

## Your European Authorized Representative

**QualRep Services B.V.**, a Qserve Group B.V. company, provides **European Authorized Representatives (EAR) services** to Non-European medical device manufacturers wanting to sell their products within the European Union.

### **Why is an European Authorized Representative (EAR) necessary?**

If a manufacturer is based outside the European Community, the European Authorities (Competent Authorities) need to be able to contact an entity or person, who is based within the European Community, and who acts on behalf of the manufacturer.

Non-European manufacturers cannot simply have a post office box located in the European Union (EU); you are obliged to have a representative that is a registered business with a legitimate EU address.

There are many policies and regulations associated with selling medical devices in the EU, and these are continually being updated and changed. Your EAR is aware of policy adjustments and regulatory changes that may occur and that may impact your business.

Your European Authorized Representative has the responsibility of ensuring the manufacturer's compliance with specific elements of the conformity assessment procedure set out in the European Directive(s) that applies to your specific product(s). These include: contacts with European authorities, Notifications, Recall and Vigilance support. QualRep Services has extensive experience in these areas and can provide whatever level of assistance you need to make sure your company remains in compliance with the regulations.

Please contact us at your convenience for a free consultation at: **+31 (0)85 74 40 000** or [qualrep\\_services@qservegroup.com](mailto:qualrep_services@qservegroup.com).

You may also contact our US-based affiliate, Qserve America, at: **001-603-369-3550** or [info@qserveamerica.com](mailto:info@qserveamerica.com).

Thank you for your attention, and we are looking forward to work with you in the future!

**Willibrord W.M. Driessen**

Director

**Qserve®**, your medical device compliance consultants