Teleflex®	DECLARATION OF CONFORMITY **DC-D-BSI-001**

Manufacturers:	**European Representative:**
Arrow International LLC Subsidiary of Teleflex Incorporated 3015 Carrington Mill Blvd. Morrisville North Carolina 27560 USA Arrow International, Inc. Subsidiary of Teleflex Incorporated 2400 Bernville Rd. Reading, PA 19605 USA	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath, Ireland

Product Name:	**Central Venous Catheterization (CVC) Kit/Set**		
TECHNICAL FILE OR DESIGN DOSSIER #	**D-BSI-001**	Classification:	**III**
Procedure Pack # (if applicable)	**P-BSI-001**	Classification:	**N/A**
GMDN Code (Optional):	**61594 – Central Venous Catheter**		

Finished Goods Product Number	Device Description	Date CE Mark First Affixed
SC-14701	1-Lumen Infusion Catheter: (SLIC(R)) for use with Arrow PSI System: 7 Fr x 20 cm	01 Mar 1999
SS-14701	1-Lumen Infusion Catheter: (SLIC®)) for use with Arrow PSI System: 7 Fr x 16 cm	01 Mar 1998

Component Product Number	Device Description
HO-14702-001A	Catheter: 2-L w/ Accessory 7 Fr x 30 cm
HO-14702-003A	Catheter: 2-L w/ Accessory 7 Fr x 30 cm
HO-14702-001B	Catheter: 2-L 7 Fr x 30 cm
HO-14702-001C	Catheter: 2-L: 7 Fr x 30 cm
HO-14703-001A	Catheter: 3-L W/Accessory: 7 Fr x 30 cm
HO-14703-001B	Catheter: 3-L: 7 Fr x 30 cm
HO-14703-001C	Catheter: 3-L: 7 Fr x 30 cm
K-04050-001A	Catheter: S-L: 16 Ga x 6"
K-04050-001B	Catheter: S-L: 16 Ga x 6"
K-04150-003A	Catheter:/Insert Tube: 20 Ga x 5"
K-04150-003B	Catheter:/Insert Tube: 20 Ga x 5"
K-04300-009A	Catheter: S-L: 16 Ga x 8"
K-04300-009B	Catheter: S-L: 16 Ga x 8"
K-04301-001A	Catheter: S-L: 16 Ga x 20 cm
K-04301-001B	Catheter: S-L: 16 Ga x 20 cm
K-04306-001A	Catheter: S-L: 16 Ga x 16 cm
K-04306-001B	Catheter: S-L: 16 Ga x 16 cm
K-04400-001A	Catheter: S-L: 16 Ga x 12"
K-04400-001B	Catheter: S-L: 16 Ga x 12"
K-04650-001A	Catheter: S-L: 24 Ga x 8 cm
K-04650-001B	Catheter: S-L: 24 Ga x 8 cm
K-04660-001A	Catheter: S-L: 24 Ga x 12.7 cm

K-04660-001B	Catheter: S-L: 24 Ga x 12.7 cm
K-50014-001A	Catheter: S-L: 14 Ga x 20 cm
K-50014-001B	Catheter: S-L: 14 Ga x 20 cm
K-50016-001A	Catheter: S-L: 16 Ga x 8"
K-50016-001B	Catheter: S-L: 16 Ga x 8"
LC-15703-001B	Catheter: 3-L: 7 Fr x 20 cm
LC-15703-001C	Catheter: 3-L: 7 Fr x 20 cm
LC-15703-001D	Catheter: 3-L: 7 Fr x 20 cm
MLZ-00701-001A	Catheter: S-L: 7 Fr x 20 cm
MLZ-00701-001B	Catheter: S-L: 7 Fr x 20 cm
MLZ-00702-001B	Catheter: 2-L: 7Fr x 21 cm
MLZ-00703-001B	Catheter: 3-L Comm: 7 Fr x 21cm
MCZ-36123-001C	Catheter: 3-L: 12 Fr x 25 cm
MC-17702-011	Catheter: 2-L: 7fr x 20 cm
MC-17702-011A	Catheter: 2-L: 7fr x 20 cm
MC-17702-011C	Catheter: 2-L: 7fr x 20 cm
MC-12402-001F	Catheter: 2-L: 4 Fr x 5 cm
MC-12402-001H	Catheter: 2-L: 4 Fr x 5 cm
MC-12402-001I	Catheter: 2-L: 4 Fr x 5 cm
MC-12402-001J	Catheter: 2-L: 4 Fr x 5 cm
MC-12553-001F	Catheter: 3-L: 5.5 Fr x 5 cm
MC-12553-001G	Catheter: 3-L: 5.5 Fr x 5 cm
MC-12702-006	Catheter: 2-L: 7 Fr x 16 cm
MC-12702-006A	Catheter: 2-L: 7 Fr x 16 cm
MC-12703-003	Catheter: 3-L: 7 Fr x 16 cm
MC-12703-003A	Catheter: 3-L: 7 Fr x 16 cm
MC-14402-003C	Catheter: 2-L: 4 Fr x 13 cm
MC-14402-003D	Catheter: 2-L: 4 Fr x 13 cm
MC-14402-003E	Catheter: 2-L: 4 Fr x 13 cm
MC-14402-003F	Catheter: 2-L: 4 Fr x 13 cm
MC-14502-001E	Catheter: 2-L: 5 Fr x 13 cm
MC-14502-001F	Catheter: 2-L: 5 Fr x 13 cm
MC-14502-003A	Catheter: 2-L: 5 Fr x 13 cm
MC-14502-003C	Catheter: 2-L: 5 Fr x 13 cm
MC-14502-003	Catheter: 2-L: 5 Fr x 13 cm
MC-14502-003B	Catheter: 2-L: 5 Fr x 13 cm
MC-14553-002F	Catheter: 3-L: 5.5 Fr x 30 cm
MC-14553-002G	Catheter: 3-L: 5.5 Fr x 30 cm
MC-14553-002H	Catheter: 3-L: 5.5 Fr x 30 cm
MC-14553-002I	Catheter: 3-L: 5.5 Fr x 30 cm
MC-14702-003	Catheter: 2-L: 7 Fr x 30 cm
MC-14703-017D	Catheter: 3-L: 7 Fr x 30 cm
MC-14703-017F	Catheter: 3-L: 7 Fr x 30 cm
MC-15402-002H	Catheter: 2-L: 4 Fr x 8 cm
MC-15402-002I	Catheter: 2-L: 4 Fr x 8 cm
MC-15402-002J	Catheter: 2-L: 4 Fr x 8 cm
MC-15402-002K	Catheter: 2-L: 4 Fr x 8 cm
MC-15553-002F	Catheter: 3-L: 5.5 Fr x 8 cm
MC-15553-002H	Catheter: 3-L: 5.5 Fr x 8 cm
MC-15553-002G	Catheter: 3-L: 5.5 Fr x 8 cm
MC-15553-002I	Catheter: 3-L: 5.5 Fr x 8 cm
MC-15703-017	Catheter: 3-L: 7 Fr x 20 cm

MC-15703-017A	Catheter: 3-L: 7 Fr x 20 cm
MC-16402-002H	Catheter: 2-L: 4 Fr x 30 cm
MC-16402-002I	Catheter: 2-L: 4 Fr x 30 cm
MC-16402-002J	Catheter: 2-L: 4 Fr x 30 cm
MC-16402-002K	Catheter: 2-L: 4 Fr x 30 cm
MC-16553-002F	Catheter: 3-L: 5.5 Fr x 13 cm
MC-16553-002G	Catheter: 3-L: 5.5 Fr x 13 cm
MC-16553-002H	Catheter: 3-L: 5.5 Fr x 13 cm
MC-16553-002I	Catheter: 3-L: 5.5 Fr x 13 cm
MC-16553-003F	Catheter: 3-L: 5.5 Fr x 13 cm
MC-16702-010A	Catheter: 2-L: 7 Fr x 20 cm
MC-16702-010C	Catheter: 2-L: 7 Fr x 20 cm
MC-16702-012B	Catheter: 2-L: 7 Fr x 20 cm
MC-16702-012A	Catheter: 2-L: 7 Fr x 20 cm
MC-17702-011	Catheter: 2-L: 7 Fr x 20 cm
MC-17702-011A	Catheter: 2-L: 7 Fr x 20 cm
MC-17702-011B	Catheter: 2-L: 7 Fr x 20 cm
MC-17702-011C	Catheter: 2-L: 7 Fr x 20 cm
MC-17752-003	Catheter: 2-L: 7 Fr x 60 cm
MC-17752-003A	Catheter: 2-L: 7 Fr x 60 cm
MC-17752-003B	Catheter: 2-L: 7 Fr x 60 cm
MC-18703-004D	Catheter: 3-L: 7 Fr x 60 cm
MC-18703-004F	Catheter: 3-L: 7 Fr x 60 cm
MC-51418-003	Catheter: 2-L: 7 Fr x 20 cm
MC-51418-003A	Catheter: 2-L: 7 Fr x 20 cm
CZ-04401-001	Catheter: S-L: 16 Ga x 30 cm
KZ-04301-002	Catheter: S-L: 16 Ga x 20 cm
KZ-04303-002	Catheter: S-L: 16 Ga x 13 cm
KZ-04306-002	Catheter: S-L: 16 Ga x 16 cm
MCZ-10703-001	Catheter: 3-L: 7 Fr x 11 cm
MCZ-10703-001A	Catheter: 3-L: 7 Fr x 11 cm
MCZ-10853-005A	Catheter: 3-L: 8.5 Fr x 11 cm
MCZ-10853-005B	Catheter: 3-L: 8.5 Fr x 11 cm
MCZ-10854-001	Catheter: 4-L: 8.5 Fr x 11 cm
MCZ-12702-003	Catheter: 2-L: 7 Fr x 16 cm
MCZ-12702-003A	Catheter: 2-L: 7 Fr x 16 cm
MCZ-12702-004	Catheter: 2-L: 7 Fr x 16 cm
MCZ-12702-004A	Catheter: 2-L: 7 Fr x 16 cm
MCZ-12703-002	Catheter: 3-L: 7 Fr x 16 cm
MCZ-12703-002A	Catheter: 3-L: 7 Fr x 16 cm
MCZ-12802-002	Catheter: 2-L: 8 Fr x 16 cm
MCZ-12802-002A	Catheter: 2-L: 8 Fr x 16 cm
MCZ-12853-008A	Catheter: 3-L: 8.5 Fr x 16 cm
MCZ-12853-008B	Catheter: 3-L: 8.5 Fr x 16 cm
MCZ-12854-002	Catheter: 4-L: 8.5 Fr x 16 cm
MCZ-12955-001	Catheter: 5-L: 9.5 Fr x 16 cm
MCZ-14403-002	Catheter: 3-L: 4 Fr x 13 cm
MCZ-14702-002	Catheter: 2-L: 7 Fr x 30 cm
MCZ-14702-002A	Catheter: 2-L: 7 Fr x 30 cm
MCZ-14703-002	Catheter: 3-L: 7 Fr x 30 cm
MCZ-14703-002A	Catheter: 3-L: 7 Fr x 30 cm
MCZ-14853-004A	Catheter: 3-L: 8.5 Fr x 30 cm

