CERTIFICATO CE

Certificato n. 1812/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene nello stabilimento di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi

Sterilizzanti chimici a freddo per dispositivi medici

Disinfettanti per dispositivi medici

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici

Disinfettanti, decontaminanti e detergenti per dispositivi medici

Disinfettanti e detergenti per dispositivi medici

Disinfettanti e decontaminanti per dispositivi medici

Sistemi di conservazione e trasporto di endoscopi

Lava disinfettatrice per endoscopi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

Digitally signed by Grabazei Alexandru
Date: 2025.06.06 16:40:07 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

Sterilizzanti chimici a freddo per dispositivi medici
Modd. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Marca CANTEL

Disinfettanti per dispositivi medici
Modd. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Marca CANTEL

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici
Modd. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Marca CANTEL

Disinfettanti, decontaminanti e detergenti per dispositivi medici
Mod. ISACLEAN, PROTEODONT.
Marca CANTEL

Disinfettanti e detergenti per dispositivi medici
Modd. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Marca CANTEL

Disinfettanti e decontaminanti per dispositivi medici
Modd. PROTEAZONE; PROTEAZONE OD.
Marca CANTEL

Sistemi di conservazione e trasporto di endoscopi
Modd. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Marca CANTEL

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Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice per endoscopi
Modd. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Marca CANTEL

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factory of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Cold chemical washer disinfector and sterilizer for endoscopes

Cold chemical sterilant for medical devices

Disinfectants for medical devices

Multi-enzyme detergent, decontaminant disinfectant for medical devices

Disinfectants, decontaminants and detergents for medical devices

Disinfectants and detergents for medical devices

Decontaminants and disinfectants for medical devices

Storage and transport systems for endoscopes

Washer disinfector for endoscopes

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

Cold chemical sterilant for medical devices
Type ref. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Trade mark CANTEL

Disinfectants for medical devices
Type ref. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Trade mark CANTEL

Multi-enzyme detergent, decontaminant disinfectant for medical devices
Type ref. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Trade mark CANTEL

Disinfectants, decontaminants and detergents for medical devices
Type ref. ISACLEAN, PROTEODONT.
Trade mark CANTEL

Disinfectants and detergents for medical devices
Type ref. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Trade mark CANTEL

Decontaminants and disinfectants for medical devices
Type ref. PROTEAZONE; PROTEAZONE OD.
Trade mark CANTEL

Storage and transport systems for endoscopes
Type ref. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Trade mark CANTEL

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Date: 2015-07-20
Updated: 2020-05-08
Substitution Date: 2020-04-07
Expiry Date: 2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Washer disinfector for endoscopes

Type ref. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Trade mark CANTEL

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2021 - 01 - 21**
Expires on: ***2024 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione di disinfettanti, sterilizzatrici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici. Progettazione, sviluppo, gestione della produzione di sistemi di conservazione e trasporto di endoscopi
Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2021-01-21	2024-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Medivators Inc.
3150 Pollok Dr.
Conroe, TX 77303
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4716)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Registration Number: MD19.4716
Certification Granted: May 30, 2012
Effective Date: June 02, 2020
Expiry Date: May 15, 2022

Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Activity	Location
HQ, Administration, Design & Development, Manufacturing, Distribution	Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716
Design & Development	Medivators Inc. 3101 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716/A
Administration, Manufacturing	Medivators Inc. 501 North Farm to Market 3083 Rd E Conroe, TX 77303 USA File No.: MD19.4716/B
Manufacturing, Distribution	Medivators Inc. 750 Conroe Park North Conroe, TX 77303 USA File No: MD19.4716/C

Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Activity	Location
Distribution	Medivators Inc. 3155 Conroe Park North Conroe, TX 77303 USA File No: MD19.4716/D

Verified by:
Operations Manager

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Three Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 18, 2020 to September 17, 2022.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

MEDIVATORS
14605 28TH AVE NORTH
Minneapolis, MN USA 55447

Name of Manufacturer

Medivators Inc
14605 28th Ave N
MINNEAPOLIS, MN USA 55447

Medivators Inc
3150 Pollok Drive
Conroe, TX USA 77303

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

Name of Owner Operator

MEDIVATORS
14605 28TH AVE NORTH
Minneapolis, MN USA 55447

Name of Manufacturer

Medivators Inc
14605 28th Ave N
MINNEAPOLIS, MN USA 55447

Medivators Inc
3150 Pollok Drive
Conroe, TX USA 77303

Name of Product(s)

