ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 003280 0006 Rev. 01

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): **Hemodialysis / Peritoneal / Central Venous / PTA Balloon Catheters and Related Accessories**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 003280 0006 Rev. 01

Report No.: ITA1527293

Valid from: 2021-01-29
Valid until: 2024-05-26

Date, 2021-01-29

[redacted]

Christoph Dicks
Head of Certification/Notified Body

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

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

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Add value.
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Covidien LLC
15 Hampshire Street
02048 MANSFIELD
USA

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter

CL 003280 0026 Rev. 00

Reference: 713234292 | GA713217822

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: US-MF-000028763

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 003280 0026 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-23

TÜV SÜD Product Service GmbH Medical and Health Services	TÜV SÜD Product Service GmbH Medical and Health Services
[redacted]	
Emiliano Gavioli Conformity Assessment Responsible (CARE)	Franziska Eckert Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ritus™ Peritoneal Dialysis Catheters **0763000B00008618A** **8810887003** **8810888003** **8810888012** **8810889003** **8811313009** **8811313010** **8811313013** **8811313014** **8811313015** **8814843001** **8814843002** **8817278001** **8817278006** **8817278007** **8817278008** **8817278010** **8888111132** **8888121132** **8888411009** **8888411405** **8888411421** **8888411447** **8888411702** **8888411710** **8888412007** **8888412015** **8888412601** **8888412619** **8888413005** **8888413013** **8888413401** **8888413419** **8888413807** **8888413815** **8888413823** **8888413831** **8888414011** **8888414029**	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 003280 0006 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
8888422170 **8888423103** **8888425702** **8888425710** **8888425728** **8888425744**			
Ritus™ Peritoneal Dialysis Catheters (Neonatal, Infant, Adolescent, Pediatric) **0763000B00008618A** **8810890003** **8810890014** **8812321001** **8812329001** **8812329002** **8815677001** **8888410506** **8888413100** **8888413101** **8888413102** **8888414201** **8888414219** **8888414227** **8888414235** **8888414508** **8888414813** **8888415307** **8888423111** **8888425785**	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 003280 0006 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-23	713234292 | GA713217822	Initial issue

Declaration of Conformity (DoC)

Manufacturer:	Covidien llc 15 Hampshire Street Mansfield, MA 02048 USA
Authorized Representative:	Covidien Ireland Limited IDA Business and Technology Park Tullamore, Ireland
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
Conformity Assessment Certificate(s):	G1 003280 0006 Rev. 01 expires 31-December-2028
Conformity Assessment Route:	Directive 93/42/ECC on Medical Devices (MDD), Annex II excluding (4)
Risk Class:	Refer to products listed in the table below
Classification rule:	Refer to products listed in the table below
Standard List:	Located in the Essential Requirements Checklist
Intended purpose:	Peritoneal Dialysis Catheters are intended for acute and chronic peritoneal dialysis treatment.

Statement:

I, the undersigned declare that the Medical Device(s) specified above/below/in Appendix X comply with Article 120 of the Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD) or 90/385/EEC (AIMD). This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of 93/42/EEC (MDD) or 90/385/EEC (AIMD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.

The validity of the certificate listed on this DoC is valid through 31 December 2028.

We, Covidien llc, declare under our sole responsibility that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

Each kind of medical device which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S and follow conformity assessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulation 2002.

Place: Mansfield, MA USA

Name: Carol Ming

Title: Regulatory Affairs Manager

Signature: 

Date: 30 October 2024

Products Covered

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8810887003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Loose Cuffs 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810888003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810888012	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Universal Tenckhoff, 2 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810890003	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 37 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810890014	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 32 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313009	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Loose Cuffs 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313010	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313013	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 60 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8811313014	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 57 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8811313015	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 57 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812321001	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 37 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812329001	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8812329002	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8814843001	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Preperitoneal Cuff 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8814843002	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Universal Tenckhoff, 1 Preperitoneal Cuff 46 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8815677001	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 1 Preperitoneal Cuff 39 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278001	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Universal Tenckhoff, 1 Preperitoneal Cuff 46 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8817278006	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278007	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 2 Cuff 57cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278008	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Tenckhoff, 2 Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8817278010	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Curl Cath, 1 Preperitoneal Cuff 60 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888111132	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Tray, Swan Neck, Curl Cath, 1 Cuff, 122.3 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	6/12/2014
8888121132	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Kit, Swan Neck, Curl Cath, 1 Cuff, 122.3 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	6/12/2014
8888410506	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Swan Neck Tenckhoff, 2 Cuff Left 37.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411009	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, Missouri Oreopoulos-Zellerman 2 Cuff, 2 Disk, 1 Bead, 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411405	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuffs 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888411421	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411447	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 47 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411702	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888411710	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 1 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412007	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Tenckhoff, 2 Cuff Left 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412015	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck 2 Cuff Right 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412601	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri, 2 Cuff Left 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888412619	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri, 2 Cuff Right 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413005	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Oreopolulos-Zellerman, 2 Cuff Left 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888413013	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Oreopolulos-Zellerman, 2 Cuff Right 44.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413100	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 38.9 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413101	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 43 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413102	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff 59 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413401	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413419	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413807	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413815	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888413823	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Swan Neck Curl Cath, 2 Cuff Left 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888413831	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Kit Swan Neck Curl Cath, 2 Cuff Right 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414011	Argyle™ (or Ritus™) Presternal Peritoneal Dialysis Catheter Swan Neck Missouri 112.8 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414029	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Moncrief-Popovich Swan Neck Curl Cath, 2 Cuff 62.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414201	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414219	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff 1 Cuff 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414227	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414235	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff 1 Cuff 31 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888414508	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 1 Cuff 39.25 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888414813	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Curl Cath, 2 Cuff Left 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888415307	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Missouri Curl Cath, 2 Cuff Left 42.5 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888422170	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888423103	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff,2 Cuff 41 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888423111	Argyle™ (or Ritus™) Neonatal Peritoneal Dialysis Catheter Tenckhoff, 2 Cuffs 30 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425702	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Oreopoulos-Zellerman Curl Cath, 1 Cuff, 1 Bubble 63 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425710	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Oreopoulos-Zellerman Curl Cath, 2 Cuff, 1 Bubble 62 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425728	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck, Tenckhoff, Special Left 20 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8888425744	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Swan Neck Teckhoff, Left, 2 Cuffs, 53 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998

CFN	Product Description	Sterilization Method	GMDN Code and Term	Class	MDD Rule	Date Approved for CE
8888425785	Argyle™ (or Ritus™) Pediatric Peritoneal Dialysis Catheter Curl Cath, 2 Loose Cuffs 39.25 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998
8810889003	Argyle™ (or Ritus™) Peritoneal Dialysis Catheter Tenckhoff, 1 Subcutaneous Cuff 42 cm	EO	47085 Peritoneal dialysis catheter, acute/chronic	IIb	8	4/27/1998