluation
44.	MDR III.	Post-market surveillance system (PMS)
45.	MDR XIV. B.	Post-market clinical follow-up (PMCF)
46.	MDR/IVDR	Cybersecurity
47.	ISO 14971	Risk management
48.	EN 62366-1	Usability Engineering
49.	EN 60601-1	Safety test of medical electrical equipment
50.	EN 61010-1	Electrical equipment for measurement, control, and laboratory use
51.	EN 61010-2-101	In vitro diagnostics (IVD) medical equipment
52.	2006/42/EC	CE marking of machines
53.	2006/42/EC EN ISO 10218-X ISO/TS 15066	CE marking of industrial robot and collaborative robot systems
54.	EN ISO 12100	Risk evaluation of industrial machines
55.	(relevant standards)	Safety and technical requirements of machines



PRECLINICAL TESTING

Biocompatibility testing		
56.	ISO 10993-3	Tests for genotoxicity, carcinogenicity and reproductive toxicity
57.	ISO 10993-4	Selection of tests for interactions with blood
58.	ISO 10993-5	Tests for in vitro cytotoxicity
59.	ISO 10993-6	Tests for local effects after implantation
60.	ISO 10993-7	Ethylene oxide sterilization residuals
61.	ISO 10993-9	Framework for identification and quantification of potential degradation products
62.	ISO 10993-10	Tests for irritation and skin sensitization
63.	ISO 10993-11	Tests for systemic toxicity
64.	ISO 10993-13	Identification and quantification of degradation products from polymeric medical devices
65.	ISO 10993-14	Identification and quantification of degradation products from ceramics
66.	ISO 10993-15	Identification and quantification of degradation products from metals and alloys
67.	ISO 10993-16	Toxicokinetic study design for degradation products and leachables
68.	ISO 10993-17	Establishment of allowable limits for leachable substances
69.	ISO 10993-18	Chemical characterization of materials
70.	ISO 11737-1	Determination of bioburden
71.	ISO 11737-2	Tests of sterility
72.	Ph. Eur.	Bacterial endotoxin test

Safety testing		
73.	EN 60601-1 (IEC 60601-1)	Medical electrical equipment
74.	EN 60601-1-6 (IEC 60601-1-6)	Medical electrical equipment – Usability
75.	EN 60601-1-8 (IEC 6060-1-8)	Alarm systems in medical electrical equipment and medical electrical systems
76.	EN 60601-2-10 (IEC 60601-2-10)	Nerve and muscle stimulators
77.	EN 60601-2-25 (IEC 60601-2-25)	Electrocardiographs
78.	EN 60601-2-26 (IEC 60601-2-26)	Electroencephalographs
79.	EN 60601-2-27 (IEC 60601-2-27)	Electrocardiographic monitoring equipment
80.	EN 60601-2-47 (IEC 60601-2-47)	Ambulatory electrocardiographic systems
81.	EN 60601-2-4 (IEC 60601-2-4)	Cardiac defibrillators
82.	EN 80601-2-30 (IEC 80601-2-30)	Automatic cycling non- invasive blood pressure monitoring equipment
83.	EN 61010-1) (IEC 61010-1)	Electrical equipment for measurement, control, and laboratory use
84.	EN 61010-2-101 (IEC 61010-2-101)	Particular requirements for in vitro diagnostic (IVD) medical equipment

Usability testing		
85.	EN 62366-1	Formative evaluation (expert review, standard review)
86.	EN 62336-1	Summative evaluation (Usability test)

Cybersecurity testing		
87.	ISO 81001-5-1 ISO 14971 AAMI TIR 57	Risk Assessment
88.	ISO 81001-5-1	Secure requirements testing
89.	ISO 81001-5-1	Threat mitigation testing
90.	ISO 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		
91.	RoHS Annex II	Determination of the concentration of hazardous substances

PRODUCTIONS EQUIPMENT TESTING

92.	(MD, LVD, EMC, ATEX)	CE conformity testing: • documentation evaluation, • visual inspection, • functional examination, • instrumental measurements (on-site or laboratory).
93.	(relevant occupational safety and health regulations)	Safety tests: • preliminary, • periodic, • extraordinary.
94.	MD, EN ISO 14159	Hygienic inspection of production equipment
95.	(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

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96.	MDR XV. Chapter II. 3.	Preparation of the Clinical Investigation Plan; data collection, literature search
97.	MDR XV. Chapter II. 1-2.	Preparation of the documentation regarding the application for clinical investigation
98.	MDR Art. 70	Prepare the Clinical Investigation authorization (submitting the application, communication with the authority)
99.	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.
100.	MDR Art. 87	Supporting the reporting of serious incidents and field safety corrective actions
101.	MDR XV. Chapter III. 4-6.	Follow the Clinical Investigation (monitoring, data management, project management)
102.	MDR XV. Chapter III. 7.	Prepare a clinical investigation report

CERTIFICATION

103.	ISO 13485	Quality Management System
104.	ISO 27001	Information security management system
105.	ISO 9001, ISO 14001 ISO 50001, ISO 45001	Management Systems
106.	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. The list of eligible Notified Bodies can be found at the following links: MDR NB IVDR NB
107.	MD	EC type - examination or certificate of conformity (CoC) of production equipment
108.	LVD	Certificate of conformity (CoC) of production equipment
109.	EMC	EC type - examination or certificate of conformity (CoC)
110.	RED	EC type - examination or certificate of conformity (CoC)
111.	RoHS	Certificate of conformity (CoC)
112.	ATEX	EC type - examination or certificate of conformity (CoC)

ABBREVIATIONS

MDR – Medical Device Regulation ((EU) 2017/745)

IVDR – In Vitro Diagnostic Medical Devices Regulation ((EU 2017/746)

MD – Machine Directive (2006/42/EC)

LVD – Low Voltage Directive (2014/35/EU)

RoHS – Restriction of the use of certain Hazardous Substances in electrical and electronic equipment Directive (2011/65/EU)

EMC – Electromagnetic Compatibility Directive (2014/30/EU)

ATEX – Equipment and protective systems intended for use in potentially explosive atmosphere (2014/34/EU)

HTA – Health Technology Assessment

QTICS MEDICAL DIVISION

QTICS Group is a **dynamically growing** industrial player in the international Testing, Inspection and Certification (TIC) sector. The **Testing, Inspection and Certification** industry is based on the demand for the conformity assessment of increasingly complex technological value creation procedures, processes, products and the persons operating them. Regarding both its professional portfolio and international expansion, QTICS Group applies the principle of network building in its strategic operations. The member companies of the Group possess and develop national, European and international authorizations (accreditations, notifications, designations) in order to be able to provide independent, objective, third party complex conformity assessment services in the selected industrial segment as a one-stop-shop. The Group operates primarily in four industrial segments:

Medical devices

Mobility & drone

Energy & industry

Consumer & IoT

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