

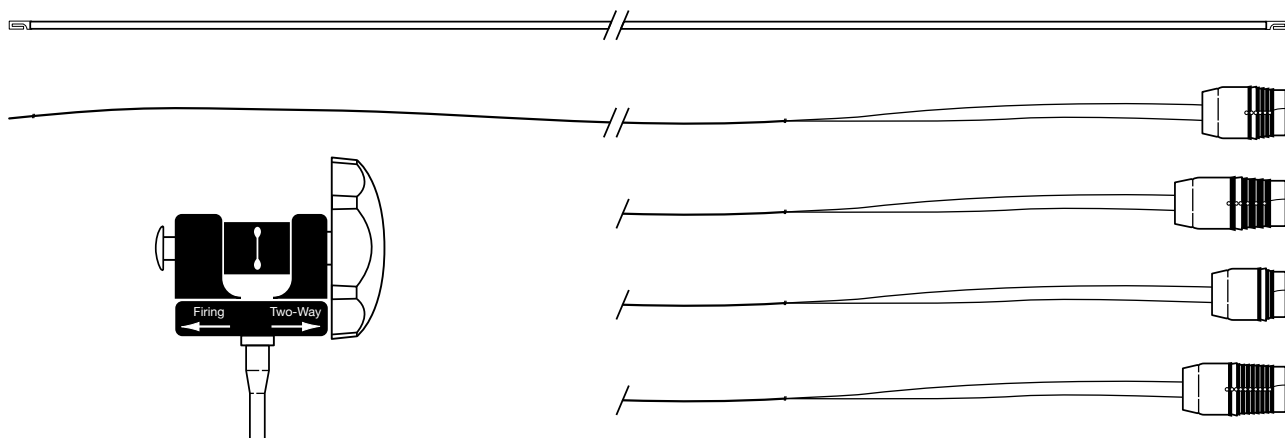
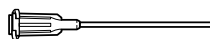
Hemostasis - Ligation



6 Shooter® Saeed® Multi-Band Ligator

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

- Barrel features two-string trigger cord and recessed bands - providing maximum endoscopic view while maintaining suction
- Clear band signals when only one band remains to be deployed
- Wide array of barrel sizes to meet a full range of procedural needs



Order Number	Reference Part Number	Endoscope Outer Diameter mm	Trigger Cord Length cm	Number of Bands	Minimum Accessory Channel mm
G24654	MBL-6-OV	9.5-11.5	122	6	2.8
G25503	MBL-6-OV-XS	8.6-9.2	122	6	2.8
G22613	MBL-4	9.5-13	122	4	2.8
G22553	MBL-6	9.5-13	122	6	2.8
G22614	MBL-10	9.5-11.5	122	10	2.8
G25423	MBL-4-XS	8.6-9.2	122	4	2.8
G25424	MBL-6-XS	8.6-9.2	122	6	2.8
G25504	MBL-10-XS	8.6-9.2	122	10	2.8
G25119	MBL-6-XL	11-14	122	6	2.8
G25220	MBL-4-XL-C	11-14	190	4	2.8
G25221	MBL-6-XL-C	11-14	190	6	2.8
G22690	MBL-4-F	9.5-13	142	4	2.8
G22692	MBL-6-F	9.5-13	142	6	2.8
G22691	MBL-10-F	9.5-11.5	142	10	2.8
G24655	MBL-6-F-OV	9.5-13	142	6	2.8

Each kit includes barrel with ligation bands and trigger cord, loading catheter, precision control handle and irrigation adapter.

Note: -F options are for use with Fuji endoscopes. -C options are for use with colonoscopes.

Caution: This product contains natural rubber latex, which may cause allergic reactions.

This device is supplied non-sterile.



Certificate of Approval

This is to certify that the Management System of:

Wilson-Cook Medical, Inc.

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

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00016927

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.



Cliff Muckleroy

Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

Certificate Schedule

Location	Activities
4900 Bethania Station Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.
5951 Grassy Creek Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Manufacturing, Quality Control, Packaging, Labeling, and Finished Goods Shipping.
5941 Grassy Creek Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Manufacturing, Purchasing, Receiving, Incoming Quality Control, and Raw material Storage.



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

Expiry Date: 14 June 2021

Certificate Identity Number: 10092875

LRQA Notified Body Number: 0088

Original Approval: 1 January 2014

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

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

Expiry Date: 14 June 2021

Certificate Identity Number: 10092881

LRQA Notified Body Number: 0088

Original Approval: 1 January 2014

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

LRQA Notified Body Number: 0088

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