ABOUT OBELIS

• MDR / IVDR Regulatory Experts
• Largest centre in Europe for CE Marking & EC REP services
• Over 30 years of service (since 1988)
• 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

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

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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!

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