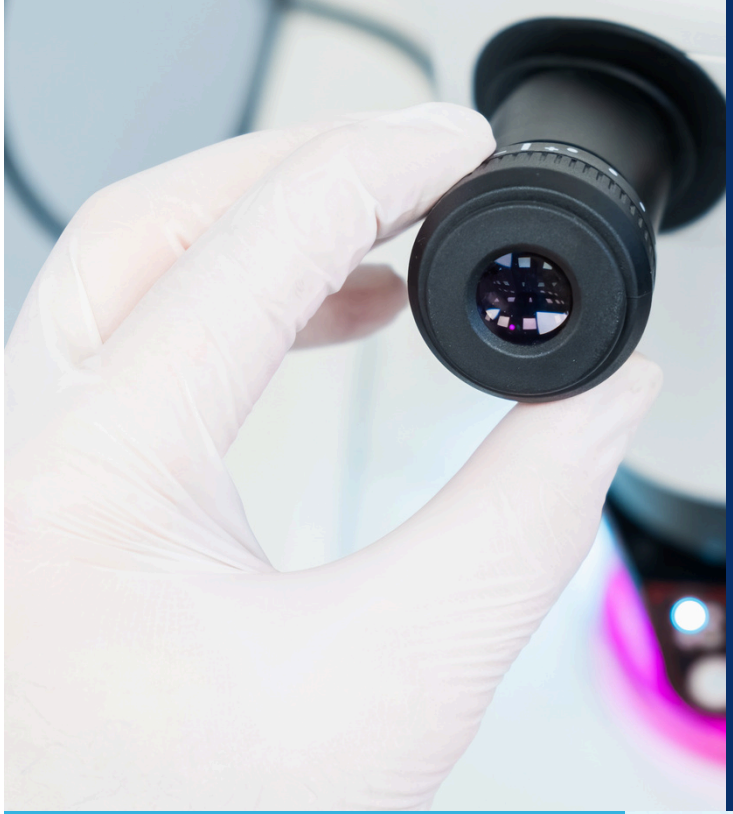
Obelis GROUP

AUTHORISED REPRESENTATIVE (EC REP)SERVICES

MEDICAL DEVICES (MDR) EUROPEAN UNION, UNITED KINGDOM, UNITED STATES, SWITZERLAND & CANADA



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 , US, Swiss & Canadian markets

Your trusted partner for regulatory compliance

What is it all about?

Compliance and sales of medical devices on the EU, UK, US and Swiss markets.

What are we going to do?

We will ensure your devices comply with the relevant regulatory requirements so that you can affix the CE, Swiss, US or UKCA marking. We will check your technical documentation and perform any necessary notifications.

As your representative, we will act as your contact point towards users, and competent authorities.

Furthermore, in the EU, we will assist you with the EUDAMED registrations (actor and devices). If appointed as Official Correspondent in the US, Obelis can take care of your registration with FDA (establishments and devices).

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 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?

30 working days

STEP 1

Agreement review signature & Payment remittance

STEP 2

Preliminary Questions & Instructions on EU, UK or Swiss regulatory requirements (Same day after payment)

STEP 3

Review & feedback of documentation (25 working days)

STEP 4

Signature of EU Mandate, Swiss Mandate or UK Responsible Person Designation Letter

STEP 5

Finalization of procedure, Notification (if necessary) to the relevant CA

STEP 6

Competent Authority Confirmation of Registration Letter

STEP 7

Issuance of Certificates (5 working days)

