



AUTHORISED REPRESENTATIVE (EC REP)SERVICES

**MEDICAL DEVICES (MDR)
EUROPEAN UNION**



**We create compliance for
safer markets**

**Since 1988, our mission
has been to deliver the
most effective compliance
processes to our clients**

**Your consultant and
representative on the EU,
UK & Swiss markets**

**Your trusted partner for
regulatory compliance**





What is it all about?

MDR compliance and sales in the European Union (EU) market.

What are we going to do?

We will ensure the regulatory requirements as outlined by the MDR are met and the CE Marking is correctly obtained and affixed to your medical devices. Our team will review your technical documentation and validate your EUDAMED registrations (actor and devices).

We will then ensure the legal mandate as a European Authorised Representative is duly signed and we will continuously support you as your official contact point in Europe, towards queries from Authorities, Notified Bodies, Distributors, and other economic operators.

Authorised Representative



Same as manufacturers, Authorised Representatives must have permanently and continuously available a **Person Responsible for Regulatory Compliance (PRRC)** who possesses necessary expertise regarding medical devices regulatory requirements in the EU – by law!

Formal qualification criteria - MDR Article 15 (6)

University degree (documented by Diploma/Certificate) in law, medicine, pharmacy, engineering or another relevant scientific discipline + at least one year of professional experience in regulatory affairs or in QMS relating to medical devices; or four years of professional experience in regulatory affairs/quality management systems relating to medical devices (...)



How long will it take?



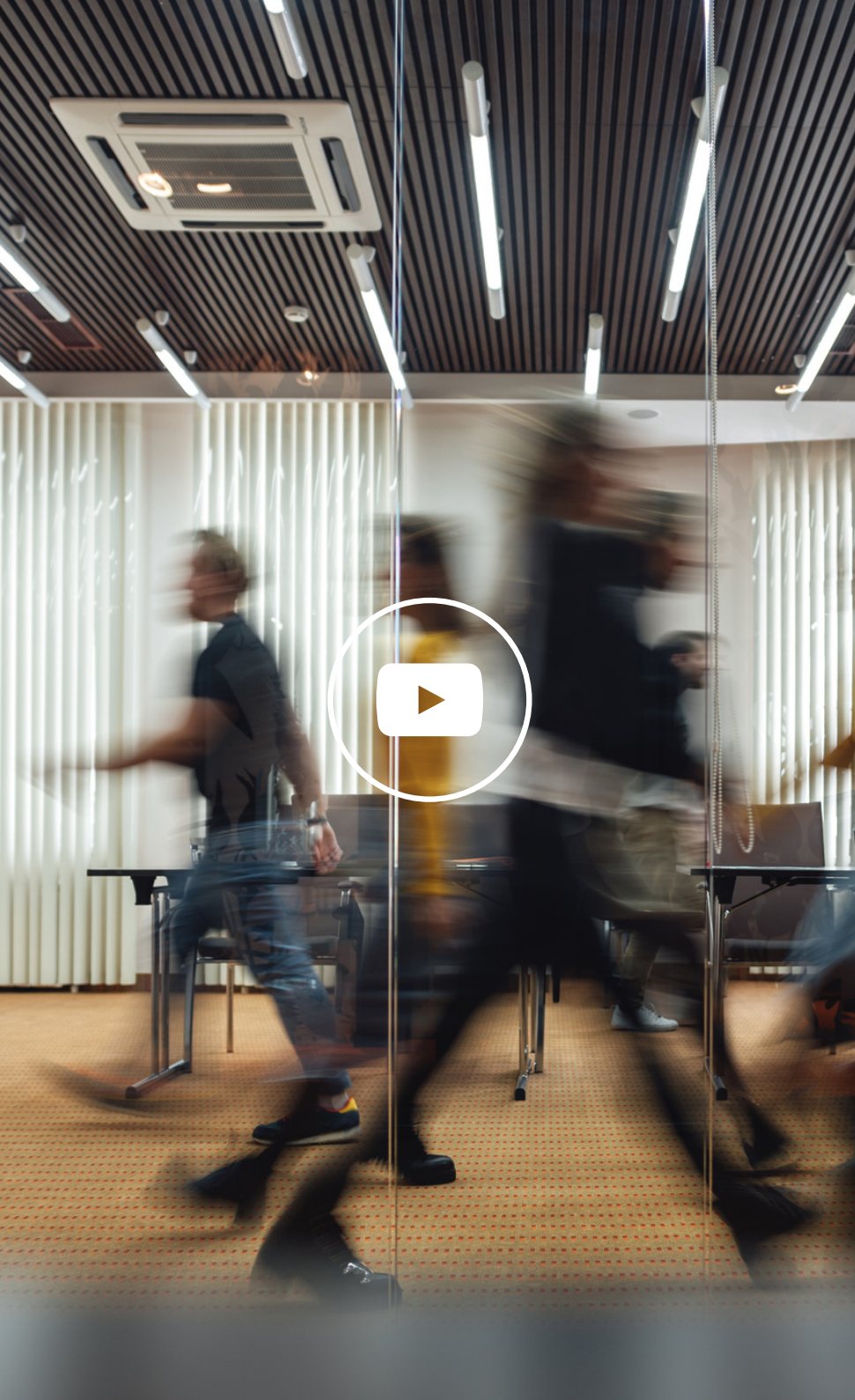
40 working days



Need a faster turnaround?

