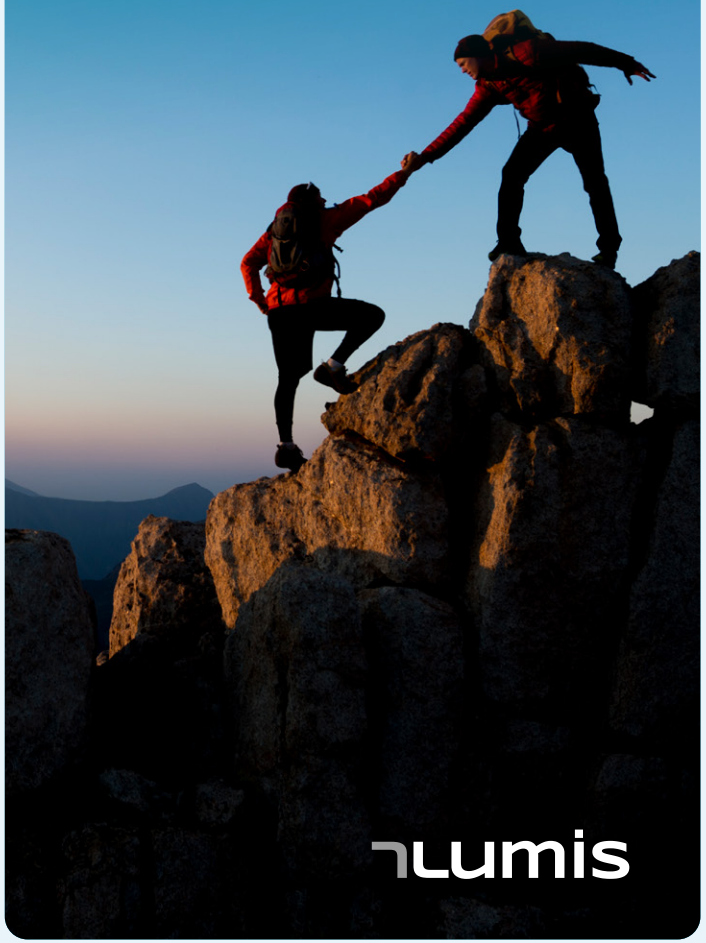
Authorized Representative Service – Raising Success to New Heights



Lumis – Your Seamless Entry to the EU Market

Are you a medical device manufacturer located outside the European Union?

Lumis International is your gateway to the European market through our authorized representative service.

We help you navigate all complex compliance processes, ensuring you meet the stringent requirements of the MDR and IVDR.

Let Lumis be your partner in accessing new markets.

The Benefits of Choosing Lumis as Your Authorized Representative

Expedited
Our state-of-the-art procedures provide fast, seamless entry to the EU market.

Efficiency
Offload regulatory burden and concentrate on growing your business.

Expert Solutions
Get full lifecycle support to ensure compliance and boost your competitive edge in the EU market.

Our approach is transparent, detailed and streamlined to ensure swift, compliant access to the EU market.

During an initial review, our team assesses your manufacturer's regulatory, quality, legal and technical documentation.

Following enrolment, Lumis will store the necessary documentation, support with vigilance reporting, review any amended documents, communicate with authorities and conduct any other activities outlined in the mandate.

1. Enrollment

- Due Diligence
- Technical File Review
- Updating Labelling

2. Maintenance

- Vigilance Procedures
- CA Communication
- Documentation Storage / Access
- Annual Check-in
- Additional Activities

3. Closeout

- Mandate Closure
- Archiving
- Continued Vigilance

Enter Europe With Confidence – Contact Us Today

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