STEP 8

Access to the market

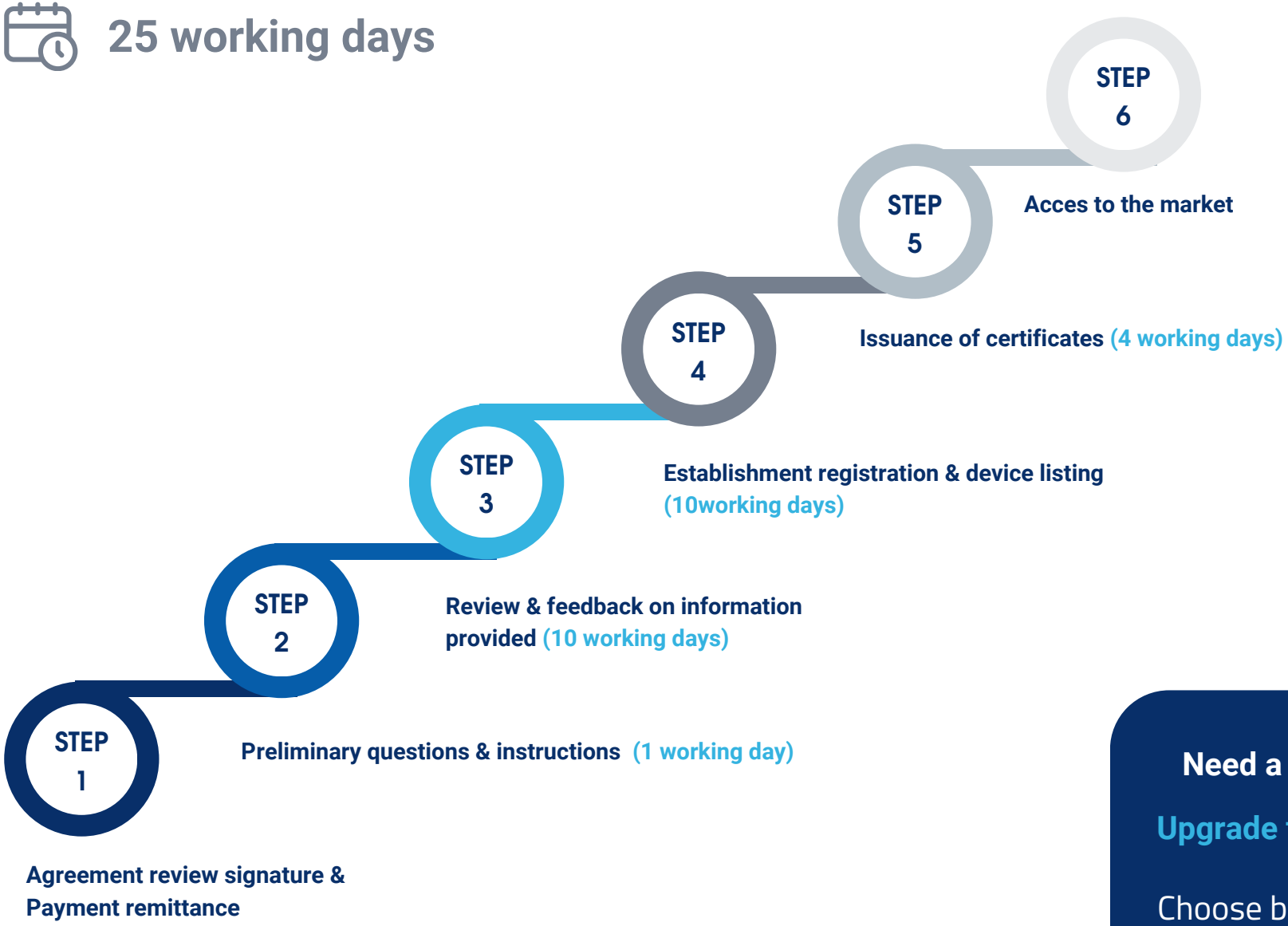
Need a faster turnaround?

Upgrade to our VIP packages

Choose between 8-5 working days delivery

How long will it take? - US Agent & Official Correspondent

25 working days



Need a faster turnaround?

