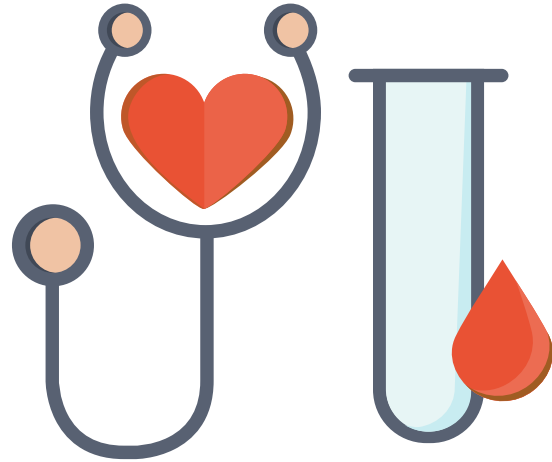




Your regulatory compliance partner

in Medical
and In Vitro
Diagnostic
Devices



company
presentation

Your partner

Metecon is your strategic partner for medical device manufacturers across the entire product life cycle. We respect our customers, listen to their wishes, and understand their requirements to create individual solutions for compliant international commercialization of their medical devices and IVDs.





Everything out of one hand

Technical documentation, clinical affairs, verification, regulatory affairs, and QM: With us, you obtain everything from a single source.

This releases immense synergy effects for your product. You are strong in development and marketing – for anything else you have us!

Our service

Documentation and market access

Consulting services and support for the preparation of technical documentation and filing of your product file.



Our service

Verification and validation

Everything about assessing and evaluating your products: starting with development of suitable test strategies right through to testing in the test laboratory.



Documentation and market access



Technical Documentation

Strategic consultation and active support for the preparation and maintenance of technical documentation



Clinical Affairs

Clinical evaluation via the literature route, clinical investigation, performance evaluation for IVDs, PMS and PMCF / PMPF



Regulatory Affairs

Consulting services and support for country-specific commercialization

Documentation and market access



Quality Management

Quality Management processes in compliance with EN ISO 13485, GxP; audits

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Medical Device Software

Consulting services and support in all regulatory tasks regarding software

Verification and validation



Verification

Verification planning, preparation of test specifications, conduction and documentation of tests, organization and controlling of examinations in accredited laboratories



Validation

Validation of measuring and inspection tasks incl. software, validation of medical devices / IVDs incl. software, validation of steril processes



Testautomation

Flexible test automation by means of a six axis robotic system, conduction of experimental runs

About us

We are experts of medical technology: as all-in-one experts, we assist you with all services around your product development.

Our 40 engineers, life scientists, and computer scientists secure with their know-how the high quality of our work, and guarantee a seamless project implementation.

Owner-managed from the beginning in 1999 until today, we place highest value on long-term and partnering relations to our customers.



Your contact partners at Metecon



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Let us start.

We look forward to
working with you.

