

First Line QA

Customer Returns Testing and Analysis Medical Device Vigilance Service



Are product complaints diverting man power and consuming resources you'd rather spend elsewhere?
Customer returns are an inevitable part of the business, but they need not be an integral part of yours!

Our unique First Line QA service makes it easy to comply with the EU MEDDEV 2.12-1 Rev 5 "Guidelines on a medical devices vigilance system" stipulating that "any manufacturer selling on the European market should make sure that their vigilance systems are updated to meet the revised guidance" (MHRA). These guidelines apply to:

- CE marked medical devices.
- Custom-made medical devices.
- Medical devices whose availability precedes CE marking.
- Other items where an incident occurs leading to corrective action on devices included above.

MET's specialist and confidential service provides an effective and simple way of facilitating the management of your product complaints within the UK, leaving you free to concentrate on your value-added activities. It is designed around a structured and time-sensitive processing of your returns. By conducting the original investigation and feeding data back to you rapidly, we enable you to provide a fast response to your end-users and react to technical failures early on. This service can be tailored to your exact requirements and includes:

- Decontamination
- Checks against specifications
- Physical diagnostic
- Compliance with standards
- Independent reports
- Archiving

First Line QA is as simple as 1, 2, 3

1. Your marketing system diverts returned products and complaints to us.
2. We analyse the complaint, decontaminate any product and bench test against your specifications
3. You receive an independent report of the product's performance and a quarterly or monthly summary of complaints and trends.