

# Our quality system standards

Regulatory requirements and customer needs have driven Intersurgical to obtain certification of our Quality Management Systems. We comply with the highest standards and regulations in order to legally design, manufacture, distribute and sell medical devices 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 9001:2008 - Quality Management Systems**

Certification to the internationally recognized Quality Management System ISO 9001:2008 enables Intersurgical to demonstrate commitment to quality and customer satisfaction. The framework of continuous improvement of company processes reinforces our corporate culture.

## **ISO 13485:2012 - Medical Device Quality Management Systems**

The basis of all regulatory requirements for placing medical devices worldwide markets is ISO 13485:2012. Regular audits by SGS help to monitor and improve our management systems.

## **FDA 21 CFR 820 - Quality System Regulation**

Intersurgical is an FDA registered and inspected company with adherence to the Quality System Regulations.

## **Product Standards**

Intersurgical products are designed to comply with applicable 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.