



Product Service

**Choose certainty.
Add value.**

Certification for Sterile Services and Decontamination Departments

TÜV Product Service

TÜV Product Service (part of the TÜV SÜD Group) is globally one of the top 10 management systems certification bodies as well as being the leading Medical Device Notified Body with in excess of 35% market share. We employ >150 experts in the medical device field and have strong expertise and experience in auditing Sterile Service and Decontamination Service Departments within the UK.

Our Services

We certify Sterile Service and Decontamination Businesses to:

- Medical Device Directive (93/42/EEC) as well as to the relevant harmonised standards:
- ISO 13485: 2003
- ISO 9001: 2000

Our approach

We have friendly, knowledgeable and competent auditors with experience of sterile service departments and their processes. We know the challenges you face and work as your partner to support you throughout the certification process to achieve legal compliance to the Medical Devices Directive. Our goal is to help you to maximise the value and effectiveness of your Quality Management System.

Certification process

- We will discuss your department needs and gather information on your activities and size.
- Provide a quotation and application forms for certification.
- Review and report on your Quality Manual and quality system documentation.
- Perform an audit on-site and report on any findings or opportunities for improvement.
- Submit all audit records to our certification panel for review and approval.
- Issue certificates.

Transfer of Certificates

- TÜV Product Service Ltd will aim to meet or better the costs of your present Certification Body when transferring certification to ourselves.
- Certificate transfer is a simple process.
- Only one audit per year therefore reducing disruption to the day-to-day running of the department.

Training

- We can arrange training specific to sterile service departments on ISO 13485: 2003 and the requirements of the Medical Device Directive.

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