Meet with ZWIERS!

Authorized representative

As an Authorized Representative Zwiers Regulatory Consultancy:

- Reviews or creates the technical dossier for your device
- Assures labelling, packaging and IFU in compliance with EU requirements
- Helps you with the selection process of Notified Body
- Submits the technical dossier to the Notified Body and coordinates the approval process
- Maintains the post approval technical dossier
- Is the direct contact between manufacturer and competent authority
- Reports critical changes of QMS and technical documentation to notified body
- Performs conformity assessment for class I devices
- Signs up declaration of conformity
- Notifies the authority for market introduction of Class I devices
- Exports certificates for all EU countries
- Preforms post market surveillance activities
- Evaluates and reports incidents
- Coordinates product recalls and issues advisory notices
- Handles customer complaints
- Is the single address for returned products
- Advizes on changing EU regulations and guidelines

Documents created by Zwiers :

- Template contract between manufacturer and authorized representative
- Template declaration of conformity
- Procedure for post market surveillance
- Procedure for vigilance
- Procedure for incidence reporting.
- Procedure customer complaint handling
- Procedure for Technical dossier maintenance
- Procedure for recall (field safety corrective action)
- CE mark logo to manufacturer

ZWIERS
Regulatory Consultancy