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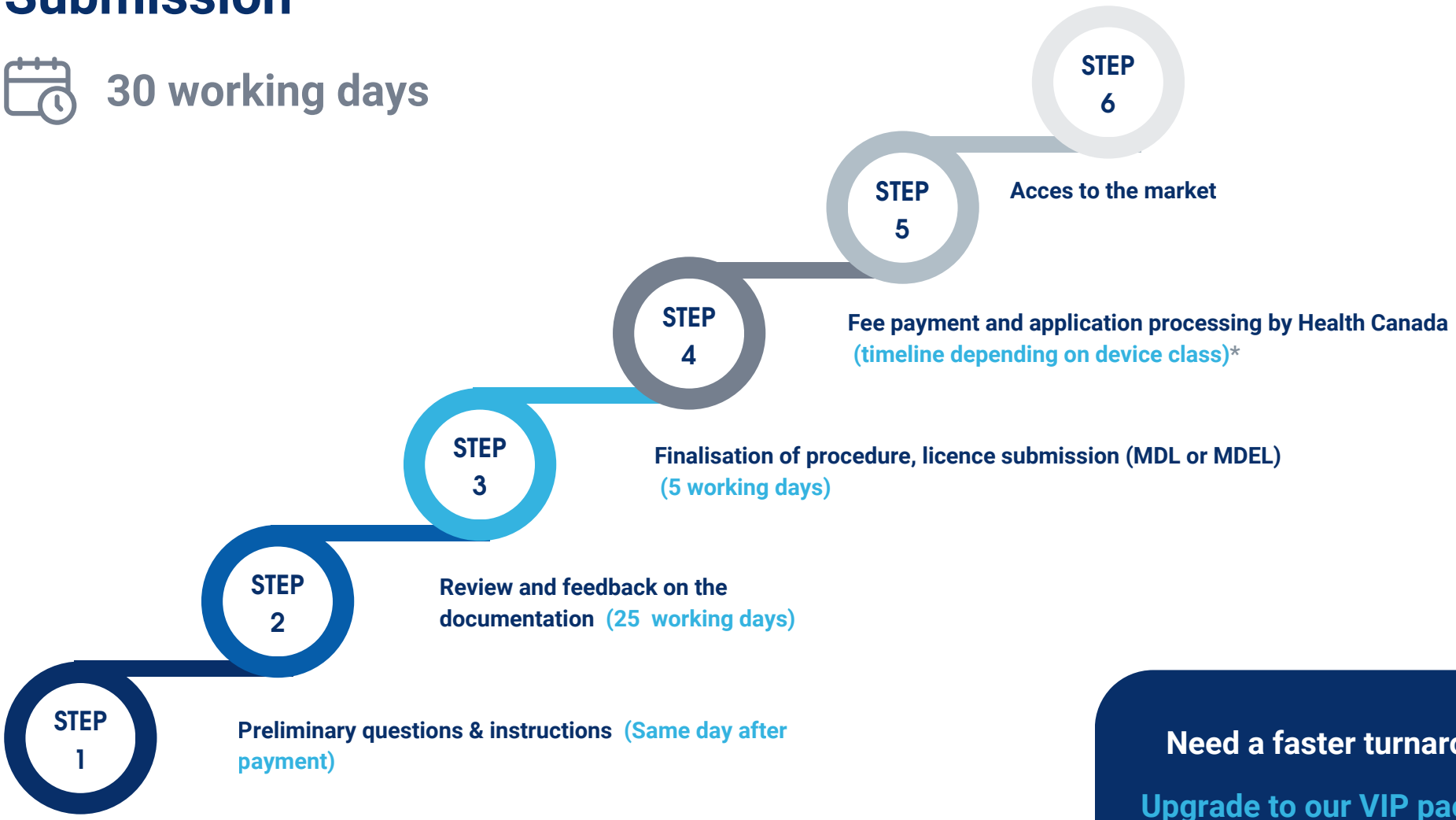
Choose between 8-5 working days delivery

How long will it take? - Medical Device Licence (MDL) Submission

30 working days



*The timeline for Health Canada to issue licenses varies depending on the device's risk classification and any feedback they may raise.

