Qserve® | Authorized Representative Services

EU Authorized Representative

Service Description

EU Authorized Representative

Why do you need a European Authorized Representative (EAR)?

The European Union requires any foreign manufacturer who intends to sell their devices in any of the Member States to designate a sole authorized representative with a physical address within one of the Member States. The EAR will represent your company to the national authorities and shall register your devices in the electronic system before commercialization.

How will the EAR operate?

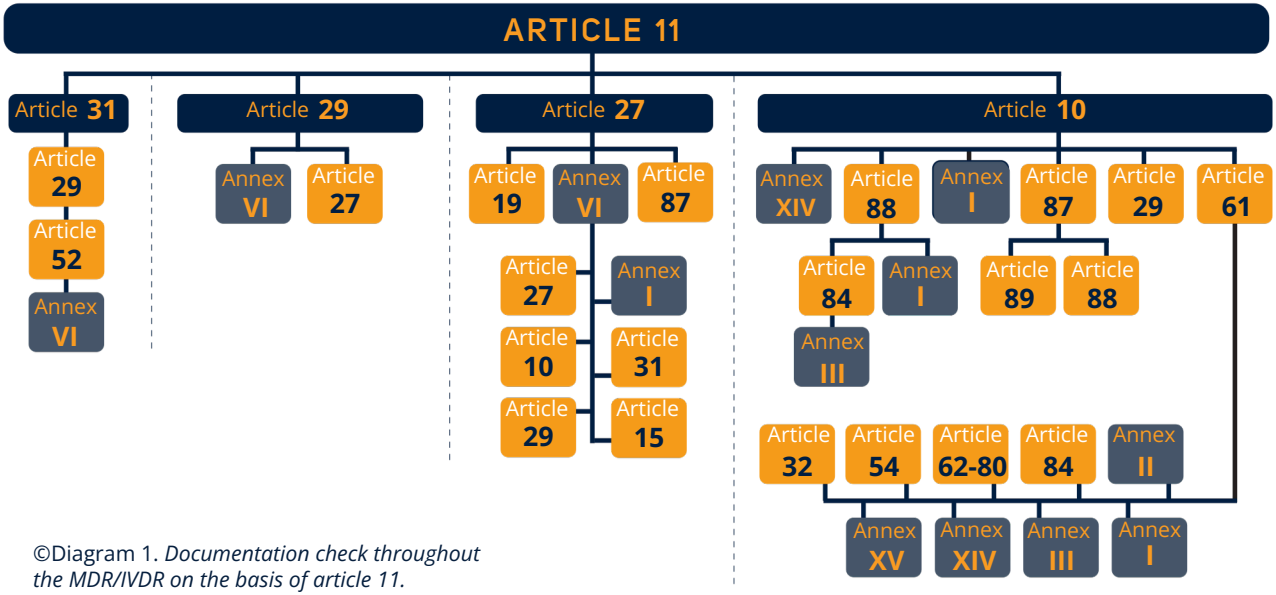
The EAR is an economicoperator under the MDR/IVDR and must fulfill the requirements as per article 11 of the regulations.

The main difference with the current situation is that the EAR shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

Therefore, the EAR will review the compliance to the requirements of article 11. For all devices, there will be a more thorough review of the technical documentation before registration. The manufacturer has to self-declare the conformity to the MDR/IVDR for class I devices whereas for class II-III devices there is a Notified Body involved and only after approval (CE certificate) the EAR can register the devices.

Article 11 refers to many other requirements throughout the MDR/IVDR, as listed in diagram 1.

Article 11 Documentation Check



©Diagram 1. *Documentation check throughout the MDR/IVDR on the basis of article 11.*

A detailed checklist with all necessary documentation as well as the requirements that will be checked will be provided to the manufacturer at the start of the review phase.

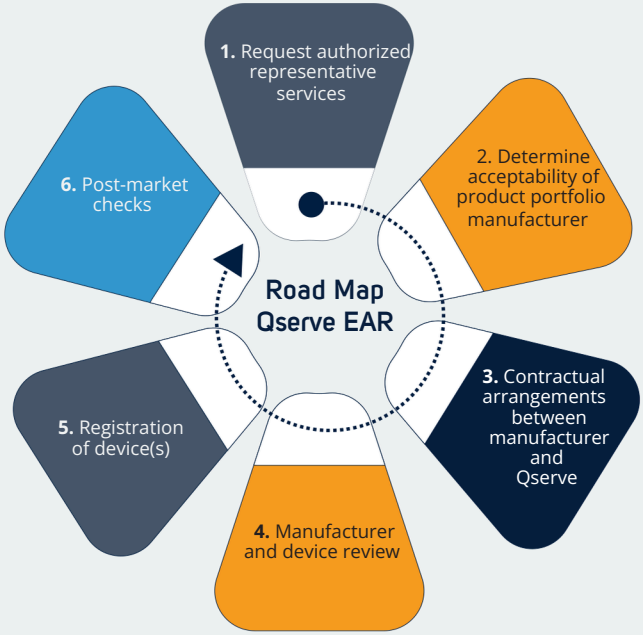
The EAR will start the review process to verify that the device is in compliance with the requirements of the MDR/ IVDR. Initially, the EAR will have to verify, besides the technical requirements, also the QMS related requirements of the manufacturer.

The EAR will specify the services that the EAR will perform in a mandate which must be signed by the manufacturer at the start.

EAR Service Package

What is included in Qserve's EAR Service Package?

- Use of name and registered address on all product related labelling.
- Official appointed contact address for European authorities.
- Assistance in communication between the competent authority and the manufacturer.
- Thorough review of your EU declaration of conformity and technical documentation.
- Preparation and registration of the initial product in the electronic system.
- Update listing of product registration in the electronic system.
- Assistance and coordination of complaint handling and incident reporting to the Competent Authorities.
- Updates regarding regulatory changes which might impact devices and registrations
- Advice on registration strategies



©Diagram 2. *Road Map EAR Services*

Price Structure

Item	Description	Price
Annual EU Authorized Representative Service	• Use of EAR name and address on label • Annual review reminder on accuracy of data in EUDAMED • Point of contact for the Competent Authority • Coverage of EU Authorized Representative requirements and liability	€ 4.185
Technical documentation review per device group	• Review of Declaration of Conformity and technical documentation • Review of MDR/IVDR requirements and records related to EU Authorized Representative service as per Appendix C	€ 1.500
Device Registration in EUDAMED	• Registration of devices in UDI & Device Module of EUDAMED. Depending on the scope, QualRep will determine the approach and hours required	Ad-hoc consultancy fee or bulk data submission service fee
Changes to device registration in EUDAMED	• Updates to registration of devices in UDI & Device Module of EUDAMED. Depending on the scope, QualRep will determine the approach and hours required	
PMS/Vigilance	• Administration on post-market data • Preventive and corrective actions • Complaint Handling • Incident Reporting • Recalls	Ad-hoc consultancy fee
Additional regulatory changes	• Communication with the Competent Authorities • Updates of regulations or guidances initiated by European Commission or Competent Authority	Ad-hoc consultancy fee or subscription to Qserve InSight