



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106138 0002 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb

Double J stent & set

Class IIa

PCN catheter & set

Ureteral catheter

Malecot catheter

Re-entry malecot catheter

Suprapubic catheter

Braided shaft catheter

Dual lumen catheter

Facial dilator

Amplatz dilator & set

Ureteral dilator & set

Ureteral balloon dilator

Double J stent & set

Mono J stent

Endopyelotomy stent

Guidewire

IP Needle

Chiba needle

Stone basket

Perk basket

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

T. Wacker

Page 1 of 3

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Legalization see reverse side

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunastrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE	
(Convention de la Haye du 5 octobre 1961)	
1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich Country: Swiss Confederation, Canton of Zürich Diese öffentliche Urkunde / This public document	
2. ist unterschrieben von has been signed by	Andreas Bachmann
3. in seiner Eigenschaft als acting in the capacity of	Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of Notariat Enge – Zürich Kanton Zürich	
5. In / at 8090 Zürich / Zurich	Bestätigt / Certified 6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich by the Chancellery of State of the Canton of Zurich	
8. unter Nr. / under N° 1179274/2020	
9. Stempel/Siegel, Stamp/seal	10. Unterschrift / Signature



S. Overkott



Product Service

Certificate

No. Q5 106138 0001 Rev. 00

Holder of Certificate: **Marflow AG**
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Facility(ies): Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2023-04-02

Date, 2020-04-03

Christoph Dicks
Head of Certification/Notified Body

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunastrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich
Country: Swiss Confederation, Canton of Zürich
Diese öffentliche Urkunde / This public document
2. ist unterschrieben von
has been signed by Andreas Bachmann
3. in seiner Eigenschaft als
acting in the capacity of Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of
Notariat Enge – Zürich Kanton Zürich
5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179275/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature



[Handwritten signature]

S. Overkott



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138 0003 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class Is

Urine bag connector

Penile clamp

Evacuator

IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

Date,

2020-04-03

Christoph Dicks
Head of Certification/Notified Body

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunastrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE	
(Convention de la Haye du 5 octobre 1961)	
1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich Country: Swiss Confederation, Canton of Zürich Diese öffentliche Urkunde / This public document	
2. ist unterschrieben von has been signed by	Andreas Bachmann
3. in seiner Eigenschaft als acting in the capacity of	Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of Notariat Enge – Zürich Kanton Zürich	
Bestätigt / Certified	
5. In / at 8090 Zürich / Zurich	6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich by the Chancellery of State of the Canton of Zurich	
8. unter Nr. / under N° 1179273/2020	
9. Stempel/Siegel, Stamp/seal	10. Unterschrift / Signature



S. Overkott

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60126740 0001

Report No.: 15056254 008

Manufacturer: Zhejiang Geyi Medical
Instrument Co., Ltd.
The 5th Floor, NO.4 Building
No.190 Chutian Road
Xixing Street, Binjiang Zone
Hangzhou
310051 Zhejiang
China

Products: Disposable Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60110361 0001

Expiry Date: 2022-12-13

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-03-21

Date: 2018-03-21

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

G-Flex Europe SPRL
20, Rue de l'Industrie
1400 - Nivelles Belgium

declares on our own responsibility that the medical device:

Product	Reference	Class	Rule
MULTIBAND LIGATOR	GF-OVL100-V2, GF-OVL200, GF-OVL200-RL, GF-OVL200-V2, GF-OVL300-V2, GF-OVL510, GF-OVL501-V2, GF-OVL100-LF, GF-OVL100-V3, GF-OVL100-LF-V2, GF-OVL300, GF-OVL501, GF-OVL100, GF-OVL510-V2, GF-OVL100-LC-01, GF-OVL100-R, GF-OVL100-RU	I	5

are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) and of its transpositions in national laws.
This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

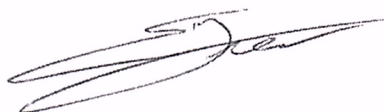
The device fulfill the essential requirements of Annex I of the MDD.

The conformity assessment procedure was established in accordance with:

Notify Body	SGS United Kingdom Limited Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA - United Kingdom
Identificaton Number	0120
Procedure	Article 10 of the Belgian Royal Decree of March 18th 1999 on Medical Devices

The device are manufactured in the European Union.

Nivelles, 12/12/2014



Thierry CREMER
Quality Manager



Certificate BE19/819943488

The management system of

G-Flex Europe Sprl

Rue de l'Industrie 20
1400 Nivelles, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, development, manufacture and sales of non-active and active (non-implantable) medical devices and accessories for application in endoscopy and respiratory.

Distribution of non-active and active (non-implantable) medical devices for application in endoscopy, urology and respiratory.

This certificate is valid from 22 May 2019 until 01 June 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 01 May 2021

Issue 2. Certified since 19 April 2019

Authorised by



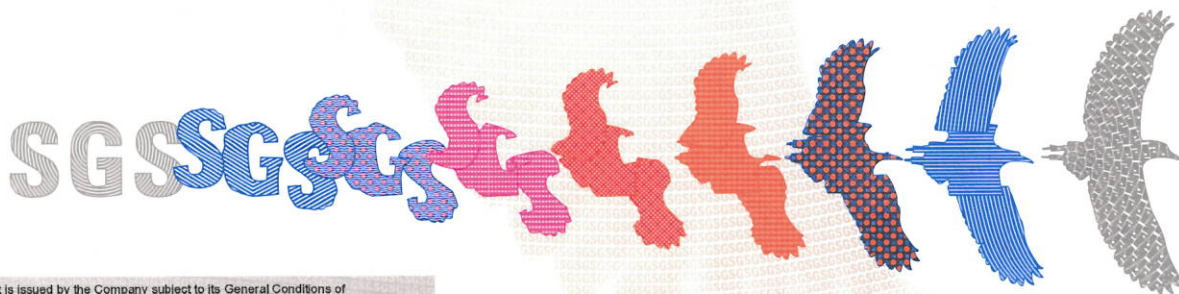
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1



0005





EC Declaration of Conformity

I, the undersigned, hereby declare that the Product(s)

***Helicobacter pylori* IgG Elisa, Cat. No. 601 040.02**
Gastrin-17 Elisa, Cat. No. 601 035
Pepsinogen I Elisa, Cat. No. 601 010.01
Pepsinogen II Elisa, Cat. No. 601 020.02
Lactose Intolerance, quick test, Cat. No.s 602 010 (25 tests) and 602 012 (10 tests)
Lactase CONTROL+, Cat. No. 602 018
***Helicobacter pylori*, quick test, Cat. No. 602 015**
BIOHIT *Helicobacter pylori* UFT300, quick test
Cat. No.s 602 005, 602 005PLA (5 tests), 602 019, 602 019PLA (50 tests)
and 602 021 (100 tests)
***Helicobacter pylori* CONTROL+, Cat. No. 602 017**
BIOHIT Celiac quick test, Cat. No. 602 070
BIOHIT ColonView, Cat. No. 602 250.02
BIOHIT Calprotectin ELISA, Cat. No. 602 260
BIOHIT Extraction Tubes, Cat. No. 602 270
BIOHIT Active B12 (Holotranscobalamin), Cat. No. 602 290
Gastrin-17 Stabilizer, Cat. No.s 601 050 (1 x 5,5 ml) and 601 051 (5 x 5,5 ml)
GastroPanel: Pepsinogen I, Pepsinogen II, *H. pylori*, Gastrin-17 Elisa, Cat No. 601 300

Conform to the applicable provisions of EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices. Category: Other/General devices.