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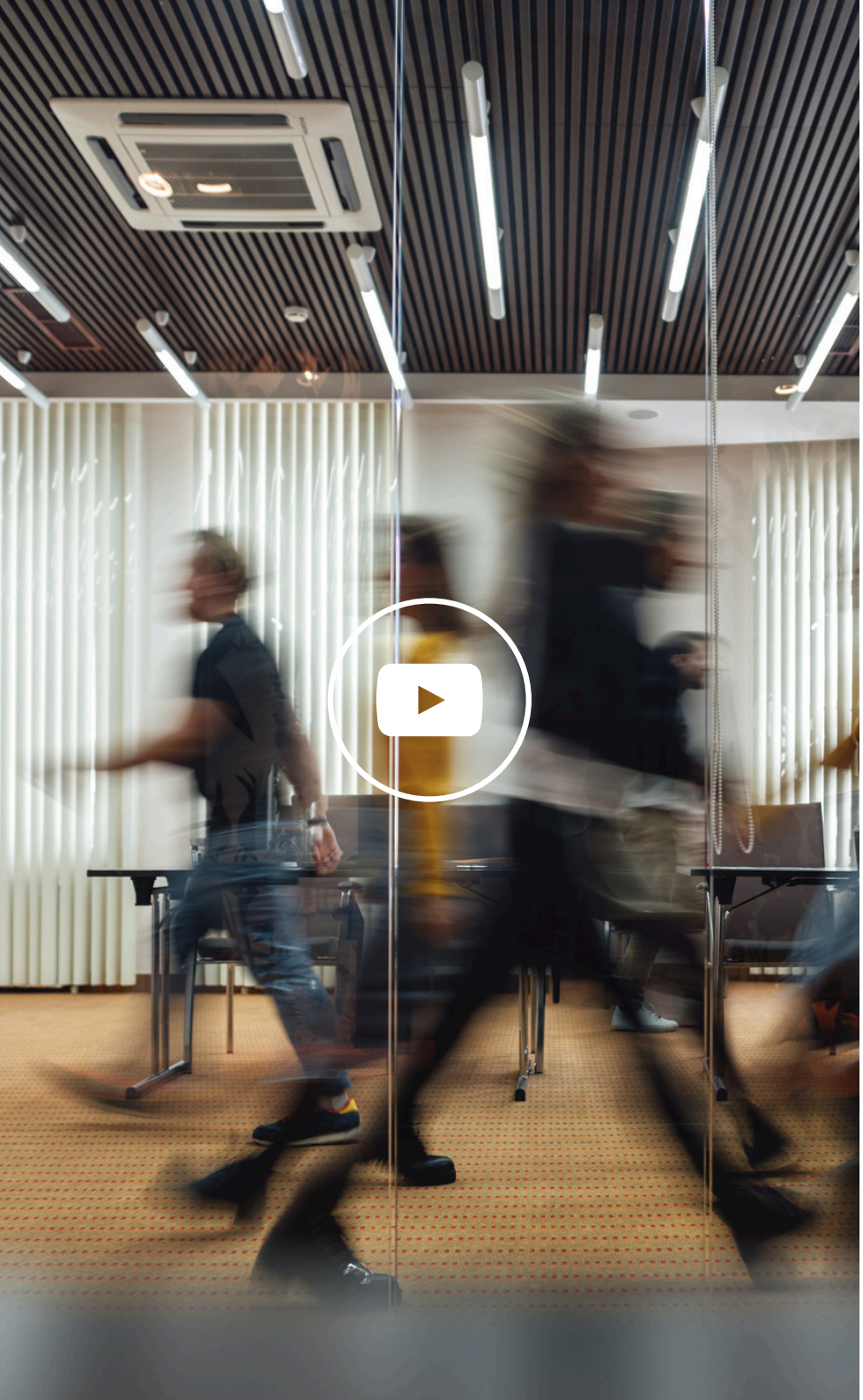


Why choose Obelis?

EXPERIENCE

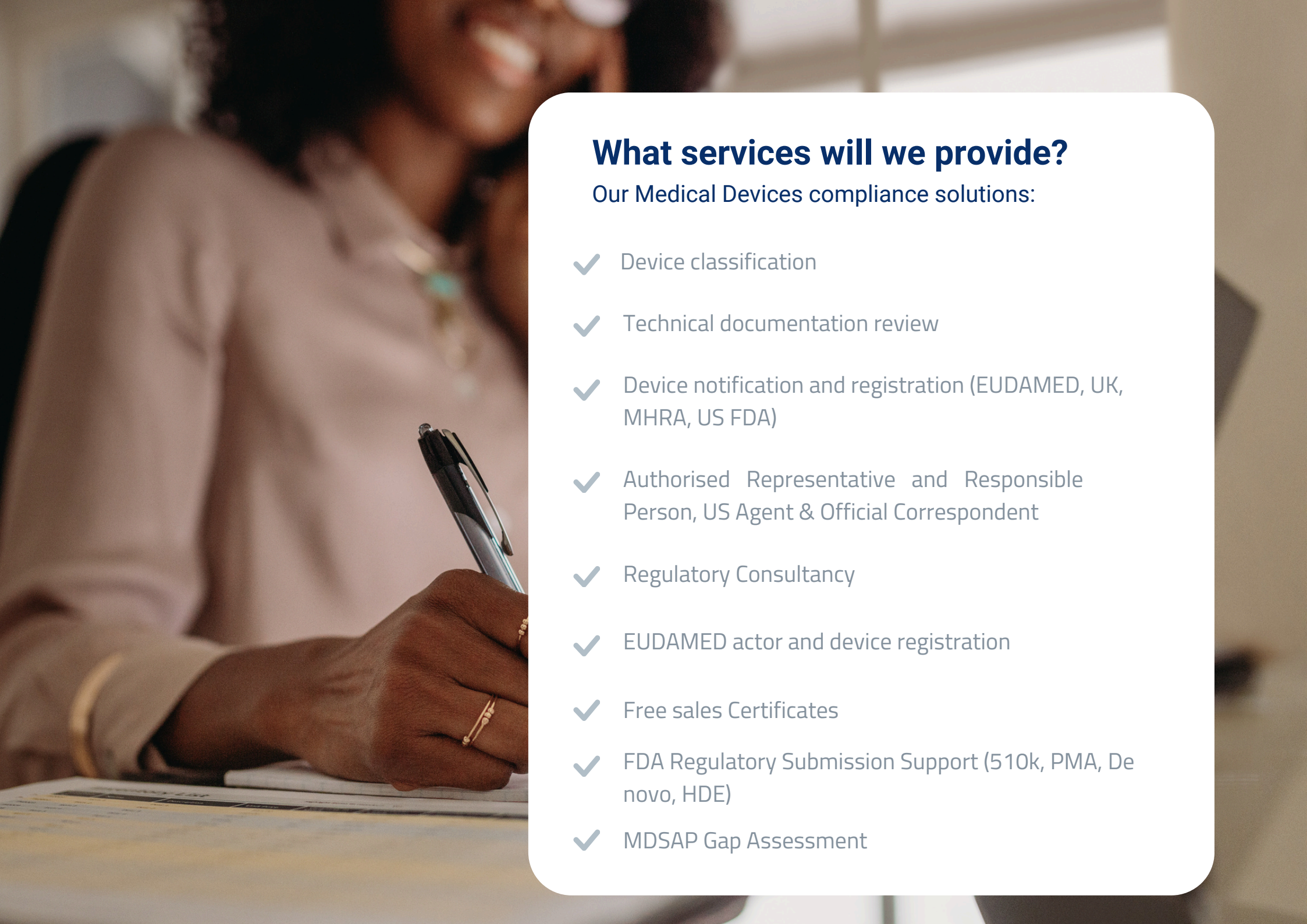
We provide regulatory advisory and representation services since 1988. With more than 35 years of experience, we have helped thousands of brand owners penetrate the EU, UK, US, Swiss & Canadian markets.

