Effectum Medical AG

assists in the development of innovative medical devices and technologies throughout the certification and life cycle management process. Acting as legal manufacturer and by offering our Plug & Play (e)QMS, we speed up your time to market and ensure compliance and excellence in every stage of development.

EFFECTUM
MEDICAL

AI/ML DEVICE CERTIFICATION

OVERVIEW ALL SERVICES

ARTIFICIAL INTELLIGENCE (AI) MACHINE LEARNING (ML) DEVICE CERTIFICATION

AI and ML Device Certification for Healthcare
Navigate AI/ML Integration with Confidence

Incorporating Machine Learning (ML) and Artificial Intelligence (AI) into medical devices brings transformative potential, but it also requires navigating a complex regulatory environment. Effectum Medical provides expert guidance to ensure your devices meet all relevant compliance standards, including the European AI Act, MDR, and IVDR.

Dr. Rolf Kaufmann
Senior Medical Device Expert MD/IVD
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COMPLIANCE SERVICES

Our Comprehensive AI/ML Compliance Services

AI Readiness & Compliance Checks

- **Gap Analyses & AI Readiness:** We review your documentation to identify any gaps, ensuring it aligns with AI Act requirements.
- **Dual or Single Regulation Assessments:** Tailored checks to meet both AI Act and MDR/IVDR compliance, providing peace of mind at every stage.

CE Certification Support

- **Expert Guidance**: Our team assists in achieving CE certification, offering specialized support for ML/AI-based software to help you navigate the approval process efficiently.

Technical Documentation Templates

- **Streamlined Preparation:** Access customizable templates that simplify the preparation of technical files, helping you maintain compliance while saving time.

AI Act Compliance Solutions

- **Harmonized Compliance Strategy:** Our established processes ensure that your systems meet both AI Act and MDR/IVDR requirements efficiently and effectively.

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LIFECYCLE SUPPORT FOR ML/AI DEVICES

From development through to post-market monitoring, we support your ML/AI device across its entire lifecycle:

- **Pre-market Conformity Assessments:** Determine if a notified body conformity assessment is necessary or if internal controls will apply. Our team will also assist in preparing technical documentation in line with both AI Act and MDR/IVDR standards.
- **Clinical Evaluation Support:** We help align clinical evaluations with ML/AI-specific regulatory requirements.
- **Continuous Monitoring Solutions:** Ensure your device remains compliant as it evolves in real-world use, meeting ongoing monitoring and regulatory requirements.

Preparing for the Future of Healthcare AI Compliance

Developing a robust ML/AI device can take 1-2 years, with conformity assessments adding another year. To meet the August 2027 deadline for high-risk applications under the EU AI Act, it's critical to start early.

Let us guide you through each step to ensure readiness for this evolving regulatory landscape.

WHY CHOOSE EFFECTUM MEDICAL?

Why Choose Effectum Medical?

- **Dual Expertise:** Specialists in AI regulation and medical device compliance.
- **Efficiency:** Streamlined processes that align with AI Act and MDR/IVDR.
- **Future-Proofing:** Preparedness for upcoming regulatory changes, ensuring your product's compliance and adaptability.

Don't let regulatory requirements stall your healthcare AI innovations. **Partner with Effectum Medical** to turn compliance into a growth opportunity and build patient trust.

Contact us for a personalized consultation to prepare your ML/AI models for the European market.

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SUPPORT OPTION

Outsourced Legal Manufacturer:
Streamline market access and compliance with our trusted legal manufacturer services. Need speed? Ask about our fast-track option!

Plug & Play (e)QMS:
Accelerate your launch with a ready-made EN ISO 13485, MDR/IVDR, and FDA-compliant quality management system.

Plug-and-Play eQMS Bootcamp:
Flexible training to empower self-management of your QMS.

Rent an Expert:
Add quality management and regulatory expertise to your team as needed.

Regulatory Opinions:
Access expert insights for global compliance and market strategy.

AI/ML Device Certification:
Certification services for AI and machine learning-based medical devices.

CH-REP (Swiss Authorized Representative):
Facilitate Swiss market access with local representation. Visit Effectum CH-REP AG for details.

For more information visit: www.effectummedical.com

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