MCZ-14853-004B	Catheter: 3-L: 8.5 Fr x 30 cm
MCZ-14854-003	Catheter: 4-L: 8.5 Fr x 30 cm
MCZ-14955-001	Catheter: 5-L: 9.5 Fr x 30 cm
MCZ-15403-003	Catheter: 3-L: 4 Fr x 8 cm
MCZ-15703-004	Catheter: 3-L: 7 Fr x 20 cm
MCZ-15703-004A	Catheter: 3-L: 7 Fr x 20 cm
MCZ-15802-003	Catheter: 2-L: 8 Fr x 20 cm
MCZ-15802-003A	Catheter: 2-L: 8 Fr x 20 cm
MCZ-15853-008A	Catheter: 3-L: 8.5 Fr x 20 cm
MCZ-15853-008B	Catheter: 3-L: 8.5 Fr x 20 cm
MCZ-15854-002	Catheter: 4-L: 8.5 Fr x 20 cm
MCZ-15955-001	Catheter: 5-L: 9.5 Fr x 20 cm
MCZ-16702-003	Catheter: 2-L: 7 Fr x 20 cm
MCZ-16702-003A	Catheter: 2-L: 7 Fr x 20 cm
MCZ-17702-002	Catheter: 2-L: 7 Fr x 20 cm
MCZ-17702-002A	Catheter: 2-L: 7 Fr x 20 cm
MCZ-17752-002	Catheter: 2-L: 7 Fr x 60 cm
MCZ-17752-002A	Catheter: 2-L: 7 Fr x 60 cm
MCZ-18703-003	Catheter: 3-L: 7 Fr x 60 cm
MCZ-18703-003A	Catheter: 3-L: 7 Fr x 60 cm
MCZ-32123-002	Catheter: 3-L: 12 Fr x 16 cm
MCZ-35123-002	Catheter: 3-L: 12 Fr x 20 cm
MDZ-10802-002	Catheter: 2-L: 8 Fr x 11 cm
MDZ-10802-002A	Catheter: 2-L: 8 Fr x 11 cm
MLB-32123-001	Catheter: 3-L: 12 Fr x 16 cm
MLB-35123-001	Catheter: 3-L: 12 Fr x 20 cm
MLB-36123-001	Catheter: 3-L: 12 Fr x 25 cm
PZ-04706-003	Catheter: S-L: 14 Ga x 16 cm
SLZ-00703-001A	Catheter: 3-L: 7 Fr x 16.3 cm
SZ-04701-002	Catheter: S-L: 14 Ga x 20 cm
SZ-04730-004	Catheter: S-L: 14 Ga x 30 cm
SZ-04730-005	Catheter: S-L: 14 Ga x 30 cm
P-04706-001A	Catheter: S-L: 14 Ga x 16 cm
P-04706-001B	Catheter: S-L: 14 Ga x 16 cm
S-04218-001A	Catheter: S-L: 18 Ga x 8"
S-04522-001A	Catheter: S-L: 22 Ga x 10 cm
S-04522-001B	Catheter: S-L: 22 Ga x 10 cm
S-04700-001A	Catheter: S-L: 14 Ga x 20 cm
S-04700-001B	Catheter: S-L: 14 Ga x 20 cm
S-04701-001A	Catheter: S-L: 14 Ga x 20 cm
S-04701-001B	Catheter: S-L: 14 Ga x 20 cm
S-04730-001C	Catheter: S-L: 14 Ga x 30 cm
S-04730-001D	Catheter: S-L: 14 Ga x 30 cm
S-04730-003B	Catheter: S-L: 14 Ga x 30 cm
SLZ-00702-001A	Catheter: 2-L: 7 Fr x 16 cm
SL-09803-001	Catheter: 1-L: 7 Fr x 8” (20 cm)
SL-09803-001A	Catheter: 1-L: 7 Fr x 8” (20 cm)
SS-14701-001	Catheter: 1-L: 7 Fr x 6” (16 cm)
SS-14701-001A	Catheter: 1-L: 7 Fr x 6” (16 cm)

Arrow International, Inc./Arrow International LLC hereby declares that the above documented product(s) meets the provisions of the Medical Device Directive, EC COUNCIL DIRECTIVE 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC as amended through 2007/47/EC on 5 September, 2007). This declaration is made on the basis of the following Annex II certificates (EC Design Examination and Quality System), issued by The British Standards Institute, with Notified Body number 2797. This declaration authorizes Arrow International, Inc./Arrow International LLC to affix the CE marking to the products listed herein.

DIRECTIVES AND STANDARDS:

☒ Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC as amended through 2007/47/EC on 05 September, 2007).

☐ Items indicated with an * are within the scope of and in compliance with European Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

☐ Other:

CERTIFICATE NUMBERS:

Annex II.3 Certificate(s) **CE 699333 (CE 511137)**

Annex II.4 Certificate (Class III products only) **CE 699342 (CE 512282)**

Annex V Certificate (Class I Sterile/Measuring Function products only) **N/A**

Procedure Pack Products

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
AD-04301	CVC Set: 16 Ga. x 20 cm	25 Mar 1998
AD-04700	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	09 Jul 2002
AD-04701	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	17 Apr 2002
AD-04730	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	13 Dec 1999
AD-12802	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 16 cm	07 May 2002
AD-12802-GH	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 16 cm	18 Feb 2000
AD-14702-EK	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	05 Nov 1998
AD-14703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	10 May 2002
AD-14854	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	15 May 2002
AD-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	31 Aug 1999
AD-16702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	01 Sep 1999
AG-14703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	20 Mar 2003
AG-04701	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	20 Mar 2003
AG-12123-F	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 12 Fr x 16 cm	12 Aug 2002
AG-15703-UN	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	02 Jun 2008
AG-15854-UN	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	02 Jun 2008
AG-16702-UN	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	10 Jun 2008
AG-15955-E	5-Lumen CVC Set with Blue FlexTip(R) Catheter: 9.5 Fr x 20 cm	02 May 2014
AG-15955-UN	5-Lumen CVC Set with Blue FlexTip(R) Catheter: 9.5 Fr x 20 cm	02 May 2014
AH-04301	CVC Kit with Blue FlexTip(R) Catheter: 16 x 20 cm	25 Jul 2007
AH-04706	CVC kit with Blue FlexTip(R) Catheter: 14 Ga. x 16 cm	12 Feb 2002
AH-11802	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 11 cm	12 Feb 2002
AH-12703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	16 Feb 2005
AH-12703-U	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	13 Aug 2009
AH-12712-U	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	02 Feb 2009
AH-12854	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	29 May 2009

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
AH-15703	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7Fr x 20 cm	18 Jul 2007
AK-04050-S	Internal Jugular Puncture Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	17 Jan 2011
AK-04150-E-S	Pediatric Jugular Puncture Kit: 20 Ga. x 12 cm	17 Jan 2011
AK-04650-E-S	CVC Kit 24 Ga. x 9 cm	17 Jan 2011
AK-04660-S	CVC Kit 24 Ga. x 12 cm	17 Jan 2011
AK-04825	Jugular Catheterization Kit16 Ga. x 16 cm	22 Jul 1999
AK-12703-EB	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	04 May 2006
AK-15703-J	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	21 Mar 2002
AK-15854-LA	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	16 Aug 2007
AK-17702-J	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	06 Dec 1999
AT-14854-TIL	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	16 Jan 2017
AU-14502	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	17 Dec 2002
BB-04706-C	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 16 cm	14 Mar 2007
BB-12853	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	17 Apr 2002
BCV-04706-KB	CVC Kit with Blue Flextip(R) Catheter: 14 Ga. x 16 cm	17 Apr 2008
BCV-12703-KB	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	20 Jan 2009
BCV-12712-KB	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	26 Jan 1998
BE-04301-CHR1	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	31 May 2018
BE-04301-ENG	CVC Kit with Blue Flextip(R) Catheter: 16 Ga. x 20 cm	04 Apr 2017
BE-04301-ETTEL	CVC Kit with Blue Flextip(R) Catheter: 16 Ga. x 20 cm	11 Feb 2010
BE-04306-AAL	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	12 Sep 2017
BE-04306-VEU1	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	02 Jul 2018
BE-04706-ARL	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 16 cm	26 Jan 2017
BE-15703-CHR1	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	31 May 2018
BE-15703-HcmC	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Dec 2016
BE-15703-VEU1	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	02 Jul 2018
BE-S15703-ISP	Multi-Lumen CVC/PSI Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	3 Aug 2018
BE-15853-Hcm1	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	02 Jul 2018
BE-16702-ETTEL	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	11 Feb 2010
BE-17702-CHR1	Two-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	31 May 2018
BE-17702-HcmC	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	15 Dec 2016
BE-17702-Hcm1	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	02 Nov 2018
BR-10854	4-Lumen CVC Set with Blue FlexTip Catheter: 8.5 Fr x 11 cm	16 Feb 2005
BR-12703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	20 Oct 1998
BR-12703-UK	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	04 Feb 2004
BR-12854	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	13 Mar 2000
BR-14703-EK	Multi-Lumen CVC Set: 7 Fr x 30 cm	09 Nov 1998
BR-14853-EK	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	16 Dec 2003
BR-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	20 Oct 1998
BR-15703-UK	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	4 Feb 2004
BR-15853-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	23 Sep 1998
BR-10703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 11 cm	20 Oct 1998
BR-12853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	21 Sep 1998
BR-15853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	15 Nov 1999
BR-15854	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter:8.5 Fr x 20 cm	02 May 2002
BR-99703	Percutaneous Sheath Introducer Multi-Lumen CVC Kit 7 Fr x 30 cm	09 Mar 2001
BUSTO-15703	CVC Kit: 3-Lumen 7Fr x 20 cm	30 Apr 2015
BUSTO-15802	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 8 Fr x 20 cm	27 Aug 2008
BUSTO-15854	CVC Kit: 4-Lumen 8.5 Fr x 20 cm	30 Apr 2015
BUSTO-15955	CVC Kit: 5-Lumen 9.5 Fr x 20 cm	30 Apr 2015
CB-04730-EK	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	01 Jun 2007