Renatron PA Dialyzer Reprocessing System
Renatron PA 100 Dialyzer Reprocessing System-- RS-8315
Renatron II Dialyzer Reprocessing System
Renatron II 100 Dialyzer Reprocessing System-- RS-8335
Renalog RM-- 78398-192, 78398-204
Renalin Cold Sterilant-- 78397-521
Renalin PA Cold Sterilant-- 78397-638, 78397-639, 78397-452
Renalin 100 Cold Sterilant-- 78398-060, 78397-844, 78397-845, 78397-846, 78397-970
Renalin 100 Cold Sterilant with test kit-- 78397-845, 78397-846, 78397-970
Renalin Indicator Test Strips --78199-000
Renalin Residual Test Strips-- 78198-000
Perassay 500 Peracetic Acid Test Strips-- 78378-000
Actril Cold Sterilant-- 78337-000, 78399-667
Actril Cold Sterilant with test kit-- 78270-000
Actril Residual Test Strips-- 78258-000
Actril Indicator Test Strips-- 78259-000
Hemocor HPH Hemoconcentrator; HPH Mini, HPH Junior
Hemocor HPH Hemoconcentrator; HPH 400, HPH 400TS
Hemocor HPH Hemoconcentrator; HPH 700, HPH 700TS
Hemocor HPH Hemoconcentrator; HPH 1000, HPH 1000TS
Hemocor HPH Hemoconcentrator; HPH 1400, HPH 1400TS
Renaflo II Hemofilter; HF Minifilter Plus
Renaflo II Hemofilter; HF Junior
Renaflo II Hemofilter; HF400
Renaflo II Hemofilter; HF700
Renaflo II Hemofilter; HF1200
Renaflo II Hemofilter; HF2000
Primus Hollow Fiber Dialyzer; Primus 1350
Fiberflo Hollow Fiber Cartridge Water Filter--FF50, FF100, FF200
Bicarbonate Concentrate Liquid; BC-1-L Renasol, MB-330-L Centrisol
Bicarbonate Concentrate Powder; Renasol BC-1, BC-1-15, BC-1-25
Bicarbonate Concentrate Powder; Centrisol MB-330, MB-330-15, MB-330-25
Acetate Concentrate Nephrosol; Acetate Concentrate
Renasol Acid Concentrate - SB-1003, SB-1014, SB-1019, SB-1020, SB-1030, SB-1057, SB-1063, SB-1078, SB-1086
Centrisol Acid Concentrate - SB-111, SB-119, SB-123, SB-127, SB-129, SB-140, SB-142, SB-143, SB-144, SB-145
Medivators Advantage Plus Endoscope Reprocessing System
Medivators Advantage Automated Endoscope Reprocessor
MDS Modular Disinfection System
ADVANTAGE PLUS Pass-Thru Automatic Endoscope Reprocessor -- ADVPT-3005, ADVPT-3006
DSD Series Automatic Endoscope Reprocessor-- DSD-201(LT)(Model No.: DSD-2007, DSD-2011), SSD-102(LT)

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Certificate No. 14038-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3

DSD Series Automatic Endoscope Reprocessor-- DSD Edge
CER Series Endoscope Reprocessor-- CER-1, CER-2, CER-1 Optima, CER-2 Optima
Veriscan Automated Endoscope Leak Detection System-- VER-LT
Rapicide PA High-Level Disinfectant-- ML02-0117, ML02-0116, ML02-0115
Rapicide OPA-28 High-Level Disinfectant-- ML02-0127, ML02-0132, ML02-0138
Rapicide PA RTU High-Level Disinfectant & Sterilant- ML02-0125
Rapicide High-Level Disinfectant and Sterilant-- ML02-0059, ML02-0108
Rapicide PA Disinfectant & Sterilant Test Strips - ML02-0118
Rapicide PA RTU High-Level Disinfectant & Sterilant Test Strips - ML02-0129
Rapicide OPA-28 Test Strips-- ML02-0137, ML02-0136
Rapicide Test Strips-- ML02-0120
MediClean EZ-- ML02-0131
Intercept Detergent-- ML02-0106, ML02-0134
Intercept Plus - ML02-0145
Intercept Wipes-- ML02-0107
Intercept Foam - ML02-0139
Scope Buddy Endoscope Flushing Aid-- EFA-US-G, EFA-IN-G (Model No. ECA-100G)
Scope Buddy Tubing Accessory Kit- 78399-669
Minncare Cold Sterilant -78398-229, 78397-983, 78397-825
Minncare Residual Test Strips -78338-000
Minncare Peracetic Acid Test Strips- 78339-000
EndoStratus Irrigation Pump EGA-500, EGA-500E, EGA-500P
EndoGator Irrigation Pump EGP-100, EGP-100E, EGP-100P
EndoStratus CO2 Insufflator EGA-501, EGA-501E, EGA-501P
EndoStratus Irrigation Pump and CO2 Insufflator System -- EGA-SYST
EndoSmartCap Irrigation Tubing and Accessories 100145, 100145U, 100145CO2, 100145CO2U
ENDO SMARTCAP Co2 Tubing 100145CO2EX, 100150CO2EX,100165CO2EX
EndoSmartCap Irrigation Tubing and Accessories 100150CO2P
EndoSmartCap Irrigation Tubing and Accessories 100150, 100150U, 100150CO2, 100150CO2U
EndoSmartCap Irrigation Tubing and Accessories 100160, 100160U, 100160P,100160S
EndoSmartCap Irrigation Tubing and Accessories 100165, 100165U 100165CO2, 100165CO2U
EndoSmartCap Irrigation Tubing and Accessories 100140, 100141, 100551, 100551P
EndoSmartCap Irrigation Tubing and Accessories 100162
EndoSmartCap Adapter 100555
ENDOGATOR Cartridge 100110
EndoGator Hybrid Irrigation Tubing 100605, 100605U, 100605S,100606, 100606U, 100606S
EndoGator Hybrid Irrigation Tubing 100608, 100608U,100608S, 100609, 100609U,100609S
EndoGator Hybrid Irrigation Tubing 100610, 100610U, 100610S
EndoGator Hybrid Irrigation Tubing 100630, 1001630U, 100631, 100631U
EndoGator Irrigation Tubing and Accessories Kits 100130P,100130, 100130U,100130F,100130FU
EndoGator Irrigation Tubing and Accessories Kits 100125, 100125F, 100126
EndoGator Irrigation Tubing and Accessories Kits 200230P
EndoGator Irrigation Tubing and Accessories Kits 200230, 200230U, 200230F, 200230FU
EndoGator Irrigation Tubing and Accessories Kits 100135, 100136, 100105
EndoGator Irrigation Tubing and Accessories Kits 100131, 100115, 100116, 100116P
EndoGator Irrigation Tubing and Accessories Kits 100241, 100242, 100242P, 100115, 100116
EndoGator Irrigation Tubing and Accessories Kits 100600, 100601, 100602
EndoGator Irrigation Tubing and Accessories Kits 100603, 100611, 100612, 100613, 100614
EndoGator Irrigation Tubing and Accessories Kits 100615, 100616, 100618
EndoGator Irrigation Tubing and Accessories Kits 100620, 100621, 100622, 100623
EndoGator Irrigation Tubing and Accessories Kits 100625, 100626, 100627, 100628, 100629
EndoGator Irrigation Tubing and Accessories Kits 100630, 100630S, 100631,100631S
Defendo Disposable Biopsy, Air/Water and Suction Valves 100301, 100302, 100303, 100305
Defendo Disposable Biopsy, Air/Water and Suction Valves 100306, 100310, 100312,100313
Defendo Disposable Biopsy, Air/Water and Suction Valves 100314,100315,100316, 100317
DEFENDO Valve and Connector Kit for Olympus GI Endoscopes 100311
DEFENDO biopsy valve 100318,100319,100320
Defendo Olympus Kit 100322, 100323