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (excluding point 6) of the Directive.

Standards applied:

ISO 9001:2008, ISO 13485:2003

Certificate No. 111839-2012-AQ-FIN-FINAS issued by DNV on 09 February 2015

ISO 14001 Certificate No. 111840-2012-AE-FIN-FINAS issued by DNV on 09 February 2015

ISO 13485:2003 Certificate No. CERT-0075001 issued by QMI SAI Global on 08 March 2015

Signed:

Date: 24th June, 2015

Name: **Semi Korpela**

Title: **President & CEO**

Company: **Biohit Oyj, Laippatie 1, 00880 Helsinki, Finland**

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 588902

Issued To:

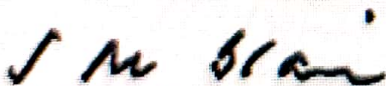
Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: 2012-08-27

Date: 2018-10-05

Expiry Date: 2023-09-24

...making excellence a habit.

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Kilmarnock, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: **Fortune Medical Instrument Corp.**
6F., No. 29, Sec. 2
Jhongjheng E. Rd.
Danshuei Dist.
New Taipei City
251
Taiwan

Holds Certificate No: **MD 588797**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products.

The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-08-23

Latest Revision Date: 2019-07-31

Effective Date: 2019-08-09

Expiry Date: 2022-08-08

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +886 (02)2656-0333.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP Tel: +44 345 080 9000
BSI Administration UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W1 1AL, UK.
A Member of the BSI Group of Companies.

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
256415-2018-AQ-FIN-FINAS

Initial certification date:
05 June 1997

Valid:
29 August 2018 - 28 February 2021

This is to certify that the management system of

Biohit Oyj

Laippatie 1, FI-00880 Helsinki, Finland

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design/development, manufacture, marketing, and sales/distribution of acetaldehyde binding medical devices and in vitro diagnostic medical devices used in the diagnosis of risk of gastric cancer, immune status, disease/health status, autoimmune status, gastric disorders, including near patient in vitro diagnostic devices.

Place and date:
Espoo, 29 August 2018



For the issuing office:
DNV GL Business Assurance Finland Oy Ab

A handwritten signature in blue ink, appearing to read "Kimmo Haarala", is placed over a horizontal line.

Kimmo Haarala
Management Representative

	Quality System Form		
	Document Number: D00062014	Revision: 035	QMS Owner: Cook Ireland Ltd.
	Page: 1 of 1		
Title: Declaration of Conformity			
Legacy Number: F3203B			



DECLARATION OF CONFORMITY

Manufacturer:

Cook Ireland Limited,
O'Halloran Road,
National Technology Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441
www.cookmedical.com

Technical File Number: ITF008-UTS/SS

Family Identification:

Urinary Tract Stents / Stent Sets

(See Product Identification List for a list of model numbers associated with the Declaration of Conformity)

Classification (MDD, Annex IX):

IIB

We herewith declare that the above-mentioned products comply with the Medical Device Directive 93/42/EEC and its transposition into Irish Law and that we, the above named manufacturer are solely responsible for same. The following standards apply. All supporting documentation is retained under the premises of the manufacturer and the notified body.

General applicable directives:

Medical Device Directive:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices. (MDD 93/42/EEC)

Standards:

Harmonised standards as amended (published in the Official Journal of the European Communities) and International Standards applicable to this product are:
Detailed in the "Standards Listing"

Notified Body: TÜV SÜD Product Service GmbH (0123)Ridlerstr. 65,
80339, Munich,
Germany

Certificate: G1 18 04 33038 028 (Annex II excluding 4)

Date of Initial CE Marking/ Date of

Initial DOC Issuance : 19 Jul 2001

Signature:



Date: 25-July-2018

Name: Sinead Burke

Position: Director Regulatory Affairs

WARNING CONFIDENTIAL PROPRIETARY PROPERTY - This document is owned by COOK Medical. It contains confidential proprietary trade secret information and must not be copied. The document and the information it contains can be used only by the recipient for the specific use for which it was requested. All other use is strictly prohibited. This document must be returned to COOK Medical immediately upon request by COOK Medical. By possession of this document, the possessor expressly agrees to comply with these terms.

© COPYRIGHT Cook Ireland Ltd. 2017

Template: F0518A (R001, CR17-0298)



Senior Regulatory Affairs Specialist: Joe Kennedy Date: 23-Feb-2017
Page 1 of 19

USI-822
USI-824
USI-826
USI-828
USI-830

Universa® Soft Ureteral Stent Set
Universa® Soft Ureteral Stent Set
Universa® Soft Ureteral Stent Set
Universa® Soft Ureteral Stent Set
Universa® Soft Ureteral Stent Set

USI-500-R
USI-520-R
USI-522-R
USI-524-R
USI-526-R
USI-528-R
USI-530-R
USI-600-R
USI-620-R
USI-622-R
USI-624-R
USI-626-R
USI-628-R
USI-630-R
USI-700-R
USI-720-R
USI-722-R
USI-724-R
USI-726-R
USI-728-R
USI-730-R
USI-822-R
USI-824-R
USI-826-R
USI-828-R
USI-830-R

Universa® Soft Multi-Length Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Multi-Length Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Multi-Length Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner
Universa® Soft Ureteral Stent and Positioner

USI-500-B
USI-520-B
USI-522-B
USI-524-B
USI-526-B
USI-528-B
USI-530-B
USI-600-B
USI-620-B
USI-622-B
USI-624-B
USI-626-B
USI-628-B
USI-630-B
USI-700-B
USI-716-B
USI-720-B
USI-722-B
USI-724-B
USI-726-B
USI-728-B
USI-730-B
USI-800-B

Universa® Soft Multi-Length Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Multi-Length Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Multi-Length Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Ureteral Stent
Universa® Soft Multi-Length Stent

Senior Regulatory Affairs Specialist: Joe Kennedy Date: 23-Feb-2017



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

USI-822-B	Universa® Soft Ureteral Stent
USI-824-B	Universa® Soft Ureteral Stent
USI-826-B	Universa® Soft Ureteral Stent
USI-828-B	Universa® Soft Ureteral Stent
USI-830-B	Universa® Soft Ureteral Stent
USI-500-RPC	Universa® Soft Multi-Length Stent Set with Roadrunner Wire Guide
USI-512-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-514-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-520-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-522-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-524-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-526-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-528-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-530-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-600-RPC	Universa® Soft Multi-Length Stent Set with Roadrunner Wire Guide
USI-616-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-620-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-622-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-624-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-626-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-628-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-630-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-700-RPC	Universa® Soft Multi-Length Stent Set with Roadrunner Wire Guide
USI-720-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-722-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-724-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-726-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-728-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-730-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-800-RPC	Universa® Soft Multi-Length Stent Set with Roadrunner Wire Guide