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
CD-10802	2-Lumen CVC Set with Blue FlexTip® Catheter: 8 Fr x 11 cm	23 Sep 1998
CE-04701	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	06 Jun 2008
CE-12703	Arrow-Howes(TM) Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Jan 1998
CE-15703	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	07 Jul 2008
CE-15802	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	29 Jul 2008
CH-04306-KSBL	S-Lumen CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	24 Aug 2018
CH-04306-KSBL1	S-Lumen CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	30 Oct 2019
CH-12703-KSBL	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	24 Aug 2018
CH-12703-KSBL1	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	30 Oct 2019
CH-12712-KSBL	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	24 Aug 2018
CH-12712-KSBL1	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	30 Oct 2019
CH-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	18 Oct 2001
CH-16702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	30 Oct 2002
CK-03000-B	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Aug 1998
CK-12703-UK	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	29 Mar 2004
CK-15703-E	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	11 Dec 2002
CK-15854-E	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	17 Jan 2003
CK-12955-E	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 9.5 Fr x 16 cm	18 Feb 2014
CO-04730-EK	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	15 Jan 1998
CO-14702-EK	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	13 Dec 1999
CO-14703-EK	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	13 Dec 1999
COE-04730-EK	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	04 Apr 2002
COE-14702-EK	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	05 Jun 2007
COE-14703-EK	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	27 Jun 2007
CS-04300	CVC Set 16 Ga. x 20 cm	13 Mar 1998
CS-04301-SE	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	23 Sep 2009
CS-04301-V	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	10 Oct 2005
CS-04306-SE	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	23 Sep 2009
CS-04306-V	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	10 Oct 2005
CS-04400	CVC Set 16 Ga. x 30 cm	02 Dec 1999
CS-04700	CVC Set 14 Ga. x 20 cm	10 Mar 1998
CS-04701	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	15 Jan 1998
CS-10853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 11 cm	23 Sep 1998
CS-12123-F	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions 12 Fr x 16 cm	26 Jan 1998
CS-12402	Pediatric 2-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 5 cm	26 Jan 1998
CS-12553-J	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 5 cm	20 Feb 1998
CS-12702-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Jan 1998
CS-12703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Jan 1998
CS-12703-E	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Jan 1998
CS-12703-K	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	29 Jul 2004
CS-12712-ES	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	10 Oct 2005
CS-12802	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 16 cm	26 Jan 1998
CS-12802-BZ	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 16 cm	11 Apr 2017
CS-12802-IT	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 16 cm	26 Apr 2006
CS-12853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	23 Sep 1998
CS-12853-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	14 Apr 1999
CS-12854-E	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	02 Feb 2006
CS-14402	Pediatric 2-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 13 cm	26 Jan 1998
CS-14403	Pediatric Multi-Lumen CVC Set 4 Fr x 13 cm	23 Mar 2000

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
CS-14502	Pediatric 2-Lumen CVC Set with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	26 Jan 1998
CS-14553	Pediatric Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for Femoral Vein Insertion 5.5 Fr x 30 cm	16 Feb 2005
CS-14703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	26 Jan 1998
CS-14703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	26 Jan 1998
CS-14854-E	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	26 Jan 1998
CS-15123-F	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions 12 Fr x 20 cm	26 Jan 1998
CS-15402-E	Pediatric 2-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 8 cm	26 Jan 1998
CS-15403	Pediatric Multi-Lumen CVC Set 4 Fr x 8 cm	12 Feb 2001
CS-15553-E	Pediatric Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	26 Jan 1998
CS-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-15703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-15703-HP	PI Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	18 Jul 2018
CS-15802	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	29 Jul 2008
CS-15802-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	26 Jan 1998
CS-15853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	29 Jul 2009
CS-15853-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	18 Dec 2009
CS-15854-E	Arrow-Howes(TM) 4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	26 Jan 1998
CS-15955	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 9.5 Fr 5-Lumen x 20 cm	11 Sep 2013
CS-15955-SE	5-Lumen CVC Set with Blue FlexTip(R) Catheter: 9.5 Fr x 20 cm	10 Oct 2014
CS-16123-F	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions 12 Fr x 25 cm	26 Jan 1998
CS-16402	Pediatric 2-Lumen CVC Set with Blue FlexTip(R) Catheter for Femoral Vein Insertion: 4 Fr x 30 cm	26 Jan 1998
CS-16553-E	Pediatric Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 13 cm	20 Feb 1998
CS-16553-J	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr 13 cm	26 Jan 1998
CS-16702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-16702-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-17702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-17702-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Jan 1998
CS-17752	2-Lumen Antecubital CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 60 cm	20 Feb 1998
CS-18763-E	Multi-Lumen Antecubital CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 60 cm	20 Feb 1998
CV-04301	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	13 Mar 1998
CV-04306	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	13 Mar 1998
CV-04701	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	13 Mar 1998
CV-04701-BZ	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	11 Apr 2017
CV-04706	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 16 cm	21 Jan 1999
CV-10854	4 Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 11 cm	06 May 2009
CV-12123-F	Arrow-Howes(TM) Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions 12 Fr x 16 cm	12 Mar 2002
CV-12702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	15 Jan 1999
CV-12702-BZ	Two-Lumen Central Venous Catheterization Set with Blue FlexTip(R) Catheter	11 Apr 2017
CV-12703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	15 Jan 1999
CV-12703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 Sep 2001

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
CV-15703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	08 Mar 1999
CV-15802	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	09 Nov 1999
CV-15854	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	13 Mar 2000
CV-12712	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	15 Jan 1999
CV-12712-Fr1	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	05 Feb 2008
CV-12853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	11 Apr 2000
CV-12854	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	21 Jul 2009
CV-12955	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5-L 9.5 Fr x 16 cm	11 Sep 2013
CV-14702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	11 Nov 1999
CV-14702-BZ	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	11 Apr 2017
CV-14703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	15 Jan 1999
CV-14703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	17 Jul 1998
CV-14703-BZ	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	11 Apr 2017
CV-15123-F	Arrow-Howes(TM) Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions 12 Fr x 20 cm	12 Mar 2002
CV-15553	Pediatric Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	13 Jul 1999
CV-15553-BZ	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 5.5 Fr x 8 cm	11 Apr 2017
CV-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Aug 1998
CV-15703-BZ	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	11 Apr 2017
CV-15703-E	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	08 Mar 1999
CV-15703-SA2	3-Lumen CVC Set with Blue FlexTip® Catheter: 7 Fr x 20 cm	22 Jun 2015
CV-15802	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	09 Nov 1999
CV-15802-BZ	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	11 Apr 2017
CV-15854	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	13 Mar 2000
CV-15854-BZ	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	11 Apr 2017
CV-15955	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5-L 9.5 Fr x 20 cm	11 Sep 2013
CV-17702-BZ	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	11 Apr 2017
CV-16702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Jan 1999
CV-16702-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	23 Jul 1998
CV-16702-SA2	2-Lumen CVC Set with Blue FlexTip (R) Catheter: 7 Fr x 20 cm	22 Jun 2015
CV-17702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Jan 1999
CV-17702-E	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Jan 1999
CV-50014	CVC Set 14 Ga. x 20 cm	10 Mar 1998
CV-50014-BF	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	10 Mar 1998
CV-50014-BZ	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	11 Apr 2017
CV-50016	CVC Set 16 Ga. x 20 cm	10 Mar 1998
CV-50016-BF	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	10 Mar 1998
CV-50016-BZ	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	11 Apr 2017
CZ-10853-KCH	CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 11 cm	02 Jul 2009
DA-04701	CVC Kit 14 Ga. x 20 cm	08 Nov 2004
DA-15703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	03 Feb 2006
DA-15854	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	15 Nov 2004
DE-04301-UKSH	CVC with Blue FlexTip(R) Catheter: Set 16 Ga. x 20 cm	14 Jun 2012
DE-04306-DSHA	1-Lumen CVC Set with Blue FlexTip® Catheter: 16 Ga x 16 cm	10 Jul 2017
DE-04306-S	1-Lumen CVC Set with Blue FlexTip® Catheter: 16 Ga x 16 cm	06 Oct 2015
DE-04400-S	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 16 Ga x 30 cm	18 Feb 2014
DE-04701-CP	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	04 Oct 2013
DE-04701-CPN	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	04 Oct 2013
DE-04701-CPNS	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	05 Nov 2013
DE-04701-CPS	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	05 Nov 2013

