

## *First Line QA*

# Medical Device Vigilance Service



Medical device manufacturers and distributors are required to provide post marketing vigilance. MET support this requirement with our specialist, confidential service. *First Line QA* provides an effective and simple way of facilitating the management of your customer returns within the UK.

Not only do we deal with the problems of decontamination and finding engineers with the time to inspect, test and assess the complaint and returned product, we do it very quickly. Our customer returns decontamination and inspection service will allow your sales representative to return to the customer with an explanation within a week. This turns a problem into an opportunity!

*First Line QA* is MET's medical device vigilance system. It is simple and effective and will deliver a saving on your engineering and administration costs. The process is simple:

1. Your marketing system diverts returned products and complaints to us.
2. We analyse the complaint, decontaminate any returned 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

We will classify the complaints according to the new vigilance terminology, notify the Competent Authority (if you have requested this), report our results to you (within agreed timescales), and provide a periodic summary reports with trend analysis and recommendations.

### ***First Line QA* is applicable to manufacturers and distributors of:**

- CE Marked medical devices.
- Custom made medical devices.
- Medical devices with availability preceding CE marking.
- Other items where an incident occurs leading to corrective action on devices above.

Contact MET today to find out how we can help you.