Senior Regulatory Affairs Specialist: Joe Kennedy Date: 23-Feb-2017
Page 3 of 19



USI-822-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-824-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-826-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-828-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-830-RPC	Universa® Soft Ureteral Stent Set with Roadrunner Wire Guide
USI-500-LP	Universa® Soft Multi-Length Stent Set with Lockable Pusher
USI-512-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-516-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-520-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-522-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-524-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-526-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-528-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-530-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-600-LP	Universa® Soft Multi-Length Stent Set with Lockable Pusher
USI-620-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-622-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-624-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-626-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-628-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-630-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-700-LP	Universa® Soft Multi-Length Stent Set with Lockable Pusher
USI-720-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-722-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-724-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-726-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-728-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-730-LP	Universa® Soft Ureteral Stent Set with Lockable Pusher
USI-512-CE	Universa® Soft Ureteral Closed End Stent Set
USI-522-CE	Universa® Soft Ureteral Closed End Stent Set
USI-524-CE	Universa® Soft Ureteral Closed End Stent Set
USI-526-CE	Universa® Soft Ureteral Closed End Stent Set
USI-528-CE	Universa® Soft Ureteral Closed End Stent Set
USI-600-CE	Universa® Soft Multi-Length Closed End Stent Set
USI-622-CE	Universa® Soft Ureteral Closed End Stent Set
USI-624-CE	Universa® Soft Ureteral Closed End Stent Set
USI-626-CE	Universa® Soft Ureteral Closed End Stent Set
USI-628-CE	Universa® Soft Ureteral Closed End Stent Set
USI-722-CE	Universa® Soft Ureteral Closed End Stent Set
USI-724-CE	Universa® Soft Ureteral Closed End Stent Set
USI-726-CE	Universa® Soft Ureteral Closed End Stent Set
USI-728-CE	Universa® Soft Ureteral Closed End Stent Set
USI-824-CE	Universa® Soft Ureteral Closed End Stent Set
USI-826-CE	Universa® Soft Ureteral Closed End Stent Set
USI-828-CE	Universa® Soft Ureteral Closed End Stent Set
USI-600-RPC-T	Universa® Soft Multi-Length Stent with Tether and Roadrunner Wire Guide
USI-614-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

USI-624-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-626-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-628-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-700-RPC-T	Universa® Soft Multi-Length Stent with Tether and Roadrunner Wire Guide
USI-724-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-726-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-728-RPC-T	Universa® Soft Ureteral Stent with Tether and Roadrunner Wire Guide
USI-526-CE-B	Universa® Soft Ureteral Closed End Stent
USI-528-CE-B	Universa® Soft Ureteral Closed End Stent
USI-626-CE-B	Universa® Soft Ureteral Closed End Stent
USI-628-CE-B	Universa® Soft Ureteral Closed End Stent
USI-726-CE-B	Universa® Soft Ureteral Closed End Stent
USI-728-CE-B	Universa® Soft Ureteral Closed End Stent
USI-526-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-624-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-626-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-628-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-726-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-728-CE-LP	Universa® Soft Ureteral Closed End Stent and Lockable Pusher
USI-600-R-T	Universa® Soft Multi-Length Stent with Tether and Positioner
USI-624-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-626-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-628-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-700-R-T	Universa® Soft Multi-Length Stent with Tether and Positioner
USI-724-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-726-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-728-R-T	Universa® Soft Ureteral Stent with Tether and Positioner
USI-526-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-622-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-624-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-626-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide

Senior Regulatory Affairs Specialist: Joe Kennedy

Date: 23-Feb-2017



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

USI-628-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-724-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-726-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-728-RPC-LP	Universa® Soft Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
USI-600-T	Universa® Soft Multi-Length Stent with Tether
USI-624-T	Universa® Soft Ureteral Stent with Tether
USI-626-T	Universa® Soft Ureteral Stent with Tether
USI-628-T	Universa® Soft Ureteral Stent with Tether
USI-728-T	Universa® Soft Ureteral Stent with Tether
USI-500-B-T	Universa® Soft Multi-Length Stent with Tether
USI-600-B-T	Universa® Soft Multi-Length Stent with Tether
USI-526-CE-R	Universa® Soft Ureteral Closed-End Stent and Positioner
USI-624-CE-R	Universa® Soft Ureteral Closed-End Stent and Positioner
USI-626-CE-R	Universa® Soft Ureteral Closed-End Stent and Positioner
USI-628-LP-PD	Universa® Soft Ureteral Stent with Distal Pigtail Sideports only and Lockable Pusher
USI-728-LP-PD	Universa® Soft Ureteral Stent with Distal Pigtail Sideports only and Lockable Pusher
USI-718-P	Universa® Soft Ureteral Stent with Pigtail Sideports only
USI-722-P	Universa® Soft Ureteral Stent with Pigtail Sideports only
USI-724-P	Universa® Soft Ureteral Stent with Pigtail Sideports only
USI-726-P	Universa® Soft Ureteral Stent with Pigtail Sideports only
USI-728-P	Universa® Soft Ureteral Stent with Pigtail Sideports only
USI-800-R-P	Universa® Soft Multi-Length Stent with Pigtail Sideports only and Positioner
USI-626-CE-RPC-T	Universa® Soft Ureteral Closed-End Stent with Tether and Roadrunner Wire Guide
UFI-522	Universa® Firm Ureteral Stent Set
UFI-524	Universa® Firm Ureteral Stent Set
UFI-526	Universa® Firm Ureteral Stent Set
UFI-528	Universa® Firm Ureteral Stent Set
UFI-530	Universa® Firm Ureteral Stent Set
UFI-622	Universa® Firm Ureteral Stent Set
UFI-624	Universa® Firm Ureteral Stent Set
UFI-626	Universa® Firm Ureteral Stent Set
UFI-628	Universa® Firm Ureteral Stent Set
UFI-630	Universa® Firm Ureteral Stent Set
UFI-722	Universa® Firm Ureteral Stent Set
UFI-724	Universa® Firm Ureteral Stent Set