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DE-04701-DN	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	31 Aug 2017
DE-04701-EKBI	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	23 May 2013
DE-04701-EKMH	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	10 Sep 2012
DE-04701-LKSCH	CVC Kit with Blue FlexTip(R) Catheter: Kit: 14 Ga x 20 cm	03 Oct 2011
DE-04701-MKHS1	CVC Kit with Blue FlexTip(R) Catheter: Kit: 14 Ga x 20 cm	25 Sep 2017
DE-04701-RKM	CVC Kit with Blue FlexTip(R) Catheter: Kit: 14 Ga x 20 cm	13 Nov 2019
DE-04701-RKRO	CVC Kit with Blue FlexTip(R) Catheter: Kit: 14 Ga x 20 cm	02 Jul 2018
DE-04701-S	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	18 Feb 2014
DE-04701-SAN	CVC Kit with Blue FlexTip(R) Catheter: Kit: 14 Ga x 20 cm	10 Apr 2019
DE-04701S-AGK	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 20 cm	03 Jun 2015
DE-04701-UKSH	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	14 Jun 2012
DE-04706-SAN	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 16 cm	10 Apr 2019
DE-04706-TMA	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 16 cm	10 Sep 2012
DE-04706-UKM	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga x 16 cm	14-Jan-2019
DE-04730-COE	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	21 Apr 2014
DE-04730-KN1	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	09 Mar 2017
DE-04730-RHE	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	06 Dec 2012
DE-04730-MV	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	11 May 2015
DE-04730-MVL	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	03 Jun 2015
DE-04730-MVS	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	11 May 2015
DE-04730-SBH	1-Lumen CVC Kit with Blue FlexTip(R) AGB Catheter: 14 Ga x 30 cm	18 Jan 2018
DE-04730-TS	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	03 Mar 2020
DE-04730S-AGK	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga x 30 cm	03 Jun 2015
DE-12123F-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 12 Fr x 16 cm	05 Nov 2013
DE-12123-MA	Multi-Lumen CVC Kit with Blue FlexTip(R)Catheter: 12 Fr x 16 cm	13 Jun 2014
DE-12123-NSK	Multi-Lumen CVC Kit with Blue FlexTip(R)Catheter: 12 Fr x 16 cm	24 Aug 2018
DE-12123-TS	Multi-Lumen CVC Kit with Blue FlexTip(R)Catheter: 12 Fr x 16 cm	07-Aug-2020
DE-12702-S	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	11 Dec 2013
DE-12702-SAN	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	10 Apr 2019
DE-12703-DSHA	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	10 Jul 2017
DE-12703-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	11 Dec 2013
DE-12802-TMA	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 16 cm	13 Mar2017
DE-12853-RKRO	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	27 Jul 2018
DE-12853-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	11 Dec 2013
DE-12853-SAN	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	10 Apr 2019
DE-12853-UKM	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	14-Jan-2019
DE-12854-DSHA	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	10 Jul 2017
DE-12854-S	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	11 Dec 2013
DE-12854-SAN	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	29 Apr 2019
DE-12854-UKSH	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	14 Jun 2012
DE-12955-S	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 16 cm	11 Dec 2013
DE-12955-SAN	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 16 cm	29 Apr 2019
DE-14403-UB	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 4 Fr x 13 cm	20 Apr 2021
DE-14502-UKSH	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 5 Fr x 13 cm	26 Jun 2012
DE-14702-COE	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	21 Apr 2014
DE-14702-KBAL	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	11 Feb 2015
DE-14702-S	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	05 Jan 2016
DE-14702-SVD	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	31 Jan 2012
DE-14702-UW1	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	09 Feb 2017
DE-14703-CB	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	03 Dec 2015
DE-14703-COE	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	21 Apr 2014

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
DE-14703-KN1	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	10 Apr 2019
DE-14703-KR	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	19 Oct 2017
DE-14703-MO	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	13 Mar 2017
DE-14703-RHE	Multi-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	06 Dec 2012
DE-14703-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 30 cm	11 Dec 2013
DE-14703-SVD	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	31 Jan 2012
DE-14703-UMZ	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	28 Oct 2020
DE-14703-UW1	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	09 Feb 2017
DE-14853-KN	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	07 Mar 2011
DE-14853-KN1	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	09 Mar 2017
DE-14854-CB	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	03 Dec 2015
DE-14854-RHE	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	10 May 2019
DE-14854-S	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	21 Jun 2013
DE-14854-UW1	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 30 cm	09 Feb 2017
DE-14955-BBV	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	19 Aug 2014
DE-14955-CB	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	26 Sep 2014
DE-14955-CV	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	08 Jul 2014
DE-14955-MVL	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	03 Jun 2015
DE-14955-MVS	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	11 May 2015
DE-14955-MKK	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	27 Jul 2018
DE-14955-UMZ	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	28 Oct 2020
DE-14955S-AGK	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 30 cm	03 Jun 2015
DE-15123-DN	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 12 Fr x 20 cm	31 Aug 2017
DE-15123-UKSH	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 12 Fr x 20 cm	14 Jun 2012
DE-15402-S	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 4 Fr x 8 cm	11 Dec 2013
DE-15402-UKSH	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 4 Fr x 8 cm	26 Jun 2012
DE-15403-UKSH	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 4 Fr x 8 cm	26 Jun 2012
DE-15703-CB	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Apr 2012
DE-15703-CP	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	04 Oct 2013
DE-15703-CPN	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	04 Oct 2013
DE-15703-CPNS	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	05 Nov 2013
DE-15703-CPS	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	05 Nov 2013
DE-15703-DK	CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	18 Jul 2011
DE-15703-DN	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	31 Aug 2017
DE-15703-EKMH	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	31 Aug 2012
DE-15703-HEM	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	24 Jul 2009
DE-15703-HZO	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Mar 2011
DE-15703-KBAY	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	15 Feb 2018
DE-15703-KKSI	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	28 Apr 2016
DE-15703-LKSCH	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	03 Oct 2011
DE-15703-MA	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	13 Jun 2014
DE-15703-RB	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	15 Jun 2017
DE-15703-RKM	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	13 Nov 2019
DE-15703-RO	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	19 Oct 2018
DE-15703-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	21 Jun 2013
DE-15703S-AGK	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	03 Jun 2015
DE-15703-UFB	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	05 Jan 2016
DE-15703-UKSH	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	14 Jun 2012
DE-15802-GKB1	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	29 Jan 2018
DE-15802-S	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 8 Fr x 20 cm	11 Dec 2013
DE-15802-UFBU	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	26 Sep 2014

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
DE-15802-KN1	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	09 Mar 2017
DE-15802-KWEN	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	06 Mar 2015
DE-15802-RKM	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	13 Nov 2019
DE-15802-TS	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	03 Mar 2020
DE-15853-BRE	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	06 Sep 2018
DE-15853-KWEN	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	06 Mar 2015
DE-15853-MKHS1	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	25 Sep 2017
DE-15853-S	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	21 Jun 2013
DE-15853-SAN	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	29 Apr 2019
DE-15853-SHA2	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	28 Feb 2019
DE-15853-UKB	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	28 Feb 2019
DE-15853-UKM	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	14 Jan 2019
DE-15853-UKSH	3-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	14 Jun 2012
DE-15854-CB	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	26 Apr 2012
DE-15854-CPS	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	25 Nov 2014
DE-15854-EKMH	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	21 Nov 2016
DE-15854-MA	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	13 June 2014
DE-15854-KKR1	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	30 Nov 2017
DE-15854-KWEN	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	06 Mar 2015
DE-15854-LG	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	19 Aug 2014
DE-15854-APOL	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	16 May 2014
DE-15854-S	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	21 Jun 2013
DE-15854-CPNS	4-Lumen CVC Set with Blue FlexTip(R)Catheter: 8.5 Fr x 20 cm	30 Sep 2016
DE-15854-HZO	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	15 Mar 2011
DE-15854-RKRO	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	27 Jul 2018
DE-15854-RO	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	19 Oct 2018
DE-15854-SAN	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	29 Apr 2019
DE-15854-UG	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	05 Nov 2019
DE-15854-UKM	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	14 Jan 2019
DE-15854-UKSH	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	14 Jun 2012
DE-15703-BSAD	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	30 Sep 2016
DE-15955-CB	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	03 Dec 2015
DE-15955-CPS	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	20 Jan 2015
DE-15955-DN	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	31 Aug 2017
DE-15955-EKMH	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	18 Jan 2019
DE-15955-MA	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	18 Feb 2014
DE-15955-RB1	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	15 Jun 2017
DE-15955-RKRO	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	27 Jul 2018
DE-15955-S	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	11 Dec 2013
DE-15955-SAN	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	29 Apr 2019
DE-15955-TS	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	03 Mar 2020
DE-15955-UG	5-Lumen CVC Kit with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	02 May 2014
DE-15955-UKSH	5-Lumen CVC Set with Blue FlexTip(R)Catheter: 9.5 Fr x 20 cm	18 Feb 2014
DE-16123F-S	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 12 Fr x 25 cm	27 Jan 2014
DE-16553-UB	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 5.5 Fr x 13 cm	20 Apr 2021
DE-16553-UKSH	3-Lumen CVC Set with Blue FlexTip(R)Catheter: 5.5 Fr x 13 cm	26 Jun 2012
DE-17702-CB	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	03 Dec 2015
DE-17702-CP	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	08 Jul 2014
DE-17702-CPS	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	20 Jan 2015
DE-17702-HEM	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	10 Aug 2009
DE-17702-KKR1	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	30 Nov 2017

