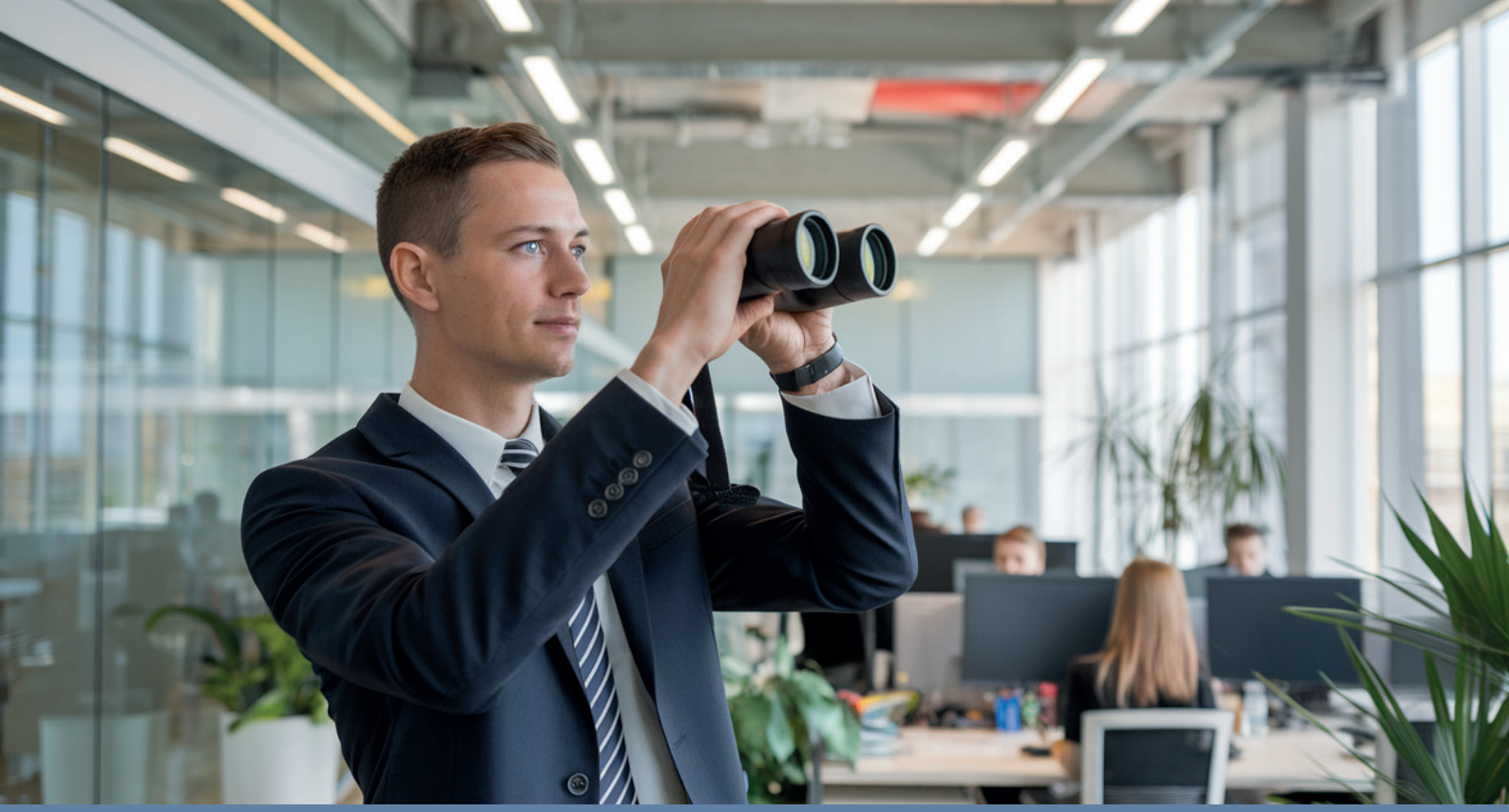
Effectum Medical AG

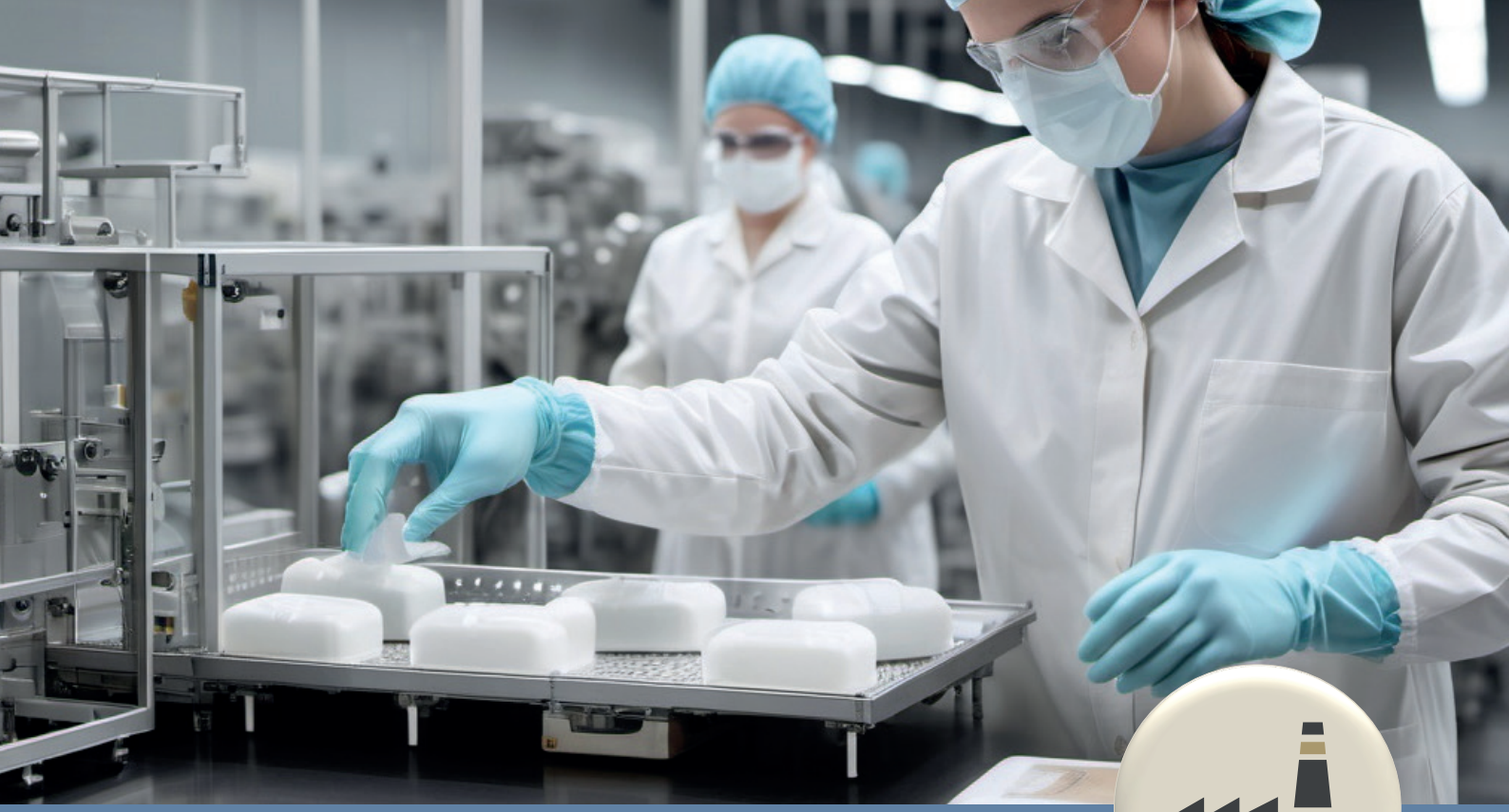
assists in the development of innovative medical devices and technologies throughout the certification and life cycle management process. Acting as legal manufacturer and by offering our Plug & Play (e)QMS, we speed up your time to market and ensure compliance and excellence in every stage of development.

EFFECTUM
MEDICAL

OUTSOURCED LEGAL MANUFACTURER



OVERVIEW ALL SERVICES



OUTSOURCED LEGAL MANUFACTURER

Unlock Your Potential with Our Services

We offer a complete solution for companies to outsource the legal manufacturing, providing a dedicated support team throughout the entire product lifecycle. With products certified under MDD, MDR, and IVDD, partnering with us can help accelerate your time-to-market significantly.

Faster Market Access

- We partner with two leading Notified Bodies, eliminating your search effort
- Take advantage of our QMS certification (ISO 13485/ MDR/IVDR/ QSR)
- „Fast track certification“ provides significant time savings

Mitigate Risks

- QMS audited annually since 2017
- Minimize risks with our approved and trusted supplier network
- Expand your team with experts in every domain of the medical device industry

Focus on your core activities

- Concentrate on new product development and lifecycle management
- Grow your business—we manage the regulatory and compliance challenges
- Maintain full control over your branding and design

Marius Wiederkehr
Head of Legal Manufacturing Services
marius.wiederkehr@effectummedical.com

FAST TRACK CERTIFICATION

Fast Track Certification:

With our Fast Track Certification, products within the same scope (MDA/MDN Codes for MDR) and similar or lower risk can be marketed immediately after completing the Technical Documentation and issuing the Declaration of Conformity without a technical file review from the notified body.

Timeline: 1–6 months* (From project start to certification)

We hold MDR certificates for several product groups (Class Is and IIa).