Upgrade to our VIP packages

Choose between 9-7-3 working days delivery



Why choose Obelis?

EXPERIENCE

We provide CE Marking advisory and Authorised Representative services since 1988. With more than 35 years of experience, we have helped thousands of brand owners penetrate the EU, UK & Swiss markets.

ISO CERTIFICATION

Our operations and procedures are certified against ISO 9001:2015 and ISO 13485:2016. Our compliance team is comprised of lawyers, chemists, pharmacists, and other regulatory experts.

COMMITMENT TO COMPLIANCE

We know that our consultants can be very meticulous in their compliance review process, but our objective remains firm: to see your products on the EU market without any incidents or being blocked at customs! We are committed to your success, and we are proud to see our customers grow their business and sales revenues through our compliance services.

What services will we provide?

Our MDR compliance solutions:

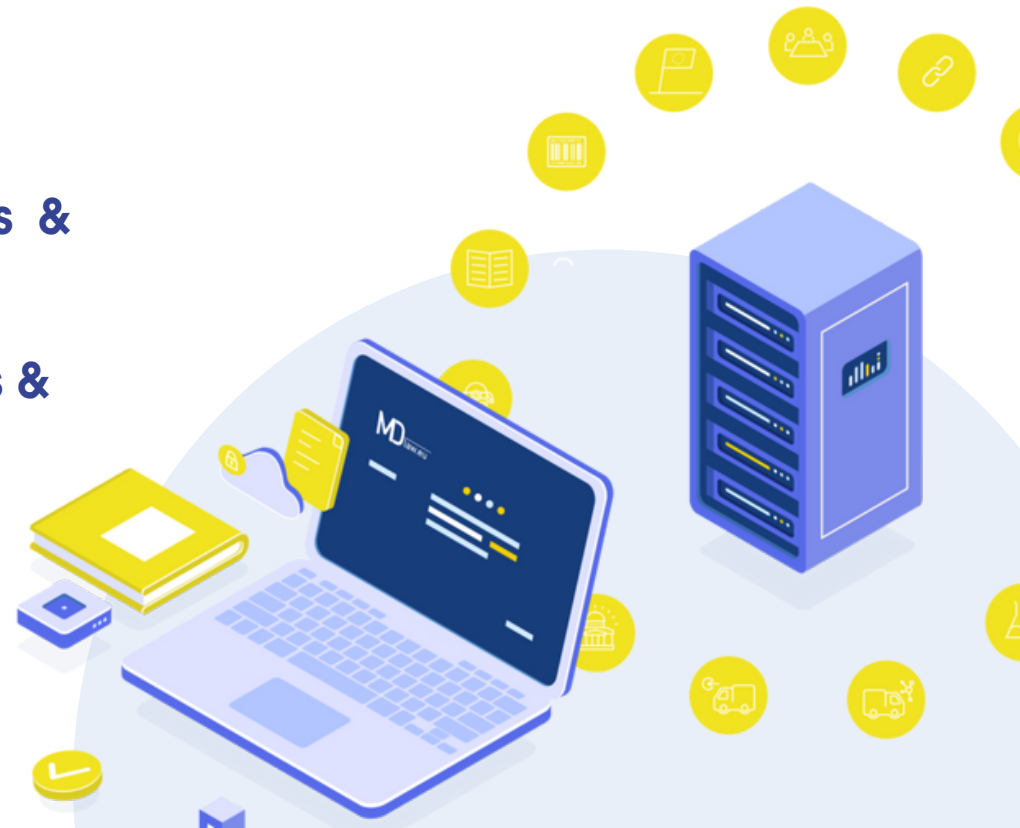
- ✓ Device Classification
- ✓ Technical Documentation Review
- ✓ Device Notification & Registration (National)
- ✓ European Authorised Representative Mandate
- ✓ EUDAMED Actor & Device Registration Validation
- ✓ Derogation Requests
- ✓ PMS and Incident Reporting (Vigilance)
- ✓ PMS Plan & Report
- ✓ Free Sales Certificate
- ✓ Notified Body Selection
- ✓ Risk Assessment Plan & Report
- ✓ Clinical Evaluation Plan & Report (CER)
- ✓ PMCF Plan & Report
- ✓ Regulatory Trainings & Support (on-site and online)
- ✓ MDlaw Membership - News, Alerts, checklists and templates



MD^{law}.eu

The most extensive & up-to-date
information platform on the EU MDR & IVDR

- Library of documents (MDCG, European Commission, CAs and more)
- MDR & IVDR checklists, templates, guidelines & other tools
- Monthly newsletter on MDR/IVDR, related news & updates
- Webinars & other educational tools





To Summarise:

What is it all about?

MDR compliance and sales in the European Union (EU) market

How long will it take?

- 40 working days under our basic package
- 9,7 or 3 working days if you upgrade to one of our VIP packages

Why choose Obelis?

- 35 years of service
- Highest standard of service
- Unique Expertise on MDR/IVDR compliance
- Commitment to compliance and to our customers

Your trusted partner for regulatory compliance!



**Request our
Service Agreement Today!**

Questions?



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www.obelis.net



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