Obelis GROUP

YOUR CONSULTANT ON EU REGULATIONS

WHO WE ARE

- More than 30 years of experience in regulatory affairs
- Helped more than 3.000 manufacturers from over 60 countries
- Largest centre for Consultancy Europe
- Certified ISO 13485
- Our Team: Lawyers, Chemists, Pharmacists and other Experts
- Member of EU Associations and EU Commission Working Groups

Obelis History

1988

Obelis was founded as a Regulatory Agency, helping EU and non-EU manufacturers to comply with the EU regulatory standards and requirements.

1996

Obelis European Authorized Representatives Center (O.E.A.R.C.) and Obelis European Responsible Person Center (O.E.R.P.C.) were officially established.

2013

ERPA become a recognized stakeholder by the European Commission and its members are currently attending various working groups at the European Commissions.

2016 - 2019

Obelis's Chinese Office was founded in 2016, while Obelis UK was established in 2019.

2003

Obelis Group became an official member of the European Association of Authorized Representatives (E.A.A.R.)

2011

Obelis Group became one of the founding members of the European Cosmetics Responsible Person Association (E.R.P.A.)

Our Industries

Healthcare, Medical Devices &
In-Vitro Diagnostics

MEDICAL DEVICES & IN-VITRO DIAGNOSTICS

As Your Professional EC REP under MDR & IVDR, Obelis will:

- Verify CE Certificates
- Confirm EUDAMED registrations
- Provide a Vigilance contact point
- Continuously ensure MDR/IVDR compliance
- Review MDR/IVDR Technical Documentation
- Enrol Person Responsible for Regulatory Compliance (PRRC)

MAIN SERVICES:

- European Authorized Representative
- MDR/ IVDR Consultants
- Technical documentation (compilation & review)
- MDD 1 Notification
- Notified Body Selection
- IVD Notification
- Vigilance
- Free Sales Certificate

MDlaw.eu

The most extensive information platform on Medical Device Regulation & In-Vitro Diagnostic Regulation

Five reasons to become an MDlaw member!

SUBSCRIBE AT www.MDLaw.eu

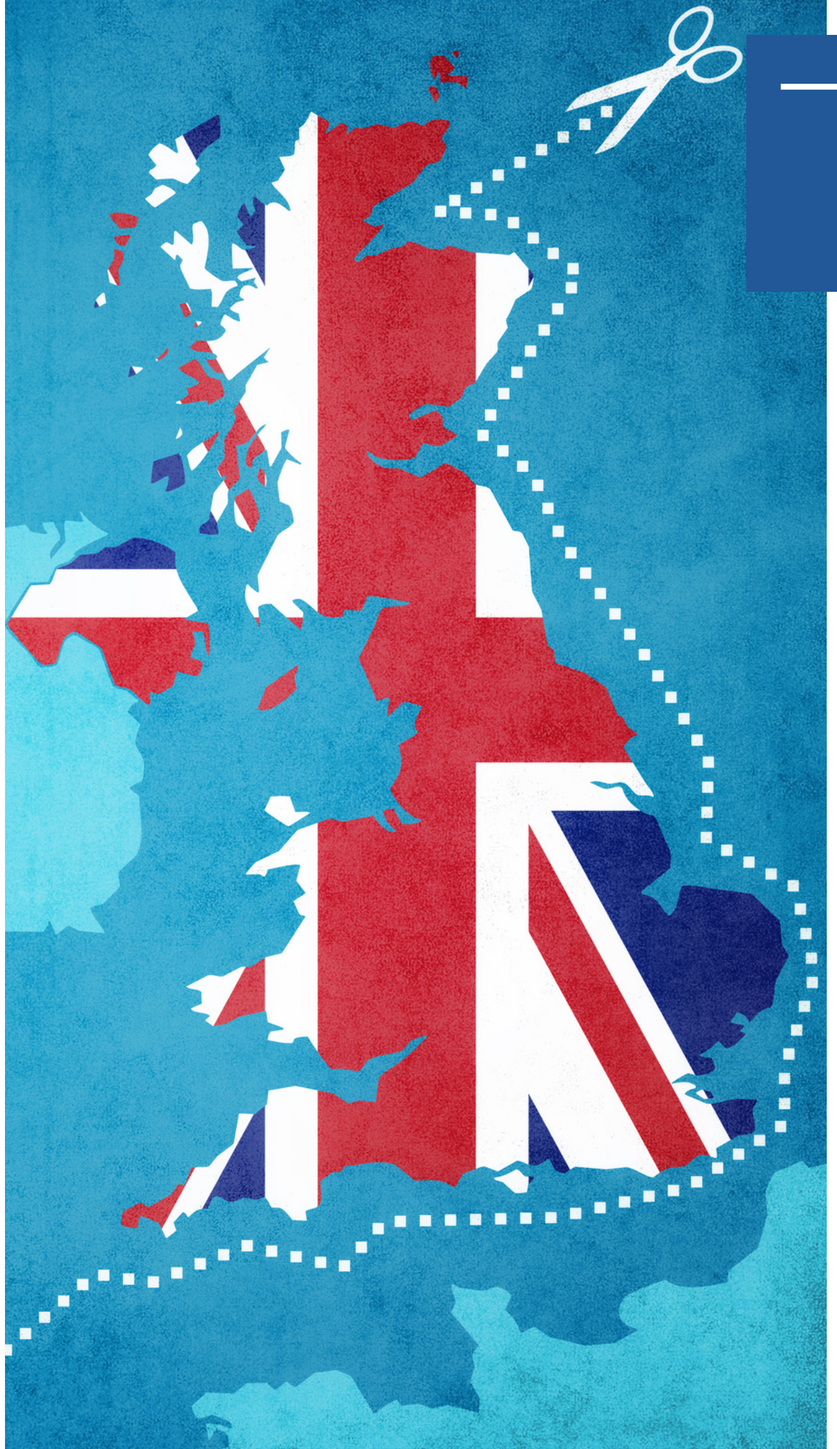
1 **UP-TO-DATE**
We are fastest in processing and communicating news on MDR & IVDR

2 **DOCUMENTS**
Libiary of documents - EU CAs, MDCG, EU Commission and more

3 **CHECKLISTS**
MDR & IVDR checklists templates, guidelines & other tools

4 **NEWSLETTER**
MDR/IVDR related news & updates

5 **EDUCATIONAL MATERIALS**
Webinars & other educational tools



UK RESPONSIBLE PERSON FOR MEDICAL DEVICES & IVDS

As of 1 January 2021, Non-UK based manufacturers will become legally obliged to designate a UK Responsible Person to place their devices on the UK market.

Under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), the role of the UK Responsible Person will be decoupled from the role of the UK importer. This means that it is highly recommended to designate a professional agency as UK Responsible Person.

As your UK Responsible Person, Obelis UK Ltd. will:

- Register devices with MHRA
- Ensure technical documentations have been drawn up
- Keep a copy of technical documentations for inspection
- Cooperate and Provide MHRA all information upon request
- Inform the manufacturer of complaints and incidents
- Represent the manufacturer

THE EUROPEAN MARKET - THE LARGEST IN THE WORLD!

With more than 500 million users, the compliance of your products and the safety of consumers are essential.

We are here to secure both!

GET IN TOUCH!

To receive more information about our industries, sign up for our services & appoint Obelis as your Consultant, please visit our websites or send us an email!

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