



## Accelerate EU Market Access via Our Legal Manufacturer Framework

Effectum acts as your Swiss-based legal manufacturer — enabling rapid CE-marking under MDR/IVDR with our QMS and Notified Body relationship.



# OUTSOURCED LEGAL MANUFACTURER



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## OUTSOURCED LEGAL MANUFACTURER

Need to enter the EU market but lack a certified QMS or local presence? Effectum Medical AG can act as your legal manufacturer. You focus on innovation - we'll take care of regulatory compliance, quality, and audits.

### Key Services

- Fast-track MDR/IVDR market entry
- CE-marking under Effectum's existing QMS
- Notified Body coordination (SGS)
- Vigilance & post-market surveillance
- PRRC services & label ownership
- Manufacturer-of-record role for MedTech and digital health.

### When to Choose This Service

- You need speed to market
- You want to postpone building an in-house QMS
- You lack EU legal presence or PRRC capabilities
- Your investors require CE-marking to release funding

### Key Benefits

- Accelerated entry: Market devices in months, not years
- Shared responsibility: Offload QMS, audits, and surveillance
- Flexibility: Transition to your own manufacturer role anytime
- Proven Model: model has proven itself for startups, SMEs, and pharma companies
- Swiss-based QMS: Established in Switzerland, centrally located



To learn more please contact:

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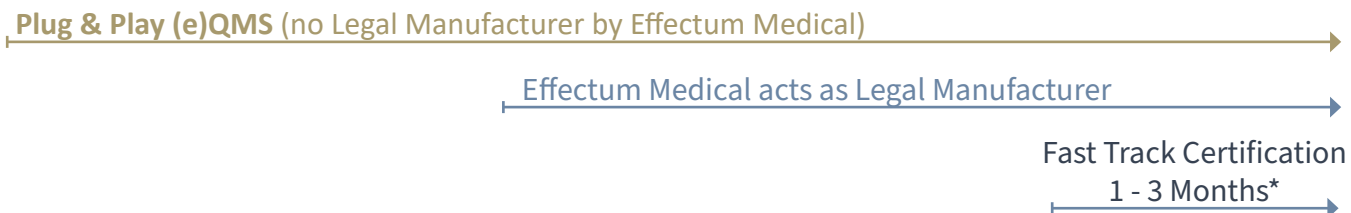
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# OUTSOURCED LEGAL MANUFACTURER - FAST TRACK

## Fast Track Certification

With our Fast Track Certification, products within the same scope and similar or lower risk can be marketed immediately after completing Technical Documentation and issuing the Declaration of Conformity. We hold MDR certificates for several product groups (Class Is and IIa). Contact us to learn more about our current scope.



\*The specified time periods are based on our experience and are non-binding. Liability is excluded. They also do not include the writing of technical documentation.



## WHAT CUSTOMERS SAY



**Klaus Hammer, Head of Regulatory & Quality - Perivision**

*„We received the CE certification benefiting from a „fast track“ due to EM’s previous certification history with their notified body. We reached MDR/CE certification approximately 12 months ahead of our time-line, which was a key benefit of our cooperation.“*



**Felix Schmidt, CEO - Deep Breath Intelligence (DBI)**

*“Choosing Effectum Medical’s Legal Manufacturing Services over building an in-house QMS brought several key advantages. First and foremost, the speed to market was significantly accelerated thanks to their QMS, which is fully compliant with EN ISO 13485, MDR/IVDR, and FDA requirements. The onboarding process was highly structured, and their deep regulatory expertise ensured compliance from day one. „*



**Emanuela Pufe - Fusi, Head of mediQ (PDAG)**

*„Effectum Medical offered us the one-stop-solution we were seeking for. We could immediately start working in their quality management systems and benefit, at the same time, from their broad experience and great know-how. It is the combination of QM infrastructure and advisory capacity what makes them unique.“*



## OUR SERVICES IN A NUTSHELL

### **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.

### **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.

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