

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 Contingency 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.

The screenshot displays a web dashboard for regulatory compliance. At the top right, there are utility buttons for 'Cart', 'Notifications', and 'Angus'. The main content area is divided into four panels:

- Med/IVD Devices 2/2:** A table listing devices with columns for device name and description. Items include 'Wheel 2000' (Electrical Wheelchair), 'Usound Portable' (Portable Ultrasound), and 'Cath20, Cath28, Cath15' (Family of catheters, different gauge). An '+ Add Device' button is present.
- Technical Files 2/2:** A table listing technical files with columns for 'Technical File ID' and 'Technical File Name'. Items include '12345' (Technical File for Wheelchair), '12346' (Technical File for Ultrasound), and '12347' (Technical File for Catheters).
- Account Users 4/4:** A list of users with columns for name, email, and role. Roles include 'Importers', 'Auth. representative', 'Distributors', and 'Manufacturer'. A 'Manage' button is at the top right.
- Notifications:** A list of notifications with columns for ID, title, and content. Items include '9H' (Technical File Wheelchair - Please review comments regarding compliance documentation), '1D' (Technical File Wheelchair - New document has been reviewed and waiting for your approval), and '2W' (Technical File Catheters - You are missing documents please review your technical file).

A left-hand navigation menu includes 'Dashboard', 'Med/IVD Devices', 'Technical Files', 'Documents', 'Support', and 'Settings'.