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
DE-17702-S	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	21 Jun 2013
DE-17702-SAN	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	10 April 2019
DE-17702-UFBU	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	26 Sep 2014
DE-S12853-LU	3-Lumen CVC/PSI Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	12 Oct 2017
DE-S17702-UFBU	2-Lumen CVC/PSI Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	11 Feb 2015
DE-18763-MV	3-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 60 cm	11 May 2015
DM-09903-x	3-Lumen CVC/ PSI Kit with Blue FlexTip(R) Catheter: 7 Ga. x 9 cm	16 Jun 2002
DM-09903-EB	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	29 Mar 2009
ES-04150	Pediatric Jugular Catheterization Set: 20 Ga. x 12 cm	10 Mar 1998
ES-04218	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 18 Ga. x 20 cm	10 Mar 1998
ES-04218-BZ	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 18 Ga. x 20 cm	11 Apr 2017
ES-04300	CVC Set: 16 Ga. x 20 cm	15 Jan 1998
ES-04301	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	15 Jan 1998
ES-04301-BK	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	10 Nov 2000
ES-04301-P	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	12 Jul 2002
ES-04306	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	15 Jan 1998
ES-04306-N	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	17 Mar 2003
ES-04400	CVC Set: 16 Ga. x 30 cm	15 Jan 1998
ES-04401-EK	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 30 cm	11 Mar 1999
ES-04522	CVC Set: 22 Ga. x 10 cm	05 Jun 1998
ES-04522-BZ	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 22 Ga. x 10 cm	11 Apr 2017
ES-04650	CVC Set: 24 Ga. x 9 cm	06 Mar 2002
ES-04660	CVC Set: 24 Ga. x 12 cm	28 May 2002
ES-04700	CVC Set: 14 Ga. x 20 cm	15 Jan 1998
ES-04701	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	15 Jan 1998
ES-04701-P	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	28 Jun 2002
ES-04706	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 16 cm	15 Jan 1998
ES-04706-D	CVC Set with Blue FlexTip (R) Catheter: 14 Ga. x 16 cm	28 Feb 2002
ES-04706-P	CVC Set with Blue FlexTip (R) Catheter: 14 Ga. x 16 cm	10 Jul 2002
ES-04706-Fr1	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 16 cm	11 Feb 2008
ES-04730	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	23 Sep 1998
ES-04730-EK	CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	28 Feb 2000
ES-04730-R	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	08 Feb 2002
ES-14402	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 4 Fr x 13 cm	26 Jan 1998
ES-14702	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	20 Feb 1998
ES-14702-D	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	08 Apr 2002
ES-14854-D	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	08 Mar 2002
ES-15703-BK	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	16 Nov 2000
ES-16702-BK	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	16 Nov 2000
EU-04150-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 20 Ga. x 12 cm	29 Jan 2014
EU-04218-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 18 Ga. x 20 cm	29 Jan 2014
EU-04301-EN	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	06 Dec 2012
EU-04301-CVT	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	13 Oct 2010
EU-04301-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	16 Nov 2012
EU-04306-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	17 Jan 2013
EU-04522-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 22 Ga. x 10 cm	29 Jan 2014
EU-04701-CVT	1-Lumen CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	27 Aug 2010
EU-04701-CVTS	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 20 cm	20 Dec 2011
EU-04701-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 20 cm	06 Dec 2012
EU-04706-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 16 cm	25 Nov 2014
EU-04706-EN	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 16 cm	26 Jun 2015

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
EU-04730-CVT	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	25 Aug 2010
EU-04730-N	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	17 Jan 2013
EU-12402-N	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 4 Fr x 5 cm	06 Feb 2014
EU-12702-EN	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	17 Jan 2013
EU-12703-N	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	17 Jan 2013
EU-12703-EN	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 16 cm	21 Jun 2013
EU-12712-N	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 16 cm	17 Jan 2013
EU-12802-N	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 16 cm	21 Jun 2013
EU-12853-N	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	17 Jan 2013
EU-12854-N	4-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	06 Dec 2012
EU-12955-CVT	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 9.5 Fr x 16 cm	21 Mar 2014
EU-14402-N	2-Lumen CVC Set with Blue FlexTip® Catheter: 4 Fr x 13 cm	18 Feb 2014
EU-14403-N	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 4 Fr x 13 cm	18 Feb 2014
EU-14502-N	2-Lumen CVC Set with Blue FlexTip® Catheter: 5 Fr x 13 cm	06 Feb 2014
EU-14553-N	Multi-Lumen CVC Set with Blue FlexTip® Catheter for Femoral Vein Insertion: 5.5 Fr x 30 cm	18 Feb 2014
EU-14702-CVT	2-Lumen CVC Set with blue Flextip(R) Catheter: 7 Fr x 30 cm	12 Oct 2010
EU-14702-N	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 30 cm	17 Jan 2013
EU-14703-CVT	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 30 cm	21 Oct 2010
EU-14703-EN	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 30 cm	21 Jun 2013
EU-14703-N	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 30 cm	17 Jan 2013
EU-14854-CVT	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	21 Jun 2013
EU-14854-EN	4-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 30 cm	21 Jun 2013
EU-14955-CVT	5-Lumen CVC Set with Blue Flextip(R) Catheter: 9.5 Fr x 30 cm	21 Mar 2014
EU-15402-N	2-Lumen CVC Set with Blue FlexTip® Catheter: 4 Fr x 8 cm	06 Feb 2014
EU-15403-N	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 4 Fr x 8 cm	18 Feb 2014
EU-15553-N	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 5.5 Fr x 8 cm	06 Feb 2014
EU-15703-CVCPS	Pressure Injectable Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	10 Sep 2012
EU-15703-CVET	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 7 Fr x 20 cm	23 May 2012
EU-15703-CVT	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	13 Oct 2010
EU-15703-CVTS	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	20 Dec 2011
EU-15703-EN	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	19 Feb 2013
EU-15703-N	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	19 Feb 2013
EU-15802-CVET	2-Lumen CVC Set with Blue FlexTip® Catheter: 8 Fr x 20 cm	23 May 2012
EU-15802-CVT	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 20 cm	21 Oct 2010
EU-15802-CVTS	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 20 cm	20 Dec 2011
EU-15802-EN	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 20 cm	07 Nov 2012
EU-15802-N	2-Lumen Central Venous Catheterization Set with Blue Flextip(R) Catheter: 8 Fr x 20 cm	16 Nov 2012
EU-15853-CVET	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	23 May 2012
EU-15853-CVT	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	13 Nov 2019
EU-15853-N	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	07 Nov 2012
EU-15854-CVET	4-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	23 May 2012
EU-15854-CVT	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	27 Aug 2010
EU-15854-CVTS	4-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	20 Dec 2011
EU-15854-EN	4-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	21 Jun 2013
EU-15955-CVET	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	02 May 2014
EU-15955-CVT	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	29 May 2014
EU-15955-CVTS	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	02 May 2014
EU-15955-EN	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 9.5 Fr x 20 cm	25 Apr 2014

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
EU-15955-N	Multi-Lumen CVC Set with Blue Flextip(R) Catheter: 9.5 Fr x 20 cm	25 Apr 2014
EU-16402-N	2-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter for Femoral Vein Insertion: 4 Fr x 30 cm	18 Feb 2014
EU-16553-N	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 5.5 Fr x 30 cm	06 Feb 2014
EU-16702-CVET	2-Lumen CVC Set with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	23 May 2012
EU-16702-CVT	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	21 Oct 2010
EU-16702-EN	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	16 Nov 2012
EU-17702-CVT	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	21 Oct 2010
EU-17702-CVTS	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	20 Dec 2011
EU-17702-N	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	16 Nov 2012
FK-04730-B	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 20 cm	10 Aug 2005
FR-04301-IPSE	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	05 Nov 2019
FR-12802-IPSE	2-Lumen CVC Set with Blue FlexTip® Catheter: 8 Fr x 16 cm	05 Nov 2019
FR-12853-DPT	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	25 Mar 2019
FR-12853-IPS	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	23 May 2018
FR-12853-IPSE	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	10 April 2019
FR-12854-DPT	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	25 Mar 2019
FR-12955-DP	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 9.5 Fr x 16 cm	18 Feb 2014
FR-12955-DPT	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 9.5 Fr x 16 cm	25 Mar 2019
FR-14702-IPSE	2-Lumen CVC Set with Blue FlexTip® Catheter: 7 Fr x 30 cm	05 Nov 2019
FR-14703-IPSE	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 30 cm	05 Nov 2019
FR-15853-IPS	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	23 May 2018
FR-15853-IPSE	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	10 April 2019
FR-15853-DPT	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 8.5 Fr x 20 cm	25 Mar 2019
FR-15854-IPSE	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 8.5 Fr x 20 cm	05 Nov 2019
FR-15955-DP	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	02 May 2014
FR-15955-DPT	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	25 Mar 2019
FR-15955-TR	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 9.5 Fr x 20 cm	11 Dec 2013
FR-12853-DP	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	14 Dec 2005
FR-15802-DP	CVC Kit with Blue Flextip(R) Catheter: 8 Fr x 20 cm	21 Dec 2009
FR-15853-DP	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	03 Nov 2006
FR-16702-DP	CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	18 Dec 2009
FR-17702-IPSE	2-Lumen CVC Set with Blue FlexTip® Catheter: 7 Fr x 20 cm	05 Nov 2019
IB-12853-GUC	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	13 Feb 2009
IB-17752	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 60 cm	01 Oct 2008
HE-04730	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	24 Jun 2003
HE-14703	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 30 cm	17 Oct 2008
HF-04730-EK	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	09 Jun 2002
HF-15853-EK	CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	14 Apr 2000
HL-15703-SK	Multi-Lumen Central Venous Catheter Kit with Blue FlexTip(R) Catheter/PSI with Hemostasis Valve/Side Port for use with 7 - 8 Fr Catheters	28 Jun 2002
HN-04701	CVC Kit with Blue Flextip(R) Catheter: 14 Ga. x 20 cm	31 Jan 2006
HN-12702	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	03 Feb 2006
HN-12703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	03 Feb 2006
HN-12854	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	24 Jan 2002
HO-14702	HANDS-OFF(R) 2-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 30 cm	26 Aug 1998
HO-14703	HANDS-OFF(R) Multi-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 30 cm	26 Aug 1998