Senior Regulatory Affairs Specialist: Joe Kennedy Date: 23-Feb-2017
Page 6 of 19



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

UFI-726	Universa® Firm Ureteral Stent Set
UFI-728	Universa® Firm Ureteral Stent Set
UFI-822	Universa® Firm Ureteral Stent Set
UFI-824	Universa® Firm Ureteral Stent Set
UFI-826	Universa® Firm Ureteral Stent Set
UFI-828	Universa® Firm Ureteral Stent Set
UFI-500	Universa® Firm Multi-Length Stent Set
UFI-600	Universa® Firm Multi-Length Stent Set
UFI-700	Universa® Firm Multi-Length Stent Set
UFI-522-R	Universa® Firm Ureteral Stent and Positioner
UFI-524-R	Universa® Firm Ureteral Stent and Positioner
UFI-526-R	Universa® Firm Ureteral Stent and Positioner
UFI-528-R	Universa® Firm Ureteral Stent and Positioner
UFI-622-R	Universa® Firm Ureteral Stent and Positioner
UFI-624-R	Universa® Firm Ureteral Stent and Positioner
UFI-626-R	Universa® Firm Ureteral Stent and Positioner
UFI-628-R	Universa® Firm Ureteral Stent and Positioner
UFI-722-R	Universa® Firm Ureteral Stent and Positioner
UFI-724-R	Universa® Firm Ureteral Stent and Positioner
UFI-726-R	Universa® Firm Ureteral Stent and Positioner
UFI-728-R	Universa® Firm Ureteral Stent and Positioner
UFI-822-R	Universa® Firm Ureteral Stent and Positioner
UFI-824-R	Universa® Firm Ureteral Stent and Positioner
UFI-826-R	Universa® Firm Ureteral Stent and Positioner
UFI-828-R	Universa® Firm Ureteral Stent and Positioner
UFI-500-R	Universa® Firm Multi-Length Stent and Positioner
UFI-600-R	Universa® Firm Multi-Length Stent and Positioner
UFI-700-R	Universa® Firm Multi-Length Stent and Positioner
UFI-622-B	Universa® Firm Ureteral Stent
UFI-624-B	Universa® Firm Ureteral Stent
UFI-626-B	Universa® Firm Ureteral Stent
UFI-726-B	Universa® Firm Ureteral Stent
UFI-500-B	Universa® Firm Multi-Length Stent
UFI-600-B	Universa® Firm Multi-Length Stent
UFI-700-B	Universa® Firm Multi-Length Stent
UFI-522-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-524-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-526-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-528-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-622-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-624-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-626-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-628-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-722-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

	Roadrunner Wire Guide
UFI-724-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-726-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-728-RPC-LP	Universa® Firm Ureteral Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-500-RPC-LP	Universa® Firm Multi-Length Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-600-RPC-LP	Universa® Firm Multi-Length Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-700-RPC-LP	Universa® Firm Multi-Length Stent with Lockable Pusher and Roadrunner Wire Guide
UFI-626-LP	Universa® Firm Ureteral Stent Set with Lockable Pusher
UFI-724-LP	Universa® Firm Ureteral Stent Set with Lockable Pusher
UFI-726-P	Universa® Firm Ureteral Stent with Pigtail Sideports only
UFI-728-P	Universa® Firm Ureteral Stent with Pigtail Sideports only
UFI-626-P	Universa® Firm Ureteral Stent with Pigtail Sideports only
UFI-628-P	Universa® Firm Ureteral Stent with Pigtail Sideports only
UFI-500-LP	Universa® Firm Multi-Length Stent with Lockable Pusher
UFI-600-LP	Universa® Firm Multi-Length Stent with Lockable Pusher
UFI-700-LP	Universa® Firm Multi-Length Stent with Lockable Pusher
USI-800	Universa® Soft Multi-Length Stent Set
USI-800-R	Universa® Soft Multi-Length Stent and Positioner

Senior Regulatory Affairs Specialist: Joe Kennedy Date: 23-Feb-2017

Appendix A

Product Identification – Non-Manufactured

Urinary Tract Stents and Stent Sets

ITF008-UTS/SS

Class IIb

009500-GRAD-5	Box of 5 Universa™ Multi-length Stent Sets
009500-GRAD-B-5	Box of 5 Universa™ Multi-length Stent
009500-GRAD-B-P	Universa™ Multi-length Stent with Pigtail Sideports only
009500-GRAD-B-T-P	Universa™ Multi-length Stent with Tether and Pigtail Sideports only
009500-GRAD-CE	Universa™ Multi-length Closed End Stent Sets
009500-GRAD-CE-B	Universa™ Multi-length Closed End Stent
009500-GRAD-CE-B-P	Universa™ Multi-length Closed End Stent and Pigtail Sideports only
009500-GRAD-CE-B-T	Universa™ Multi-length Closed End Stent with Tether
009500-GRAD-CE-B-T-P	Universa™ Multi-length Closed End Stent with Tether and Pigtail Sideports only
009500-GRAD-CE-LP	Universa™ Multi-length Closed End Stent Set with Lockable Pusher
009500-GRAD-CE-LP-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
009500-GRAD-CE-LP-T	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Tether.
009500-GRAD-CE-LP-T-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009500-GRAD-CE-P	Universa™ Multi-length Closed End Stent Set with Pigtail Sideports only
009500-GRAD-CE-R	Universa™ Multi-length Closed End Stent with Positioner
009500-GRAD-CE-R-P	Universa™ Multi-length Closed End Stent with Positioner and Pigtail Sideports only.
009500-GRAD-CE-RPC	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide
009500-GRAD-CE-RPC-LP	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide and Lockable Pusher.
009500-GRAD-CE-RPC-LP-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher and Pigtail Sideports only.
009500-GRAD-CE-RPC-LP-T	Universa™ Multi-length Closed End stent with Roadrunner Wire guide, Lockable Pusher and Tether.
009500-GRAD-CE-RPC-LP-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher, Tether and Pigtail Sideports only.
009500-GRAD-CE-RPC-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide and Pigtail Sideports only.
009500-GRAD-CE-RPC-T	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide and Tether
009500-GRAD-CE-RPC-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide, Tether and Pigtail Sideports only.
009500-GRAD-CE-R-T	Universa™ Multi-length Closed End Stent with Positoner and Tether.
009500-GRAD-CE-R-T-P	Universa™ Multi-length Closed End Stent with Positoner, Tether and Pigtail Sideports only
009500-GRAD-CE-T	Universa™ Multi-length Closed End Stent Set with Tether
009500-GRAD-CE-T-P	Universa™ Multi-length Closed End Stent Set with Tether and Pigtail Sideports only
009500-GRAD-LP-P	Universa™ Multi-length Stent Set with Lockable Pusher and

