



EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**Heeley Surgical Ltd
04 Park Square, Thorncliffe Business Park,
Sheffield S35 2PH
United Kingdom**

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4008519/B

Original Approval: 2 May 2014

Current Certificate: 2 May 2017

Certificate Expiry: 1 May 2020

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE CERTIFICATE LRQ 4008519/B SCHEDULE

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

Heeley Surgical Ltd
04 Park Square, Thorncliffe Business Park,
Sheffield S35 2PH
United Kingdom

**Single use sterile and non-sterile stainless steel surgical instruments and sets,
including:**

Class IIa Products

Forceps - Biopsy, Bone Holding, Bone Rongue, Cholecystectomy, Debakey
Dissecting, Dental probes, Descalers, Dialating, Dissecting all types, Dissectors,
Haemostats (clamps), Hooks, Introducing, Ligature, Lung, Nasal, Ovum,
Peritoneum, Probes, Retractors, Scissors all types, Scoops, Splinter, Tissue, Tonsil
Holding, Uterine, Vasectomy.
Suction Tubes - various
Podiatry - Nail Splitter & Nail Elevator

Class I Sterile Products

Foreceps - Aural, ENT, Midwifery Obstetric, Sinus, Uterine, Vulsellum,
Speculae - ENT
Gallipots stainless steel bowl

Schedule Issue: 01

Date of Schedule Issue: 2 May 2017

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