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
IB-15703-S	Multi-Lumen CVC Set with Blue FlexTip® Catheter: 7 Fr x 20 cm	25 Apr 2014
IB-15854-S	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	30 Oct 2017
IB-15955-S	5-Lumen CVC Set with Blue Flextip(R) Catheter: 9.5 Fr x 20 cm	30 Oct 2017
IB-16702-S	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	25 Apr 2014
IB-17702-S	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 20 cm	30 Oct 2017
IB-18763	Multi-Lumen Antecubital CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 60 cm	31 Jul 2007
ICU-12123-F	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 12 Fr x 16 cm	23 Jun 2009
ICU-15123-F	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 12 Fr x 20 cm	06 Dec 2006
ICU-15853	3-Lumen CVC Kit 8.5 Fr x 20 cm	02 Mar 2009
ICU-15854	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	14 Jul 2006
IE-12854-SJH	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	10 Oct 2019
IT-15703-GR	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	06 May 2010
IT-16123-FMSB	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 12 Fr x 25 cm	08 Nov 2013
IT-16702-GR	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	06 May 2010
KL-04301-B	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	05 Jun 2000
KL-04306-M	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 16 cm	09 Sep 2002
LG-15802-E	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	24 Jan 2002
LES-04301	CVC Kit with Blue FlexTip(R) Catheter: 16 Ga. x 20 cm	13 Nov 2007
LS-15853	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	10 Jan 2001
LS-17702	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	16 Oct 2003
MA-04301	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	26 Jul 2002
MA-14703	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 30 cm	31 Mar 2004
MA-15703	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 20 cm	26 Jul 2002
MC-12702	2-Lumen Central Venous Catheter: with Blue FlexTip(R) 7 Fr x 16 cm	03 Sep 1998
MC-12703	Arrow-Howes(TM) Multi-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 16 cm	06 Jun 1998
MC-14703	Arrow-Howes(TM) Multi-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 30 cm	20 Feb 1998
MC-15703	Arrow-Howes(TM) Multi-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 20 cm	20 Feb 1998
MC-16702	2-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 20 cm	20 Feb 1998
MC-17702	2-Lumen Central Venous Catheter with Blue FlexTip(R): 7 Fr x 20 cm	20 Feb 1998
MH-04701-C	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 20 cm	02 Mar 2007
MH-14703-C	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 30 cm	14 Mar 2007
ML-00701	Central Venous Catheter with Blue FlexTip(R) for use only with Arrow MAC(TM) 2-Lumen Central Venous Access Device: 7 Fr	09 Oct 2000
ML-00702	❖ 2-Lumen Central Venous Catheter with Blue FlexTip(R) for use only with Arrow MAC(TM) 2-Lumen Central Venous Access Device: 7 Fr x 21cm	09 Oct 2000
ML-00703	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) for use only with Arrow MAC(TM) 2-Lumen Central Venous Access Device: 7 Fr	09 Oct 2000
MO-12123-F	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions: 12 Fr x 16 cm	08 Mar 2001
NL-04301-MCA	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 16 Ga. x 20 cm	28 Aug 2015
NL-04306-OSS	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 16 Ga. x 16 cm	09 May 2013
NL-04701-ANNA	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	17 Apr 2002
NL-04701-EB	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	05 Aug 2005
NL-04706-AZIC	1-Lumen CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 16 cm	29 Apr 2019

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
NL-09306-CZE	Central Venous Catheterization/ Percutaneous Sheath Introducer Kit with Blue FlexTip® Catheter and Integral Hemostasis Valve/Side Port for used with 7 Fr Catheters	23 May 2017
NL-10853-AZN	3- Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 11 cm	21 Jan 2016
NL-12123F-AZN	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions: 12 Fr x 16 cm	12 Oct 2017
NL-12702-BRA	2-Lumen CVC Kit with Blue FlexTip(R)Catheter: 7 Fr x 16 cm	8 Jun 2018
NL-12702-Fr	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	07 Nov 2012
NL-12702-MST	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	03 Jul 2018
NL-12702-ZZV	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 16 cm	06 Mar 2015
NL-12703-ANNA	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	30 Nov 2017
NL-12703-AZIC	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	29 Apr 2019
NL-12703-BRA	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	8 Jun 2018
NL-12703-ETZ	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	04 Nov 2016
NL-12703-OSS	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	09 May 2013
NL-12703-LUMC	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	07 Aug 2017
NL-12703-MZR	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	11 Feb 2015
NL-12703-MZR1	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	16 Jan 2019
NL-12703-TL	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	11 Dec 2013
NL-12703-ZZV	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 16 cm	06 Mar 2015
NL-12853-MUMC	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 8.5 Fr x 16 cm	03 Dec 2015
NL-12853-CZE	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 8.5 Fr x 16 cm	23 May 2018
NL-12854-AZIC	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	29 Apr 2019
NL-12854-LUMC	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	07 Aug 2017
NL-12854-TL	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	06 Oct 2015
NL-15703-AMCH	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	23 May 2012
NL-15703-ELK	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	24 Feb 2015
NL-15703-LUMC	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	07 Aug 2017
NL-15703-MCA	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	28 Aug 2015
NL-15703-MMC	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	16 Sep 2010
NL-15703-TGH	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 7 Fr x 20 cm	16 May 2014
NL-15854-LUMC	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	07 Aug 2017
NL-15854-MCZ	4-Lumen CVC Kit with Blue Flextip(R) Catheter: 8.5 Fr x 20 cm	18 Feb 2014
NL-16123F-AZN	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions: 12 Fr x 25 cm	12 Oct 2017
NL-17702-LUMC	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	07 Aug 2017
NL-17702-MCZ	2-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 20 cm	18 Feb 2014
NL-S12712-UMCR	Multi-Lumen Central Venous Catheter Kit with Blue FlexTip(R) Catheter/PSI with Hemostasis Valve/Side Port for use with 7 - 8 Fr Catheters	26 Mar 2013
NM-12402	Pediatric 2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 4 Fr x 5 cm	26 Jan 2005
NM-12702	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	24 Jan 2005
NM-12703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	02 Jun 2005
NM-12802	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 16 cm	17 Oct 2008
NM-12853	3-Lumen CVC Kit 8.5 Fr x 16 cm	16 May 2008
NM-14502	Pediatric 2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	26 Jan 2005
NM-15402	Pediatric 2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 4 Fr x 8 cm	27 Jan 2005
NM-15553	Pediatric Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	26 Jan 1998
NM-15703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	20 Dec 2005
NM-16702	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	24 Jan 2005

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
NZL-12703-IM	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	11 Dec 2013
OW-04701-E	CVC Set with Blue FlexTip(R) Catheter: 14 Ga. x 20 cm	21 Jan 2003
OW-14703-E	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	12 Jul 2002
OW-14854-E	4-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8.5 Fr x 30 cm	16 Apr 2002
OW-15123-F	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 12 Fr x 20 cm	06 Sep 2002
OW-15802-E	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 8 Fr x 20 cm	26 Jul 2002
PL-12402-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 4 Fr x 5 cm	19 Nov 2019
PL-12702-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	3 Aug 2018
PL-15402-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 4 Fr x 8 cm	19 Nov 2019
PL-15553-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	19 Nov 2019
PL-16553-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 5.5 Fr x 13 cm	19 Nov 2019
PL-17702-MSB	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	3 Aug 2018
PO-14703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	10 Jan 2003
RB-15703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	12 Jul 2006
RO-15703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	17 Mar 2004
SA-12402	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 5 cm	28 Aug 2015
SA-12702	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 16 cm	15 Jul 2009
SA-12703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	09 Jul 2009
SA-12802	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 16 cm	15 Jul 2009
SA-12853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	23 Sep 1998
SA-12854	4-Lumen CVC Set with Blue Flextip(R) Catheter: 8.5 Fr x 16 cm	26 Jul 2002
SA-14402	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 13 cm	28 Aug 2015
SA-14403	3-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 13 cm	28 Aug 2015
SA-14703	3-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 30 cm	22 Jul 2009
SA-15402	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 8 cm	28 Aug 2015
SA-15403	3-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 8 cm	28 Aug 2015
SA-15553	3-Lumen CVC Set with Blue Flextip(R) Catheter: 5.5 Fr x 8 cm	28 Aug 2015
SA-15703	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	13 Feb 2009
SA-15802	2-Lumen CVC Set with Blue Flextip(R) Catheter: 8 Fr x 20 cm	22 Jul 2009
SA-15853	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 20 cm	09 Nov 1998
SA-15854	4-Lumen CVC Set with Blue Flextip(R)Catheter: 8.5 Fr x 20 cm	13 Feb 2009
SA-15955	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 9.5 Fr x 20 cm	18 Feb 2014
SA-16553	3-Lumen CVC Set with Blue Flextip(R) Catheter: 5.5 Fr x 13 cm	28 Aug 2015
SA-16702	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	13 Feb 2009
SA-17702	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	17 Jul 2009
SA-17752	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 60 cm	17 Jul 2009
SK-04301-BK	CVC Set 16 Ga. x 20 cm	05 Sep 2005
SL-04303	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 13 cm	10 Mar 1998
SE-15854-L	4-Lumen CVC Kit with Blue FlexTip(R) Catheter/PSI with Integral Hemostasis Valve/Side Port: 8.5 Fr x 20 cm	18 Sep 2002
SS-14702	2-Lumen Central Venous Catheter: with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	24 Sep 2001
SS-14703	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) for use only with Arrow PSI: 7 Fr x 16 cm	24 Sep 2001
SV-04301-EN	CVC Set with Blue FlexTip(R) Catheter 16 Ga. x 20 cm	08 Jan 2018
SV-04301-N	CVC Set with Blue FlexTip(R) Catheter 16 Ga. x 20 cm	22 Jan 2018
SV-04306-EN	CVC Set with Blue FlexTip(R) Catheter 16 Ga. x 16 cm	08 Jan 2018
SV-04306-N	CVC Set with Blue FlexTip(R) Catheter 16 Ga. x 16 cm	22 Jan 2018
SV-12703-N	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) 7 Fr x 16 cm	08 Jan 2018
SV-12712-N	2-Lumen Central Venous Catheter: with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	22 Jan 2018