009500-GRAD-LP-T	Pigtail Sideports only
009500-GRAD-LP-T-P	Universa™ Multi-length Stent Set with Lockable Pusher and Tether
009500-GRAD-P	Universa™ Multi-length Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009500-GRAD-R-5	Universa™ Multi-length Stent Set with Pigtail Sideports only
009500-GRAD-R-P	Box of 5 Universa™ Multi-length Stents with Positioner
	Universa™ Multi-length Stent with Positioner and Pigtail Sideports only
009500-GRAD-RPC-LP	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Lockable Pusher
009500-GRAD-RPC-LP-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
009500-GRAD-RPC-LP-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
009500-GRAD-RPC-LP-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
009500-GRAD-RPC-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
009500-GRAD-RPC-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Tether
009500-GRAD-RPC-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
009500-GRAD-R-T	Universa™ Multi-length Stent with Positioner and Tether
009500-GRAD-R-T-P	Universa™ Multi-length Stent with Positioner, Tether and Pigtail Sideports only
009500-GRAD-T	Universa™ Multi-length Stent Set with Tether
009500-GRAD-T-P	Universa™ Multi-length Stent Set with Tether and Pigtail Sideports
009600-GRAD-5	Box of 5 Universa™ Multi-length Stent Sets
009600-GRAD-B-5	Box of 5 Universa™ Multi-length Stent
009600-GRAD-B-P	Universa™ Multi-length Stent with Pigtail Sideports only
009600-GRAD-B-T-P	Universa™ Multi-length Stent with Tether and Pigtail Sideports only
009600-GRAD-CE-B	Universa™ Multi-length Closed End Stent
009600-GRAD-CE-B-P	Universa™ Multi-length Closed End Stent and Pigtail Sideports only
009600-GRAD-CE-B-T	Universa™ Multi-length Closed End Stent with Tether
009600-GRAD-CE-B-T-P	Universa™ Multi-length Closed End Stent with Tether and Pigtail Sideports only
009600-GRAD-CE-LP	Universa™ Multi-length Closed End Stent Set with Lockable Pusher
009600-GRAD-CE-LP-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
009600-GRAD-CE-LP-T	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Tether.
009600-GRAD-CE-LP-T-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009600-GRAD-CE-P	Universa™ Multi-length Closed End Stent Set with Pigtail Sideports only
009600-GRAD-CE-R	Universa™ Multi-length Closed End Stent with Positioner
009600-GRAD-CE-R-P	Universa™ Multi-length Closed End Stent with Positioner and Pigtail Sideports only.
009600-GRAD-CE-RPC	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide



009600-GRAD-CE-RPC-LP	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide and Lockable Pusher.
009600-GRAD-CE-RPC-LP-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher and Pigtail Sideports only.
009600-GRAD-CE-RPC-LP-T	Universa™ Multi-length Closed End stent with Roadrunner Wire guide, Lockable Pusher and Tether.
009600-GRAD-CE-RPC-LP-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher, Tether and Pigtail Sideports only.
009600-GRAD-CE-RPC-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide and Pigtail Sideports only.
009600-GRAD-CE-RPC-T	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide and Tether
009600-GRAD-CE-RPC-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide, Tether and Pigtail Sideports only.
009600-GRAD-CE-R-T	Universa™ Multi-length Closed End Stent with Positoner and Tether.
009600-GRAD-CE-R-T-P	Universa™ Multi-length Closed End Stent with Positoner, Tether and Pigtail Sideports only
009600-GRAD-CE-T	Universa™ Multi-length Closed End Stent Set with Tether
009600-GRAD-CE-T-P	Universa™ Multi-length Closed End Stent Set with Tether and Pigtail Sideports only
009600-GRAD-LP-P	Universa™ Multi-length Stent Set with Lockable Pusher and Pigtail Sideports only
009600-GRAD-LP-T	Universa™ Multi-length Stent Set with Lockable Pusher and Tether
009600-GRAD-LP-T-P	Universa™ Multi-length Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009600-GRAD-P	Universa™ Multi-length Stent Set with Pigtail Sideports only
009600-GRAD-R-5	Box of 5 Universa™ Multi-length Stents with Positioner
009600-GRAD-R-P	Universa™ Multi-length Stent with Positioner and Pigtail Sideports only
009600-GRAD-RPC-LP	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Lockable Pusher
009600-GRAD-RPC-LP-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
009600-GRAD-RPC-LP-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
009600-GRAD-RPC-LP-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
009600-GRAD-RPC-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
009600-GRAD-RPC-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
009600-GRAD-R-T-P	Universa™ Multi-length Stent with Postioner, Tether and Pigtail Sideports only
009600-GRAD-T-P	Universa™ Multi-length Stent Set with Tether and Pigtail Sideports
009700-GRAD-5	Box of 5 Universa™ Multi-length Stent Sets
009700-GRAD-B-5	Box of 5 Universa™ Multi-length Stent
009700-GRAD-B-P	Universa™ Multi-length Stent with Pigtail Sideports only
009700-GRAD-B-T	Universa™ Multi-length Stent with Tether
009700-GRAD-B-T-P	Universa™ Multi-length Stent with Tether and Pigtail Sideports only
009700-GRAD-CE	Universa™ Multi-length Closed End Stent Sets
009700-GRAD-CE-B	Universa™ Multi-length Closed End Stent
009700-GRAD-CE-B-P	Universa™ Multi-length Closed End Stent and Pigtail

Senior Regulatory Affairs Specialist: Yvonne Kennedy Date: 23-Feb-2017

009700-GRAD-CE-B-T	Sideports only
009700-GRAD-CE-B-T-P	Universa™ Multi-length Closed End Stent with Tether
009700-GRAD-CE-LP	Universa™ Multi-length Closed End Stent with Tether and Pigtail Sideports only
009700-GRAD-CE-LP-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher
009700-GRAD-CE-LP-T	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
009700-GRAD-CE-LP-T-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher and Tether.
009700-GRAD-CE-P	Universa™ Multi-length Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009700-GRAD-CE-R	Universa™ Multi-length Closed End Stent Set with Pigtail Sideports only
009700-GRAD-CE-R-P	Universa™ Multi-length Closed End Stent with Positioner
009700-GRAD-CE-RPC	Universa™ Multi-length Closed End Stent with Positioner and Pigtail Sideports only.
009700-GRAD-CE-RPC-LP	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide
009700-GRAD-CE-RPC-LP-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide and Lockable Pusher.
009700-GRAD-CE-RPC-LP-T	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher and Pigtail Sideports only.
009700-GRAD-CE-RPC-LP-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher and Tether.
009700-GRAD-CE-RPC-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire guide, Lockable Pusher, Tether and Pigtail Sideports only.
009700-GRAD-CE-RPC-T	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide and Tether
009700-GRAD-CE-RPC-T-P	Universa™ Multi-length Closed End Stent with Roadrunner Wire Guide, Tether and Pigtail Sideports only.
009700-GRAD-CE-R-T	Universa™ Multi-length Closed End Stent with Positioner and Tether.
009700-GRAD-CE-R-T-P	Universa™ Multi-length Closed End Stent with Positioner, Tether and Pigtail Sideports only
009700-GRAD-CE-T	Universa™ Multi-length Closed End Stent Set with Tether
009700-GRAD-CE-T-P	Universa™ Multi-length Closed End Stent Set with Tether and Pigtail Sideports only
009700-GRAD-LP-P	Universa™ Multi-length Stent Set with Lockable Pusher and Pigtail Sideports only
009700-GRAD-LP-T	Universa™ Multi-length Stent Set with Lockable Pusher and Tether
009700-GRAD-LP-T-P	Universa™ Multi-length Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
009700-GRAD-P	Universa™ Multi-length Stent Set with Pigtail Sideports only
009700-GRAD-R-5	Box of 5 Universa™ Multi-length Stents with Positioner
009700-GRAD-R-P	Universa™ Multi-length Stent with Positioner and Pigtail Sideports only
009700-GRAD-RPC-LP	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Lockable Pusher
009700-GRAD-RPC-LP-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
009700-GRAD-RPC-LP-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether



