STERIS
Instrument Management Services

Quality processes are at the core of the STERIS IMS commitment to compliance

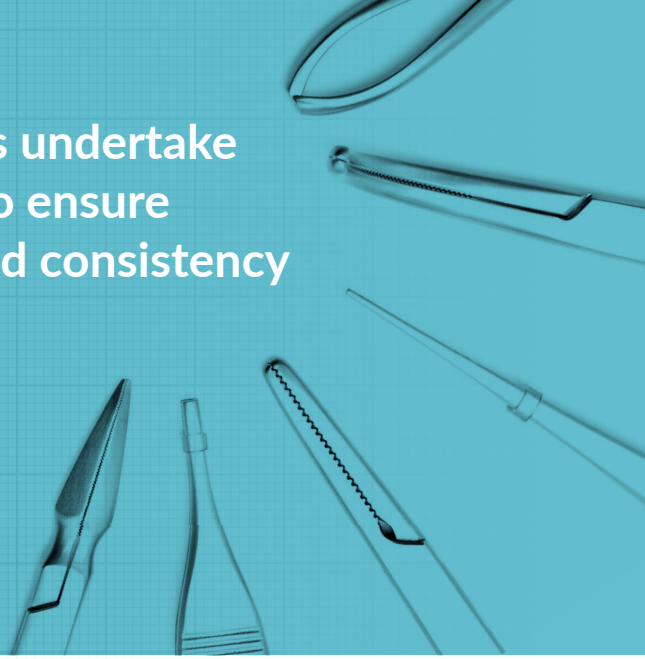
We encourage the pursuit of continuous improvement so that we can offer our Customers the benefits of expertise and quality assurance – always.

Our comprehensive internal quality management system ensures we continually meet the requirements of ISO 13485 and all applicable legislative requirements.

We know that the services and products we supply are crucial to patient safety and therefore we never stop seeking excellence in quality through continuous improvement initiatives.

All our instruments undertake thorough testing to ensure required quality and consistency

- ☑ Standard processes
- ☑ Attention to detail
- ☑ Stringent final inspections
- ☑ A perfect finish



COMPLIANCE WITH MDR

The Medical Device Regulation (MDR, Regulation (EU) 2017/745) constitutes the European Unions' regulatory framework for medical devices. The MDR sets high standards of quality and safety for medical devices in order to meet common safety concerns, to ensure a high level of protection of health for patients and clinicians.

All medical devices need to be compliant to the EU MDR before they can be placed on the EU market. The EU MDR defines a 3-year transitional period before implementation in May 2020.

Class I Medical Devices need to be compliant by 26th May 2020. Class Ir, Is, IIa, IIb and III devices require issuance of EC certificates to the EU MDR. Medical devices covered by an existing EC certificate under the MDD can continue to be placed on the market until the expiration date of the certificate, but not later than May 2024.

Like all responsible manufacturers of medical devices, STERIS is working to make sure that our products and processes comply with the expanded requirements of the EU MDR, especially in key areas including: device classifications, technical documentation and labelling, clinical evaluations, quality management system/ vigilance and post market surveillance, UDI and data reporting, and new legal responsibilities for economic operators.

Visit our website to find out more:
STERIS-IMS.co.uk

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