

Our quality and environmental system standards



Regulatory requirements and customer needs have driven Intersurgical to obtain certification of our Quality and Environmental Management Systems. We comply with the highest standards and regulations in order to legally design, manufacture, distribute and sell medical devices throughout the world and to give our customers confidence that our products are of the highest quality.

Intersurgical has chosen SGS United Kingdom Limited to provide certification services. SGS was chosen because they have a global reputation and use a transparent and logical approach to certification which helps us to meet our business objectives.

ISO 9001:2015 - Quality Management Systems

Certification to the internationally recognised Quality Management System ISO 9001:2015 enables Intersurgical to demonstrate commitment to quality and customer satisfaction. The framework of continuous improvement of company processes reinforces our corporate culture.



ISO 13485:2016 - Medical Device Quality Management Systems

The basis of all regulatory requirements for placing medical devices worldwide markets is ISO 13485:2016. Regular audits by SGS help to monitor and improve our management systems.



93/42/EEC - the Medical Devices Directive

Access into European markets is made possible by certification to the Medical Devices Directive. This enables CE marking of all Intersurgical products. The combination of certification to this Directive and ISO 13485:2016 is accepted for market entry in many countries.

FDA 21 CFR 820 - Quality System Regulation, USA

All Intersurgical manufacturing sites are registered with the Food and Drug Administration (FDA), which enables Intersurgical products to be sold in the USA.

ISO 14001:2015 - Environmental Management Systems

Customers are increasingly demanding environmentally responsible products and services. Intersurgical Ltd is certified to ISO 14001:2015, demonstrating commitment to minimising our environmental impacts. The system also provides a framework for managing the company's environmental aspects, and complying with relevant legislation.



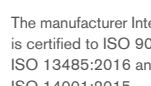
Product Standards

Intersurgical products are designed to comply with applicable European and International product standards which ensures that performance requirements are met and that our products can be safely used with devices and equipment made by other manufacturers who work to the same standards.



Intersurgical Ltd, Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

T: +44 (0)118 965 6300 F: +44 (0)118 965 6356 info@intersurgical.com www.intersurgical.com



The manufacturer Intersurgical Ltd is certified to ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015

Please think before you print

Save energy and paper.

If you must print this information

sheet please print it double sided.

Quality Standards • RLP/DAW • Issue 7 01.20