Covered Codes (As of 10/2024)

MDN 1202
Non-active non-implantable devices for administration, management and removal of substances including dialysis products (class Is)

MDA 0204
Other active non-implantable devices for monitoring and/or diagnosis (class IIa)

MDA 0308
Active non-implantable devices for wound and skin care (class IIa)

MDA 0313
Active, non-implantable protheses and devices for rehabilitation (class IIa)

MDA 0315
Software (class IIa)

QMS setup and certification after 9-15 Months*	ISO/ MDR Audit	**Technical File / Product Certification** after 12-24 Months*	MDR **CE**

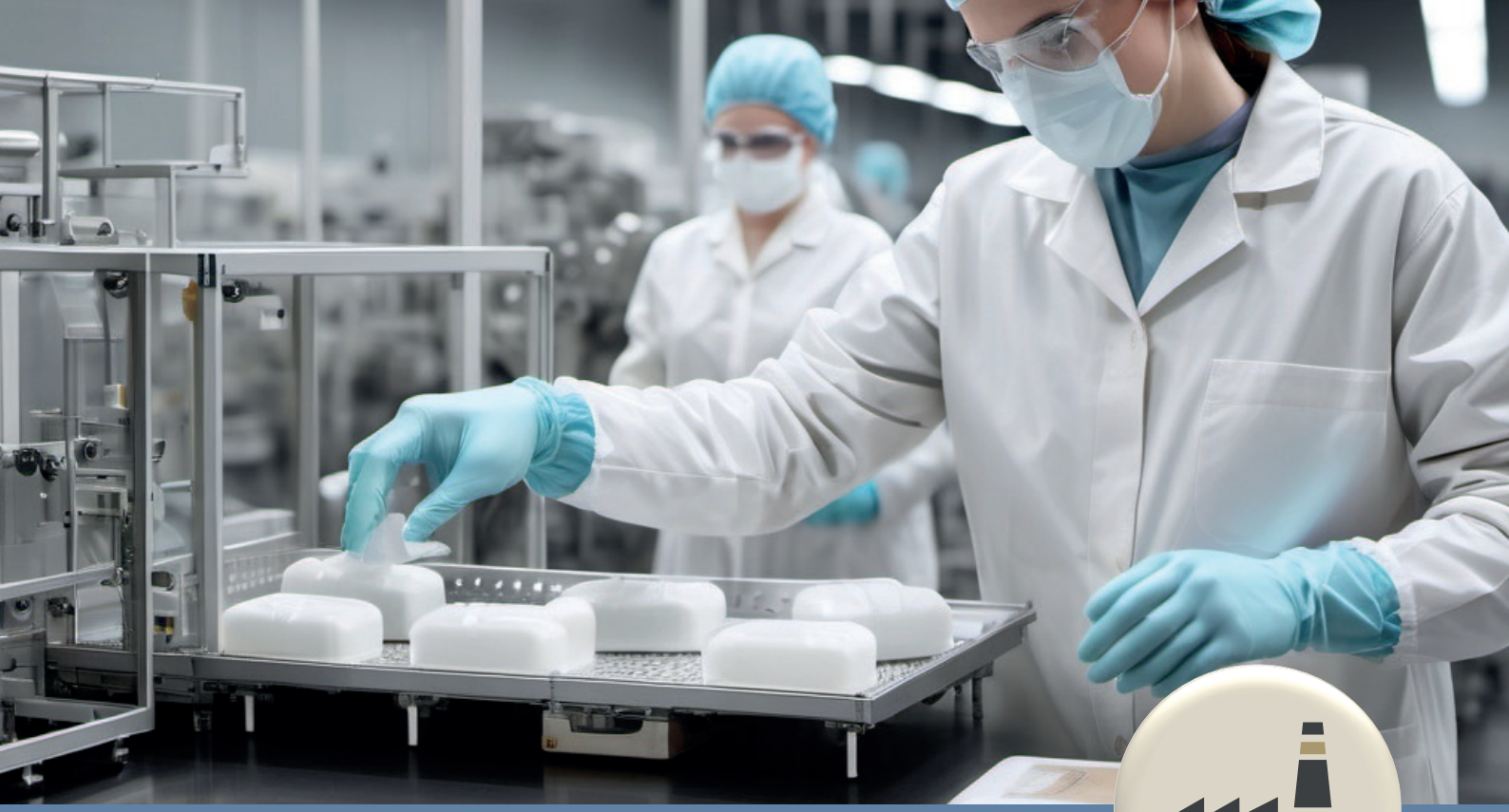
Plug & Play (e)QMS (no Legal Manufacturer by Effectum Medical)

Effectum Medical acts as **Legal Manufacturer**

Fast Track Certification

*The specified time periods are based on our experience and are non-binding. Liability is excluded.

Contact us today to find out how we can help streamline your product certification process and get your products to market faster!



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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