009700-GRAD-RPC-LP-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
009700-GRAD-RPC-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
009700-GRAD-RPC-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
009700-GRAD-R-T-P	Universa™ Multi-length Stent with Positioner, Tether and Pigtail Sideports only
009700-GRAD-T	Universa™ Multi-length Stent Set with Tether
009700-GRAD-T-P	Universa™ Multi-length Stent Set with Tether and Pigtail Sideports
009800-GRAD-B-P	Universa™ Multi-length Stent with Pigtail Sideports only
009800-GRAD-B-T-P	Universa™ Multi-length Stent with Tether and Pigtail Sideports only
009800-GRAD-P	Universa™ Multi-length Stent Set with Pigtail Sideports only
009800-GRAD-RPC-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
009800-GRAD-RPC-T-P	Universa™ Multi-length Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
009800-GRAD-R-T-P	Universa™ Multi-length Stent with Positioner, Tether and Pigtail Sideports only
009800-GRAD-T-P	Universa™ Multi-length Stent Set with Tether and Pigtail Sideports
009500-GRAD	Universa™ Multi-length Stent Set
009500-GRAD-B	Universa™ Multi-length Stent
009500-GRAD-B-T	Universa™ Multi-length Stent with Tether
009500-GRAD-LP	Universa™ Multi-length Stent Set with Lockable Pusher
009500-GRAD-R	Universa™ Multi-length Stent with Positioner
009500-GRAD-RPC	Universa™ Multi-length Stent Set with Roadrunner Wire Guide
0095XX-GRAD	Universa™ Double Pigtail Stent Set
0095XX-GRAD-B	Universa™ Double Pigtail Stent
0095XX-GRAD-B-P	Universa™ Double Pigtail Stent with Pigtail Sideports only
0095XX-GRAD-B-T	Universa™ Double Pigtail Stent with Tether
0095XX-GRAD-B-T-P	Universa™ Double Pigtail Stent with Tether and Pigtail Sideports only
0095XX-GRAD-CE-B	Universa™ Double Pigtail Closed End Stent
0095XX-GRAD-CE-B-P	Universa™ Double Pigtail Closed End Stent with Pigtail Sideports only
0095XX-GRAD-CE-B-T	Universa™ Double Pigtail Closed End Stent with Tether
0095XX-GRAD-CE-B-T-P	Universa™ Double Pigtail Closed End Stent with Tether and Pigtail Sideports only
0095XX-GRAD-CE-LP	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher
0095XX-GRAD-CE-LP-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
0095XX-GRAD-CE-LP-T	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Tether
0095XX-GRAD-CE-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
0095XX-GRAD-CE-P	Universa™ Double Pigtail Closed End Stent Set with Pigtail Sideports only
0095XX-GRAD-CE-R	Universa™ Double Pigtail Closed End Stent with Positioner
0095XX-GRAD-CE-R-P	Universa™ Double Pigtail Closed End Stent with Positioner and Pigtail Sideports only
0095XX-GRAD-CE-RPC	Universa™ Double Pigtail Closed End Stent Set with

0095XX-GRAD-CE-RPC-LP	Roadrunner Wire Guide
0095XX-GRAD-CE-RPC-LP-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide and Lockable Pusher
0095XX-GRAD-CE-RPC-LP-T	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0095XX-GRAD-CE-RPC-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0095XX-GRAD-CE-RPC-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Pigtail Sideports only
0095XX-GRAD-CE-RPC-T	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Tether
0095XX-GRAD-CE-RPC-T-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0095XX-GRAD-CE-R-T	Universa™ Double Pigtail Closed End Stent with Positioner and Tether
0095XX-GRAD-CE-R-T-P	Universa™ Double Pigtail Closed End Stent with Positioner, Tether and Pigtail Sideports only
0095XX-GRAD-CE-T	Universa™ Double Pigtail Closed End Stent Set with Tether
0095XX-GRAD-CE-T-P	Universa™ Double Pigtail Closed End Stent Set with Tether and Pigtail Sideports only
0095XX-GRAD-LP	Universa™ Double Pigtail Stent Set with Lockable Pusher
0095XX-GRAD-LP-P	Universa™ Double Pigtail Stent Set with Lockable Pusher and Pigtail Sideports only
0095XX-GRAD-LP-T	Universa™ Double Pigtail Stent Set with Lockable Pusher and Tether
0095XX-GRAD-LP-T-P	Universa™ Double Pigtail Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
0095XX-GRAD-P	Universa™ Double Pigtail Stent Set with Pigtail Sideports only
0095XX-GRAD-R	Universa™ Double Pigtail Stent with Positioner
0095XX-GRAD-R-P	Universa™ Double Pigtail Stent with Positioner and Pigtail Sideports only
0095XX-GRAD-RPC	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide
0095XX-GRAD-RPC-LP	Universa™ Double Pigtail Stent Set with Roadrunner Wire guide and Lockable Pusher
0095XX-GRAD-RPC-LP-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0095XX-GRAD-RPC-LP-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
0095XX-GRAD-RPC-LP-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0095XX-GRAD-RPC-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
0095XX-GRAD-RPC-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Tether
0095XX-GRAD-RPC-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0095XX-GRAD-R-T	Universa™ Double Pigtail Stent with Positioner and Tether
0095XX-GRAD-R-T-P	Universa™ Double Pigtail Stent with Positioner, Tether and Pigtail Sideports only
0095XX-GRAD-T	Universa™ Double Pigtail Stent Set with Tether
0095XX-GRAD-T-P	Universa™ Double Pigtail Stent Set with Tether and Pigtail Sideports only



