

## 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:

### Wilson-Cook Medical, Inc.

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

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. 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: 10092875

LRQA Notified Body Number: 0088

Approval Certificate Number: MDD – 0078058



Lloyd's  
Register

## EC Certificate – PRODUCTION QUALITY ASSURANCE CERTIFICATE IDENTITY No.10092875 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 I Sterile Products

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

Retrieval Devices  
ERCP Catheters  
ERCP Catheter Adaptors  
Wire Guides  
Wire Guide Locking Devices  
Extraction Balloons  
Extraction Baskets  
Dilation Catheters  
Balloon Dilators  
Manometry Catheters  
Cytology Brushes

#### Class I Measuring Devices

Biliary and Quantum Balloon Inflation Devices

Schedule Issue: 1  
Date of Schedule Issue: 15 June 2018  
Certificate Identity Number: 10092875  
LRQA Notified Body Number: 0088

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