ARAZY GROUP CONSULTANTS INC.

European Regulatory Representative Services

EU AR | UK REP | Swiss Representative

Providing you Knowledge Above the Cloud.

With the new MDR, IVDR and Contingency MedDO changes, it is more important than ever to select the best service provider when choosing a dedicated EU AR, UK REP and Swiss representative. Arazy Group has acted as an EU AR to many clients since 1996 and has established significant experience with the UK (MHRA), German (BfArM) and Irish (HPRA) competent authorities.

Regulatory Compliance Technology

We believe in simplifying regulatory compliance to ensure your products' continuous placement in the EU, UK and Swiss markets. Arazy Group's propriety online Medtech regulatory system allows your regulatory information to be easily accessible (in real-time) with us, acting as your EU Authorized Representative, UK Responsible Person and Swiss representative in compliance with the latest MDR, EUDAMED, MHRA and Contigency MedDO requirements. You can also share selective documents with Notified Bodies, competent authorities, distributors, and importers as necessary. As a client of Arazy Group, all the benefits of using an advanced online technology are directly passed to you.

How We Service You

Our regulatory compliance system provides the following for the EU, UK and Swiss markets:

- device-specific Technical File checklist for each line of products
- easy and simple upload of compliance documents
- gap analysis report for each Technical File
- real-time document viewing and sharing
- consultation to amend non-conformities
- product and company registration with local authorities

Extra Security

The security and safety of confidential documents are an important priority to us which is why we use Amazon Web Services for our cloud-based system. AWS infrastructure is in full compliance with security best practices and IT security standards.

Email us at info@arazygroup.com to receive our EU AR, UK REP and/or Swiss representative contract(s) or to speak with one of our EU Regulation Experts.