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
SV-12955-N	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) 9.5 Fr x 16 cm	08 Jan 2018
SV-14703-N	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) 7Fr x 30 cm	22 Jan 2018
SV-14854-EN	4-Lumen Central Venous Catheter with Blue FlexTip(R) 8.5 Fr x 30 cm	22 Jan 2018
SV-14854-N	4-Lumen Central Venous Catheter with Blue FlexTip(R) 8.5 Fr x 30 cm	22 Jan 2018
SV-15703-N	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) 7 Fr x 20 cm	08 Jan 2018
SV-15854-N	4-Lumen Central Venous Catheter with Blue FlexTip(R) 8.5 Fr x 20 cm	08 Jan 2018
SV-15955-N	Multi-Lumen Central Venous Catheter with Blue FlexTip(R) 9.5 Fr x 20 cm	08 Jan 2018
SV-17702-N	2-Lumen Central Venous Catheter: with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	22 Jan 2018
SW-04401-EK	CVC Set with Blue FlexTip(R) Catheter: 16 Ga. x 30 cm	26 Sep 2000
SW-04730-EK	CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	26 Sep 2000
SW-14702-EK	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	26 Sep 2000
SW-14703-EK	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	25 Sep 2000
TI-04701-VING	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 20 cm	09 Sep 2014
TI-04706-VING	1-Lumen CVC Set with Blue FlexTip(R)Catheter: 14 Ga. x 16 cm	09 Sep 2014
TI-12702-GCC	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	16 Jul 2015
TI-14702-GCC	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	16 Jul 2015
TI-14502-GCC	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	16 Jul 2015
TI-14402-GCC	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 13 cm	16 Jul 2015
TI-17702-GCC	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	16 Jul 2015
TI-12703-GCC	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	30 Jul 2015
TI-14403-GCC	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 13 cm	30 Jul 2015
TI-14703-GCC	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	30 Jul 2015
TI-15703-GCC	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	30 Jul 2015
TI-16553-GCC	3-Lumen CVC Set with Blue FlexTip® Catheter: 5.5 Fr x 13 cm	30 Jul 2015
TI-12402-ME	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 5 cm	18 Aug 2016
TI-14402-ME	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 13 cm	04 Aug 2016
TI-14502-ME	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	18 Aug 2016
TI-14553-ME	Multi-Lumen CVC Set with Blue FlexTip® Catheter for Femoral Vein Insertion: 5.5 Fr x 30 cm	18 Aug 2016
TI-15402-ME	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 8 cm	04 Aug 2016
TI-15553-ME	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	04 Aug 2016
TI-16402-ME	2-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter for Femoral Vein Insertion: 4 Fr x 30 cm	18 Aug 2016
TI-16553-ME	3-Lumen CVC Set with Blue FlexTip® Catheter: 5.5 Fr x 13 cm	04 Aug 2016
TR-12402-S	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 5 cm	17 Feb 2017
TR-12703-S	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	26 May 2017
TR-12703-S1	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	05 Jun 2019
TR-12712-S	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 16 cm	01 Oct 2018
TR-12853-S	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	01 Oct 2018
TR-12853-S1	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 8.5 Fr x 16 cm	05 Jun 2019
TR-14402-S	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 13 cm	17 Feb 2017
TR-14403-S	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 4 Fr x 13 cm	25 May 2017
TR-14502-S	2-Lumen CVC Set with Blue FlexTip(R) Catheter: 5 Fr x 13 cm	17 Feb 2017
TR-15402-S	2-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 8 cm	17 Feb 2017
TR-15403-S	3-Lumen CVC Set with Blue Flextip(R) Catheter: 4 Fr x 8 cm	25 May 2017
TR-15553-S	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 5.5 Fr x 8 cm	25 May 2017
TR-15703-S	Multi-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	21 Oct 2009
TR-15703-S1	3-Lumen CVC Set with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	05 Jun 2019
TR-17702-S	2-Lumen CVC Set with Blue Flextip(R) Catheter: 7 Fr x 20 cm	01 Oct 2018
UB-04730	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	21 Apr 2000

Procedure Pack Product Numbers	Device Description	Date Procedure Pack Released
UD-12123	Large-Bore Multi-Lumen CVC Set with Blue FlexTip(R) Catheter for High Volume Infusions: 12 Fr x 16 cm	02 Jul 2004
UF-14702	2-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	17 Apr 2002
UF-14703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	17 Apr 2002
UG-15123-F	Large-Bore Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter for High Volume Infusions: 12 Fr x 20 cm	26 Jan 2001
UH-15853	Multi-Lumen CVC Kit with Blue FlexTip® Catheter: 8.5 Fr x 20 cm	12 Jan 2009
UK-12854-MRI	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	10 Mar 2021
UK-12854-MSB	4-Lumen CVC Kit with Blue FlexTip(R)Catheter: 8.5 Fr x 16 cm	25 Nov 2014
UK-14703-C	Multi-Lumen CVC Kit with Blue Flextip(R) Catheter: 7 Fr x 30 cm	19 Jan 2007
US-04730-EK	CVC Kit with Blue FlexTip(R) Catheter: 14 Ga. x 30 cm	17 Oct 2002
UW-04730-EK	1-Lumen CVC Kit with Blue FlexTip(R)Catheter: 14 Ga. x 30 cm	19 Jul 2007
UW-14702-EK	2-LumenCVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	18 May 2001
UW-14703-EK	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 30 cm	18 May 2001
VN-15703	Multi-Lumen CVC Kit with Blue FlexTip(R) Catheter: 7 Fr x 20 cm	03 Nov 2005

Arrow International, Inc./Arrow International LLC declares that the devices listed as Procedure Pack Products conform to Article 12 of the Medical Device Directive, EC COUNCIL DIRECTIVE 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC as amended through 2007/47/EC on 5 September, 2007) by verifying that:

- It has verified the mutual compatibility of these medical devices in accordance with the manufacturers' instructions and has carried out its assembly operations in accordance with these instructions.
- The relevant instructions for use for the individual devices are provided with the procedure pack.
- All its operations are subject to appropriate methods of internal control and inspection.

DIRECTIVES AND STANDARDS:

☒ Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June, 1993 concerning medical devices (MDD 93/42/EEC as amended through 2007/47/EC on 05 September, 2007).

☐ Other: _____

CERTIFICATE NUMBERS:

Annex II.3 Certificate(s) **CE 699333 (CE 511137)**

Annex II.4 Certificate (Class III products only) **CE 699342 (CE 512282)**

Annex V Certificate (Class I Sterile/Measuring Function products only) **N/A**

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REVISION HISTORY

Rev. Level	Date	Description
108	29 Aug 2017	See Revision 107 for complete revision history for revisions 0-107. Per ECR-031215 move the following codes to procedure pack section: BR-12703-UK, BR-15703-UK, BR-15853-E, CS-15955, CV-12955, CV-15955, ES-14702-D, ES-14854-D, OW-14703-E, OW-15802-E, SS-14702, UF-14703, CS-12123-F, CS-12402, CS-12553-J, CS-14502, CS-14553, CS-14703, CS-15123-F, CS-15553-E, CS-15854-E, CS-15854-E, CS-15854-E, CS-15854-E, CS-15854-E, CS-15854-E, CS-16123-F, CS-16553-E, CS-16553-E, CS-16553-E, CS-16553-J, CS-16702-E, CS-17702, CS-17702-E, CV-04306, CV-12123-F, CV-12123-F, CV-15123-F, CV-17702-E, ES-04306, AK-04050-S, AK-04150-E-S, AK-04650-E-S, AK-04660-S, AK-04825, CE-12703, CK-03000-B, CS-04400, CS-04700, CS-04701, ES-04150, CS-04300, CS-12702-E, CS-12703, CS-12802, CS-12802, CS-15703, CS-15703-E, CS-15802-E, CS-16702, CS-17752, CV-15553, CV-16702, CV-17702, CV-50014, CV-50014-BF, CV-50016, CV-50016-BF, ES-04300, ES-04400, ES-04700, ES-04706, AK-17702-J, CS-14703-E, CV-04301, CV-04701, CV-04706, CV-12702, CV-12703, CV-14703, CV-15703, ES-04301, ES-04701, ES-04730, ES-14702, ES-04522, BR-15853-E, SS-14702, MO-12123-F, OW-04701-E, OW-14854-E, OW-15123-F, PO-14703, SK-04301-BK, SK-04701-BK, SK-15802-BK, SK-16072-BK, SW-14702-EK, UG-14703-C, UW-14702-EK, UW-14703-EK, LES-04301, KL-04306-M, HE-14703, ES-16702-BK, ES-15703-BK, ES-04706-Fr1, ES-04301-BK, CV-16702-FB, CV-12712-Fr1, CV-10854, BCV-12712-KB, BCV-12703-KB, BCV-04706-KB, AK-15854-LA, AH-15703, AH-12854, AH-12712-U, AH-12703-U, AK-15703-J, CV-12712, and CS-18763-E.
109	12-Sep-2017	Per ECR-031215 move the following codes to procedure pack section: AK-12703-TL, ES-04306-N, KL-04301-B, SL-04303, CZ-10853-KCH, DA-04701, DA-15703, DA-15854, DE-04301-UKSH, DE-04701-UKSH, DE-12854-UKSH, DE-15403-UKSH, DE-15703-HZO, DE-15703-UKSH, DE-15853-UKSH, and DE-15854-HZO.
110	27-Sep-2017	Add new procedure pack kits DE-04701-DN, DE-15123-DN, DE-15703-DN and DE-15955-DN as per ECR-031029 Add new procedure pack kits BE-15703-VEU and BE-04306-VEU as per ECR-031900. Move CH-15703, CH-16702, IB-17752 and IB-12853-GUC to Procedure Pack section as per ECR-031253. Add new procedure pack kit BE-04306-AAL as per ECR-031961. Move BUSTO-15802 to Procedure Pack section as per ECR-031215.
111	16-Nov-2017	Moved AH-04301, AH-04706, AH-11802, and AH-12703 to the procedure pack section per ECO-046033.
112	28-Nov-2017	Add new procedure pack kits DE-04701-MKHS1, DE-15853-MKHS1, DE-S12853-LU, NL-12123F-AZN, NL-16123F-AZN, DE-14703-KR, IB-17702-S, IB-15955-S and IB-15854-S as per ECR-032065, ECR-032171, ECR-032049, ECR-032190 and ECR-032256.
113	6-Dec-2017	Add new procedure pack kits DE-15854-KKR1, DE-17702-KKR1, NL-12703-ANNA as per ECR-032406 and ECR-032419. Updated QA Management from Kathleen Whanger to Matt Winton.
114	14-Dec-2017	Periodic review to have DOCs align with Agile data: Removed the following FGs due to them being made inactive/obsolete: AH-04706-L, AH-12702, AK-04150-E, CS-14703-S, CS-15123-E, DE-04522-UKSH, ES-04706-ANG, EU-12702-IMIN, EU-12703-IMIN, EU-12802-IMIN, EU-12853-IMIN, EU-15703-IMIN, EU-15855-CVET, EU-16702-IMIN, KL-12802-AZM, MC-12123, NL-15703-SFG, EU-12402-IMIN, EU-14502-IMIN, EU-15402-IMIN, and EU-15553-IMIN