009600-GRAD	Universa™ Multi-length Stent Set
009600-GRAD-B	Universa™ Multi-length Stent
009600-GRAD-B-T	Universa™ Multi-length Stent with Tether
009600-GRAD-CE	Universa™ Multi-length Closed End Stent Sets
009600-GRAD-LP	Universa™ Multi-length Stent Set with Lockable Pusher
009600-GRAD-R	Universa™ Multi-length Stent with Positioner
009600-GRAD-RPC	Universa™ Multi-length Stent Set with Roadrunner Wire Guide
009600-GRAD-RPC-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Tether
009600-GRAD-R-T	Universa™ Multi-length Stent with Positioner and Tether
009600-GRAD-T	Universa™ Multi-length Stent Set with Tether
0096XX-GRAD	Universa™ Double Pigtail Stent Set
0096XX-GRAD-5	Box of 5 Universa™ Double Pigtail Stent Set
0096XX-GRAD-B	Universa™ Double Pigtail Stent
0096XX-GRAD-B-5	Box of 5 Universa™ Double Pigtail Stents
0096XX-GRAD-B-P	Universa™ Double Pigtail Stent with Pigtail Sideports only
0096XX-GRAD-B-T	Universa™ Double Pigtail Stent with Tether
0096XX-GRAD-B-T-P	Universa™ Double Pigtail Stent with Tether and Pigtail Sideports only
0096XX-GRAD-CE	Universa™ Double Pigtail Closed End Stent Set
0096XX-GRAD-CE-B	Universa™ Double Pigtail Closed End Stent
0096XX-GRAD-CE-B-P	Universa™ Double Pigtail Closed End Stent with Pigtail Sideports only
0096XX-GRAD-CE-B-T	Universa™ Double Pigtail Closed End Stent with Tether
0096XX-GRAD-CE-B-T-P	Universa™ Double Pigtail Closed End Stent with Tether and Pigtail Sideports only
0096XX-GRAD-CE-LP	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher
0096XX-GRAD-CE-LP-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
0096XX-GRAD-CE-LP-T	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Tether
0096XX-GRAD-CE-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
0096XX-GRAD-CE-P	Universa™ Double Pigtail Closed End Stent Set with Pigtail Sideports only
0096XX-GRAD-CE-R	Universa™ Double Pigtail Closed End Stent with Positioner
0096XX-GRAD-CE-R-P	Universa™ Double Pigtail Closed End Stent with Positioner and Pigtail Sideports only
0096XX-GRAD-CE-RPC	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide
0096XX-GRAD-CE-RPC-LP	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide and Lockable Pusher
0096XX-GRAD-CE-RPC-LP-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0096XX-GRAD-CE-RPC-LP-T	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
0096XX-GRAD-CE-RPC-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0096XX-GRAD-CE-RPC-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Pigtail Sideports only
0096XX-GRAD-CE-RPC-T	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Tether

Senior Regulatory Affairs Specialist: Jim Kennedy Date: 23-Feb-2017



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

0096XX-GRAD-CE-RPC-T-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0096XX-GRAD-CE-R-T	Universa™ Double Pigtail Closed End Stent with Positioner and Tether
0096XX-GRAD-CE-R-T-P	Universa™ Double Pigtail Closed End Stent with Positioner, Tether and Pigtail Sideports only
0096XX-GRAD-CE-T	Universa™ Double Pigtail Closed End Stent Set with Tether
0096XX-GRAD-CE-T-P	Universa™ Double Pigtail Closed End Stent Set with Tether and Pigtail Sideports only
0096XX-GRAD-LP-P	Universa™ Double Pigtail Stent Set with Lockable Pusher and Pigtail Sideports only
009628-GRAD-LP-PD	Universa™ Double Pigtail Stent Set with Lockable Pusher and Pigtail Sideports only
0096XX-GRAD-LP-T	Universa™ Double Pigtail Stent Set with Lockable Pusher and Tether
0096XX-GRAD-LP-T-P	Universa™ Double Pigtail Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
0096XX-GRAD-P	Universa™ Double Pigtail Stent Set with Pigtail Sideports only
0096XX-GRAD-R	Universa™ Double Pigtail Stent with Positioner
0096XX-GRAD-R-5	Box of 5 Universa™ Double Pigtail Stent with Positioner
0096XX-GRAD-R-P	Universa™ Double Pigtail Stent with Positioner and Pigtail Sideports only
0096XX-GRAD-RPC	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide
0096XX-GRAD-RPC-LP	Universa™ Double Pigtail Stent Set with Roadrunner Wire guide and Lockable Pusher
0096XX-GRAD-RPC-LP-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0096XX-GRAD-RPC-LP-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
0096XX-GRAD-RPC-LP-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0096XX-GRAD-RPC-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
0096XX-GRAD-RPC-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Tether
0096XX-GRAD-RPC-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0096XX-GRAD-R-T	Universa™ Double Pigtail Stent with Positioner and Tether
0096XX-GRAD-R-T-P	Universa™ Double Pigtail Stent with Positioner, Tether and Pigtail Sideports only
0096XX-GRAD-T	Universa™ Double Pigtail Stent Set with Tether
0096XX-GRAD-T-P	Universa™ Double Pigtail Stent Set with Tether and Pigtail Sideports only
009700-GRAD	Universa™ Multi-length Stent Set
009700-GRAD-B	Universa™ Multi-length Stent
009700-GRAD-LP	Universa™ Multi-length Stent Set with Lockable Pusher
009700-GRAD-R	Universa™ Multi-length Stent with Positioner
009700-GRAD-RPC	Universa™ Multi-length Stent Set with Roadrunner Wire Guide
009700-GRAD-RPC-T	Universa™ Multi-length Stent Set with Roadrunner Wire Guide and Tether
009700-GRAD-R-T	Universa™ Multi-length Stent with Positioner and Tether
0097XX-GRAD	Universa™ Double Pigtail Stent Set
0097XX-GRAD-5	Box of 5 Universa™ Double Pigtail Stent Set
0097XX-GRAD-B	Universa™ Double Pigtail Stent

Senior Regulatory Affairs Specialist:

Yvonne Kennedy
Page 16 of 19

Date: *23 Feb 2017*



0097XX-GRAD-B-5	Box of 5 Universa™ Double Pigtail Stents
0097XX-GRAD-B-P	Universa™ Double Pigtail Stent with Pigtail Sideports only
0097XX-GRAD-B-T	Universa™ Double Pigtail Stent with Tether
0097XX-GRAD-B-T-P	Universa™ Double Pigtail Stent with Tether and Pigtail Sideports only
0097XX-GRAD-CE-B	Universa™ Double Pigtail Closed End Stent
0097XX-GRAD-CE-B-P	Universa™ Double Pigtail Closed End Stent with Pigtail Sideports only
0097XX-GRAD-CE-B-T	Universa™ Double Pigtail Closed End Stent with Tether
0097XX-GRAD-CE-B-T-P	Universa™ Double Pigtail Closed End Stent with Tether and Pigtail Sideports only
0097XX-GRAD-CE-LP	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher
0097XX-GRAD-CE-LP-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Pigtail Sideports only
0097XX-GRAD-CE-LP-T	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher and Tether
0097XX-GRAD-CE-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Lockable Pusher, Tether and Pigtail Sideports only
0097XX-GRAD-CE-P	Universa™ Double Pigtail Closed End Stent Set with Pigtail Sideports only
0097XX-GRAD-CE-R	Universa™ Double Pigtail Closed End Stent with Positioner
0097XX-GRAD-CE-R-P	Universa™ Double Pigtail Closed End Stent with Positioner and Pigtail Sideports only
0097XX-GRAD-CE-RPC	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide
0097XX-GRAD-CE-RPC-LP	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide and Lockable Pusher
0097XX-GRAD-CE-RPC-LP-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0097XX-GRAD-CE-RPC-LP-T	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
0097XX-GRAD-CE-RPC-LP-T-P	Universa™ Double Pigtail Closed End Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0097XX-GRAD-CE-RPC-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Pigtail Sideports only
0097XX-GRAD-CE-RPC-T	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide and Tether
0097XX-GRAD-CE-RPC-T-P	Universa™ Double Pigtail Closed End Stent Sets with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0097XX-GRAD-CE-R-T	Universa™ Double Pigtail Closed End Stent with Positioner and Tether
0097XX-GRAD-CE-R-T-P	Universa™ Double Pigtail Closed End Stent with Positioner, Tether and Pigtail Sideports only
0097XX-GRAD-CE-T	Universa™ Double Pigtail Closed End Stent Set with Tether
0097XX-GRAD-CE-T-P	Universa™ Double Pigtail Closed End Stent Set with Tether and Pigtail Sideports only
0097XX-GRAD-LP	Universa™ Double Pigtail Stent Set with Lockable Pusher
0097XX-GRAD-LP-P	Universa™ Double Pigtail Stent Set with Lockable Pusher and Pigtail Sideports only
009728-GRAD-LP-PD	Universa™ Double Pigtail Stent Set with Lockable Pusher and Pigtail Sideports only
0097XX-GRAD-LP-T	Universa™ Double Pigtail Stent Set with Lockable Pusher and Tether
0097XX-GRAD-LP-T-P	Universa™ Double Pigtail Stent Set with Lockable Pusher,

