Obelis GROUP

AUTHORISED REPRESENTATIVE (EC REP)SERVICES

IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

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?

IVDR (IVD Regulation) 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 IVDR are met and the CE Marking is correctly obtained and affixed to your In-vitro diagnostic 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

EC REP

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

Formal qualification criteria - IVDR Article 15 (6)

University degree (documented by Diploma/Certificate) in law, medicine, pharmacy, engineering or another relevant scientific discipline + at least 1 year of professional experience in regulatory affairs or in QMS relating to in vitro diagnostic medical devices; or 4 years of professional experience in regulatory affairs / in quality management systems relating to in vitro diagnostic medical devices (...)

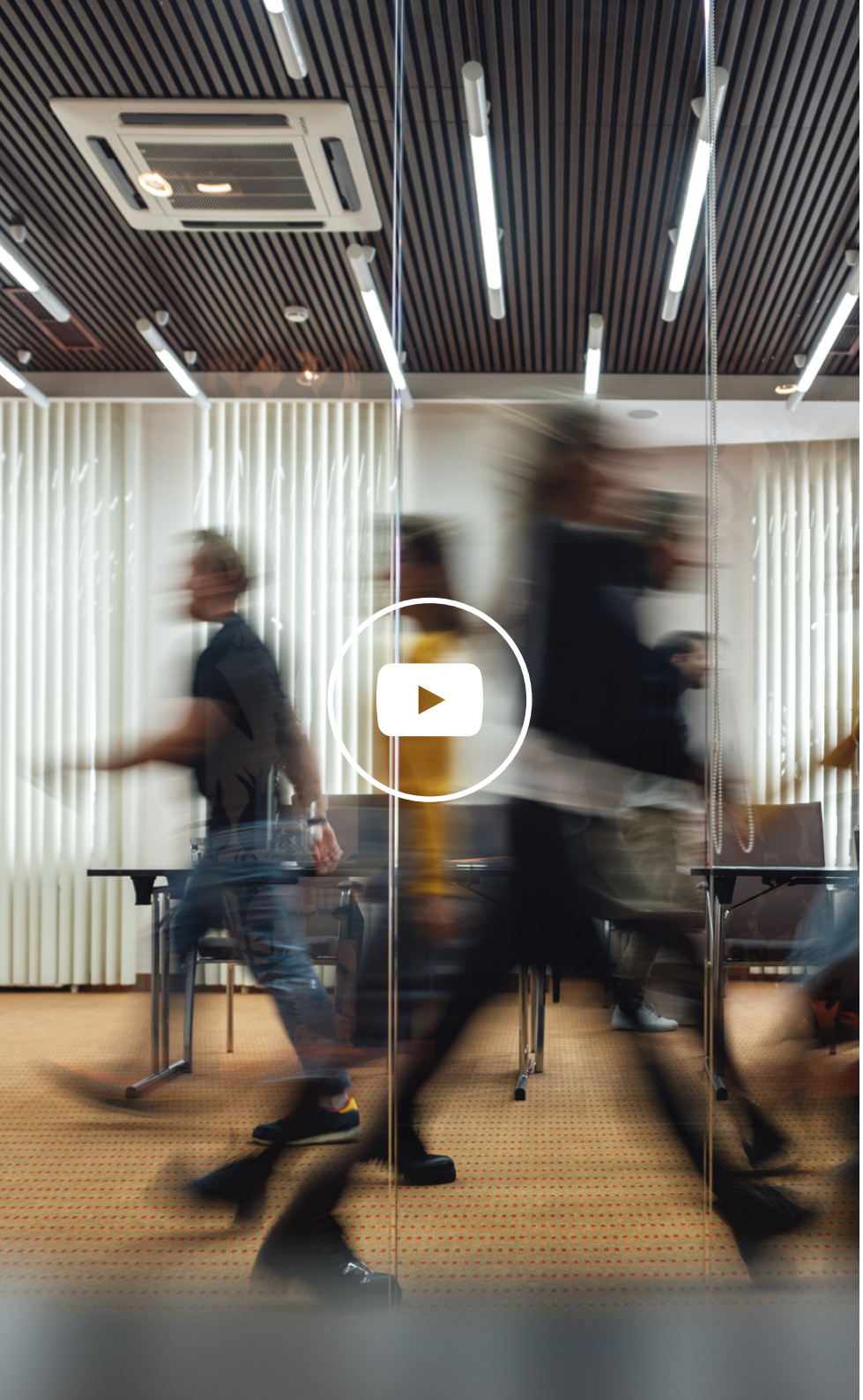
How long will it take?

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 IVDR 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
- Performance Evaluation Plan & Report
- PMPF Plan & Report
- Regulatory Trainings & Support (on-site and online)
- MDlaw Membership - News, Alerts, checklists and templates

SUBSCRIBE TODAY

MDlaw.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?

IVDR 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 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!

Obelis GROUP

Request our Service Agreement Today!

Questions?

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