

The management system of

Intersurgical Ltd.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 31 October 2019 until 26 November 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 26 September 2020

Issue 30. Certified since 11 January 1995

Certification is based on reports numbered GB/PC 04303

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

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Intersurgical Ltd.

Directive 93/42/EEC

on medical devices: Annex II (excluding section 4)

Issue 30

Detailed scope

- Sterile and non-sterile Heat and Moisture Exchangers
- Sterile and non-sterile Heated Wire Breathing Systems, Heated Wires and attachments (electrical adaptor leads)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

UAB Intersurgical Arnioniu

60, LT-18170 Pabradė, Lithuania

Circuit House, Pitronnerie Road, Industrial Estate,

St Peter Port, Guernsey, GY1 2RL, UK