0097XX-GRAD-P	Tether and Pigtail Sideports only Universa™ Double Pigtail Stent Set with Pigtail Sideports only
0097XX-GRAD-R	Universa™ Double Pigtail Stent with Positioner
0097XX-GRAD-R-5	Box of 5 Universa™ Double Pigtail Stent with Positioner
0097XX-GRAD-R-P	Universa™ Double Pigtail Stent with Positioner and Pigtail Sideports only
0097XX-GRAD-RPC	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide
0097XX-GRAD-RPC-LP	Universa™ Double Pigtail Stent Set with Roadrunner Wire guide and Lockable Pusher
0097XX-GRAD-RPC-LP-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Pigtail Sideports only
0097XX-GRAD-RPC-LP-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher and Tether
0097XX-GRAD-RPC-LP-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Lockable Pusher, Tether and Pigtail Sideports only
0097XX-GRAD-RPC-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
0097XX-GRAD-RPC-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Tether
0097XX-GRAD-RPC-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0097XX-GRAD-R-T	Universa™ Double Pigtail Stent with Positioner and Tether
0097XX-GRAD-R-T-P	Universa™ Double Pigtail Stent with Positioner, Tether and Pigtail Sideports only
0097XX-GRAD-T	Universa™ Double Pigtail Stent Set with Tether
0097XX-GRAD-T-P	Universa™ Double Pigtail Stent Set with Tether and Pigtail Sideports only
009800-GRAD-B	Universa™ Multi-length Stent
009800-GRAD-R-P	Universa™ Multi-length Stent with Positioner and Pigtail Sideports only
009800-GRAD-RPC	Universa™ Multi-length Stent Set with Roadrunner Wire Guide
0098XX-GRAD	Universa™ Double Pigtail Stent Set
0098XX-GRAD-B	Universa™ Double Pigtail Stent
0098XX-GRAD-B-P	Universa™ Double Pigtail Stent with Pigtail Sideports only
0098XX-GRAD-B-T	Universa™ Double Pigtail Stent with Tether
0098XX-GRAD-B-T-P	Universa™ Double Pigtail Stent with Tether and Pigtail Sideports only
0098XX-GRAD-CE	Universa™ Double Pigtail Closed End Stent Set
0098XX-GRAD-P	Universa™ Double Pigtail Stent Set with Pigtail Sideports only
0098XX-GRAD-R	Universa™ Double Pigtail Stent with Positioner
0098XX-GRAD-R-P	Universa™ Double Pigtail Stent with Positioner and Pigtail Sideports only
0098XX-GRAD-RPC	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide
0098XX-GRAD-RPC-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Pigtail Sideports only
0098XX-GRAD-RPC-T	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide and Tether
0098XX-GRAD-RPC-T-P	Universa™ Double Pigtail Stent Set with Roadrunner Wire Guide, Tether and Pigtail Sideports only
0098XX-GRAD-R-T	Universa™ Double Pigtail Stent with Positioner and Tether
0098XX-GRAD-R-T-P	Universa™ Double Pigtail Stent with Positioner, Tether and



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

0098XX-GRAD-T
0098XX-GRAD-T-P

0095XX-GRAD-CE
0096XX-GRAD-LP
0097XX-GRAD-CE

Pigtail Sideports only
Universa™ Double Pigtail Stent Set with Tether
Universa™ Double Pigtail Stent Set with Tether and Pigtail
Sideports only
Universa™ Double Pigtail Closed End Stent Set
Universa™ Double Pigtail Stent Set with Lockable Pusher
Universa™ Double Pigtail Closed End Stent Set

Senior Regulatory Affairs Specialist:

Joe Kennedy
Page 19 of 19

Date:

23-Feb-2017



COOK IRELAND LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.COM

Standards listing

TECHNICAL FILE ID: ITF008-UTS/SS

The standards used for demonstration of conformity of products referenced in technical file Essential Requirements Checklist are as follows:

Standard	Standards Title
EN ISO 13485: 2012/ AC 2012	<i>Medical Devices – Quality Management Systems – requirements for regulatory purposes Technical Corrigendum 1.</i>
EN ISO 14971 :2012	<i>Medical devices – Application of risk management to medical devices.</i>
EN ISO 10993-1:2009 / AC 2010	<i>Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</i>
EN ISO 11135-1:2007	<i>Sterilization of healthcare products – Ethylene oxide – part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices.</i>
EN ISO 10993-7 :2008 / AC 2009	<i>Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.</i>
EN ISO 11737-1 :2006 /AC : 2009	<i>Sterilization of medical devices. Microbiological methods Part 1: Determination of a population of micro-organisms on products.</i>
EN 980 :2008	<i>Symbols for use in the labelling of medical devices.</i>
EN 1041 :2008	<i>Information Supplied by the manufacturer of Medical Devices.</i>
EN 556-1 :2001 / AC : 2006	<i>Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices.</i>
EN ISO 14644-1: 2015	<i>Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration</i>
EN ISO 14644-2: 2015	<i>Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration</i>

Note: This standards listing only applies to manufactured products. For non-manufactured products, refer to the previous standards listings. Reference *Appendix A* for the list of manufactured and non-manufactured products.

Review and Approval¹:

Date:

Regulatory:

Yue Fan
Anna Siegel

17-Feb-2017

Quality Systems:

17th Feb 2017

Senior Microbiologist:

Saba Ad

17-Feb-17

Engineering:

Travis Campbell

23 Feb 2017

Clinical Communications:

Ken Car

17 Feb 2017,

Sterilisation Engineer:

Helen Honeywood

17 Feb 2017

¹ Signatures for review and approval are completed by the relevant standard owners.