Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

YOUR CONSULTANT ON EUROPEAN REGULATION

EUROPEAN AUTHORIZED REPRESENTATIVE CENTER
SINCE 1988
OBELIS

ABOUT OBELIS

- **MDR / IVDR** Regulatory Experts
- Largest centre in Europe for **CE Marking** & **EC REP** services
- Over **30 years** of service (since 1988)
- Certified **ISO 9001:2015** & **ISO 13485:2016**
- Helped over **3,000 manufacturers** from over **60 countries**
- Member of **EU Associations** & **EU Commission Working Groups**
- Our Team: **Lawyers, Chemists, Pharmacists** and **other Experts**

MDlaw.eu
Information Platform on EU Medical Devices Regulation

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

- Library of documents (NB-MED, MDCG, EU Commission and more)
- MDR & IVDR checklists, templates, guidelines & other tools
- Weekly Newsletter on MDR / IVDR, related news & updates
- Webinars & other educational tools

SUBSCRIBE AT WWW.MDLAW.EU

INDUSTRIES WE COVER

- Medical Devices
- In-Vitro diagnostics
- Cosmetics
- Food Supplements
- Personal Protective Equipment
- Machinery, Pressure, Electrical and more

YOUR STEPS TO EU COMPLIANCE

1. **Have you ensured a correct EU classification?**
   Several EU laws may apply to your product!
2. **Have you compiled technical documentation?**
   Mandatory for all product types!
3. **Have you created a clinical evaluation report?**
   Mandatory for all medical devices!
4. **Have you created your labels & IFUs?**
   24 official languages in Europe!
5. **Have you designated a Notified Body?**
   Mandatory for some product types!
6. **Have you designated an EC REP?**
   Mandatory for all product types!

SPECIAL SERVICES

MDR/IVDR SUPPORT - FREE SALES CERTIFICATES - UK REPRESENTATIVE

CONTACT US TODAY!

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