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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10903 New Hampshire Avenue
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Certificate No. 14038-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3

Endo Carry-on Kit 100800, 100801, 100802, 100803, 100305, 100310
Endoscope Cleaning Brushes and Pull Thru Channel Cleaning Devices 100401, 100402, 100403
Endoscope Cleaning Brushes and Pull Thru Channel Cleaning Devices 100405, 100406
Intercept Beside Kit 100900
Double Balloon Pull Thru SPUP 100414
Micro Pull Thru SPUP 100415
Bite Blocks , Standard Adult 100411
Bite Blocks , Standard Pediatric 100412
EconoTrap 1 Single Chamber Polyp Trap 100101
EconoTrap 2 Double Chamber Polyp Trap 100102
Advantage Polyp Trap Collection Container 100104
AmplifEYE - EYE-101, EYE-102
----------END OF PRODUCT LIST----------

DICHIARAZIONE DI CONFORMITA CE
EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	**CANTEL MEDICAL (ITALY) S.R.L.**
Indirizzo del Fabbricante Manufacturer's address	Via Laurentina, 169 – 00071 Pomezia (Roma) - Italy
Nome del Dispositivo Medico Name of the Medical Device	**MEDIVATORS ISA**
Codice Identificativo Identification code	**ISA/CE/007**
Classe del prodotto Device Class	**IIb**
Destinazione d'uso Fields covered	Lava-Disinfettatrice chimica a freddo per endoscopi. Cold chemical Wash Disinfector for endoscopes
Sistema di Qualità Quality System	**UNI EN ISO 9001 – UNI EN ISO 13485**
Organismo Notificato Notified Body	IMQ S.P.A.– via Quintiliano,43 – 20138 Milano – Italy
Numero Certificato CE CE Certificate No.	1812/MDD

La sottoscritta CANTEL MEDICAL (ITALY) S.R.L. , dichiara che il dispositivo Medico **MEDIVATORS ISA** è conforme ai requisiti dell' Allegato II della Direttiva 93/42/CEE e s.m.i. e risponde ai requisiti essenziali della direttiva suddetta ad esso applicabili, in tutte le fasi dalla progettazione al controllo finale.
La CANTEL MEDICAL (ITALY) S.R.L. dichiara, inoltre, che il prodotto è conforme alle seguenti normative:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

The undersigned CANTEL MEDICAL (ITALY) S.R.L.. declares that the medical device **MEDIVATORS ISA** meets the requirements of Annex II of EEC Directive 93/42 and its revised version and meets the applicable provisions thereof with the relevant essential requirements of the aforementioned directive from design to final inspection and testing.
CANTEL MEDICAL (ITALY) S.R.L. also claims that the product meets the following standards:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

MANAGING DIRECTOR

Data/date 11/09/2017 V. M. SUPEKAR

GIORNO/DAY - MESE/MONTH - ANNO/YEAR