

## EC Certificate – FULL QUALITY ASSURANCE SYSTEM

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:

### Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

has been assessed against the requirements of Annex II 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. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

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.



Chris Koci – President, LRQA Americas  
Issued By: Lloyd's Register Quality Assurance Ltd

Current Certificate: 15 June 2018

Original Approval: 1 January 2014

Expiry Date: 14 June 2021

Certificate Identity Number: 10092881

LRQA Notified Body Number: 0088

Approval Certificate Number: MDD – 0078058



Lloyd's  
Register

# EC Certificate – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE IDENTITY No.10092881 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

## Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

### Class II Products

Re-useable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and surgery including:

Hot Biopsy Forceps, Plastic Biliary Stents  
Metal Biliary Stent Sets  
Pancreatic Stents  
Sphincterotomes  
Sphinctertomes (Active Cords)  
Papillotomes  
Polypectomy Devices  
Gastrostomy Devices  
Gastrostomy Devices (Adaptors)  
Gastrostomy Replacement Devices  
Gastro-Jejunal Feeding Tubes  
Nasal Jejunal Feeding Tubes  
Ligation Devices, Endoscopic Clipping Devices  
Coagulation Devices  
Injection Needles  
Aspiration Needles  
Disposable Biopsy Forceps  
Endoscopic Ultra Fiducial Needles

### Class IIa Products

Disposable (Cold) Biopsy Forceps  
Active Cords  
Injection Needles  
Aspiration Needles  
Gastrostomy Adaptors  
Nasal Jejunal Feeding Tubes  
Ligation Devices  
Coagulation Devices

### Class IIb Products

Hot Biopsy Forceps  
Biliary Stents  
Metal Biliary Stents/Sets  
Pancreatic Stents  
Sphincterotomes  
Papillotomes  
Endoscopic Ultra Fiducial Needles  
Polypectomy Devices  
Gastrostomy Devices  
Gastrostomy Replacement Devices  
Gastro Jejunal Feeding Tubes  
Ligation Devices (Endoscopic Clipping Devices)  
Coagulation Devices (Bipolar Probes).

Schedule Issue: 1

Date of Schedule Issue: 15 June 2018

Certificate Identity Number: 10092881

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Chris Koci – President, LRQA Americas  
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