ISO CERTIFICATION

Our operations and procedures are certified against ISO 9001:2015 and ISO 13485:2016. Our compliance team is comprised of lawyers, chemists, toxicologists, 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, UK, US, Swiss & Canadian markets 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 Medical Devices compliance solutions:

- Device classification
- Technical documentation review
- Device notification and registration (EUDAMED, UK, MHRA, US FDA)
- Authorised Representative and Responsible Person, US Agent & Official Correspondent
- Regulatory Consultancy
- EUDAMED actor and device registration
- Free sales Certificates
- FDA Regulatory Submission Support (510k, PMA, De novo, HDE)
- MDSAP Gap Assessment

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

One-Time Fees:

One-time fees explained

AR/RP/US Agent Certificate

Evidence that you have appointed an Authorised Representative or Responsible Person or US Agent.

File Submission

Submission of the documents to the competent authority (when necessary)

Notification Certificate

Evidence that Obelis has notified the devices to the competent authority.

Technical documentation review

Obelis verifies that your technical documentation meets the law requirements.

Certificate of EUDAMED device verification (EU only)

Demonstrates that Obelis has verified the data concerning your devices registered in EUDAMED.

Refundable Deposit

Aims to ensure that all the legal obligations are met when requesting to terminate the agreement (as Obelis holds the regulatory responsibility over the products on the market). Once the termination requirements have been fulfilled FULL Deposit shall be refunded.

Monthly Fee

Why do we charge a monthly retainer?

Because certain aspects of the service need to be maintained continuously such as:

- Maintaining Device registrations valid (National & MHRA)
- Maintaining the Authorized Representative and Responsible Person Legal Mandate valid
- Maintaining your Technical Documentation readily available for inspections
- Maintaining a regulatory consultant available for support and advice
- Maintaining a set-up of news, expertise, and alerts on regulatory changes
- Maintaining a set-up for market surveillance and incident reporting

DISCLAIMERS

- All cost projections are valid for 30 days
- The 15% or 35% of discount is available in case of advanced payments.
- Monthly Fee is billed bi-annually - January and July
- The Guarantee Deposit is fully reimbursable upon completion of the Agreement termination requirements and upon payment of all outstanding fees due to Obelis.

To Summarise:

What is it all about?

Compliance and sales of medical devices in the European Union, the United Kingdom, The United States, Switzerland and Canada.

How long will it take?

- 30 working days under our basic package
- 8-5 working days if you upgrade to one our VIP packages

Why choose Obelis?

- Experts since 1988
- 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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www.obelis.net

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