

CLINICAL EVALUATION

of Medical Devices

SERVICES



CLINICAL EVALUATION

We create your clinical evaluation in accordance with MDR requirements. Our approach is modular and based on a close exchange with you to incorporate your expertise, the product history and technical details into the assessment.



DEVELOPMENT of your clinical strategy

A thorough clinical evaluation is an essential prerequisite for the approval of your medical devices. To ensure its success, we assist you in the early phase of product development and define your clinical strategy together with you.



REVIEW of your clinical evaluation

We review your existing clinical evaluation taking into account the MDR requirements and our expertise from Notified Body feedback.



PERFORMANCE EVALUATION for In-vitro Diagnostics

We create your performance evaluation according to IVDR, develop a performance evaluation strategy or review your existing performance evaluation taking into account the latest regulatory requirements and feedback from Notified Bodies.



EFFICIENT & HIGHLY COMPETENT

With our extensive expertise, years of experience and profound understanding of the regulatory requirements, we act as your reliable partner for independent and objective clinical evaluations.

- interdisciplinary team of experts
- experience from over 200 clinical evaluations
- experience in cooperation with Notified Bodies and authorities in Europe and worldwide
- in-house knowledge management
- experts network from various medical fields

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