Rev. Level	Date	Description
		Moved the following codes to the procedure pack section: AD-04301, AD-04701, AD-12802-GH, AD-14702-EK, AD-14703, AD-15703, AD-16702, AG-14703, BES-04301-ENG, BR-10854, BR-12703, BR-12854, BR-14703-EK, CD-10802, CS-12854-E, CS-15802, CV-12703-E, CV-15703-E, CV-15802, CV-15854, DE-15703-LKSCH, DM-09903-EB, ES-04301-P, ES-04401-EK, ES-04701-P, ES-04706-D, ES-04706-P, ES-04730-EK, LG-15802-E, LS-17702, NL-15703-AMCH, NL-15703-ELK, NL-15703-SFG, and AU-14502
115	21-Dec-2017	Add new procedure pack kits SV-04301-EN, SV-04306-EN, SV-12703-N, SV-12955-N, SV-15703-N, SV-15854-N and SV-15955-N as per ECR-032680.
116	26-Jan-2018	Add new procedure pack kits DE-04730-SBH as per ECR-032663. Add new procedure pack kits SV-04301-N, SV-04306-N, SV-12712-N, SV-14703-N, SV-14854-EN, SV-14854-N, and SV-17702-N as per ECR-032734. Corrected Date CE Mark Affixed for procedure pack kits SV-04301-EN, SV-04306-EN, SV-12703-N, SV-12955-N, SV-15703-N, SV-15854-N and SV-15955-N as per ECO-048185 release date. Corrected the certificates listed in Annex II.4 Certificate section to state CE 512282.
117	29-Jan-2018	Add new procedure pack kits DE-15802-GKB1 as per ECR-032819.
118	22-Feb-2018	Added MC-16702-010A (new catheter without injection sites) per ECO-047356.
119	28-Feb-2018	Added DE-15703-KBAY (CVC KIT: 3-LUMEN 7Fr x 20cm) per ECO-048610. Converted the 2-digit years to 4-digits. Added the following catheters per ECO-048065 for the injection site removal project: MC-12402-001H, MC-15402-002I, and MC-15553-002G.
120	09-Mar-2018	Added catheter LC-15703-001B per ECO-048006 for the injection site removal project.
121	23-Mar-2018	Added catheter MC-12702-006 per ECO-047703 for the injection site removal project.
122	11-Apr-2018	Added catheter MC-16553-002G per ECO-048066 for the injection site removal project.
123	26-Apr-2018	Added catheters MC-14402-003D and MC-14553-002G per ECO-048521 for the injection site removal project.
124	30-May-2018	Added new procedure packs NL-09306-CZE, NL-12853-CZE as per ECR-033333/ECO-049360. Added new procedure packs FR-15853-IPS and FR-12853-IPS as per ECR-033352/ECO-049397. Added catheters MC-14703-017D and MC-17702-011A per ECO-048933 for the injection site removal project Moved HO-14702 and HO-14703 to the procedure pack section of the DOC per ECO-048367
125	14-June-18	Added new procedure packs BE-04301-CHR1, BE-15703-CHR1, BE-17702-CHR1 as per ECR-033606/ECO-049961. Added new procedure packs NL-12702-BRA and NL-12703-BRA as per ECR-033439/ECO-049569
126	02-Jul-2018	Added new procedure pack DE-04701-RKRO as per ECR-033862/ECO-050446 for a new EASK Kit. Added new procedure pack NL-12702-MST as per ECR-033850/ECO-050424 for new EASK kit Added new procedure pack BE-15853-Hcm1 as per ECR-033748/ECO-050222 for new EASK kit Added new procedure packs BE-04306-VEU1 and BE-15703-VEU1 as per ECR-033871/ECO-050460 for new EASK kits Typo correction of code BE-15703-CHR1 in Revision history Rev.125

Rev. Level	Date	Description
127	03-Jul-2018	Typo correction of code NL-12702-NST in Revision history Rev. 126 (added new procedure pack NL-12702-MST as per ECR-033850/ECO-050424 for new EASK kit)
128	18-Jul-2018	Added new procedure pack CS-15703-HP as per ECR-033798/ECO-050312 for new EASK Kit that will be sold in Australia
129	27-Jul-2018	Added new procedure pack DE-14955-MKK as per ECR-033907/ECO-050511 for new EASK kit. Added new procedure packs DE-12853-RKRO, DE-15854-RKRO and DE-15955-RKRO as per ECR-033820/ECO-050358 for new EASK Kits. Revised to new template revision 08 (which changed the header from Arrow to Teleflex..
130	3-Aug-2018	Added new procedure pack PL-12702-MSB as per ECR-033948/ECO-049815 for new EASK Kit. Added new procedure pack PL-17702-MSB as per ECR-033960/ECO-049984 for new EASK Kit. Added new procedure pack BE-S15703-ISP as per ECR-033727/ECO-050186 for new EASK Kit. Updated to rev 08 of the DOC template RAQA-T066
131	10-Aug-2018	Moved the following finished goods to the procedure pack section of the DOC: MC-12702, MC-14703, MC-15703, MC-16702, MC-17702, ML-00702. This was documented under ECO-048367.
132	24-Aug-2018	Added new procedure pack CH-04306-KSBL, CH-12703-KSBL and CH-12712-KSBL as per ECR-034202/ECO-050878 for new EASK Kit. Added new procedure pack DE-12123-NSK as per ECR-034143/ECO-050776 for new EASK Kit.
133	06-Sep-2018	Added new procedure pack DE-15853-BRE as per ECR-034335/ECO-051123 for new EASK Kit.
134	01-Oct-2018	Added new procedure packs TR-12712-S, TR-12853-S and TR-17702-S as per ECR-034385/ECO-051237. (New EASK finished goods for Turkey)
135	19-Oct-2018	Added new procedure packs DE-15703-RO and DE-15854-RO as per ECR-034578/ECO-051623. (New EASK finished goods for Germany)
136	02-Nov-2018	Added new procedure pack BE-17702-Hcm1 as per ECR-034673/ECO-051880. (New EASK finished goods for Belgium)
137	14-Jan-2019	Added new procedure packs DE-04706-UKM, DE-12853-UKM, DE-15853-UKM and DE-15854-UKM as per ECR-034802/ECO-052165. (New EASK finished goods for Germany)
138	18-Jan-2019	Added new procedure pack DE-15955-EKMH as per ECR-035007/ECO-052527. (New EASK Finished Good for Germany) Added new procedure packs NL-12703-MZR1 as per ECR-035020/ECO-052550 (New EASK Finished Good for the Netherlands)
139	05-Mar-2019	Annual review of DoC. Changed the format of the part table to remove the Czech part number column and move any part numbers to the left column. The Czech part number column is no longer needed as all parts are in Agile. Delete the following due to being made obsolete/inactive or not used in any CE marked finished goods: (Change Order Number, if applicable)

Obsolete	Not a Catheter Assembly Number
KZ-04150-001 (MCO-004808)	LCZ-12703-001A
M4-00701-001A (MCO-005768)	MCZ-14703-001B
M4-14702-001B (MCO-005768)	MCZ-14703-004B
M4-16702-002A (MCO-005768)	MCZ-15703-003B
MC-12402-001G (ECO-036233)	MCZ-20688-002B
MCZ-16402-001 (MCO-004808)	

Rev. Level	Date	Description
		MC-16553-002E (MCO-004235) MCZ-14553-001 (MCO-004808) M4-35123-001B (ECO-046237) AK-04306-EB (MCO-005472) BR-15853-SA (MCO-005472) CV-15703-SA1 (MCO-005472) DE-04706-EKMH (MCO-005472) DE-12703-EKMH (MCO-005472) EU-15855-EN (MCO-005472) MA-12123 (MCO-005473) NL-12702-SFG (MCO-005473) NL-12703-TIL (MCO-005473) NL-12802-MUMC (MCO-005473) NL-15955-SFG (MCO-005473) TI-15403-JO (MCO-005473) TI-15553-JO (MCO-005473) TI-16553-JO (MCO-005473) <u>Not a valid part Number</u> M4-36123-003A <u>Inactive and No Inventory</u> AK-12703-TL BE-04301-CHR BE-04306-VEU BE-15703-CHR BE-15703-VEU BE-17702-CHR BES-04301-ENG CH-03000-CHUV CV-16702-FB DE-04301-KMUC DE-04701-BGH DE-04701-DK DE-04701-HEM DE-04701-MKHS DE-12712-S DE-12854-BBT DE-14703S-AGK DE-14854-UW DE-15703-KKR DE-15703-KMUC DE-15802-DK DE-15802-GKB DE-15802-ZWKC DE-15853-GKB DE-15853-HEM DE-15853-MKHS DE-15854-KKR DE-15955-KMUC DE-15955-RB DE-17702-BGH DE-17702-KKR DE-17702-UFB DM-12853 DM-09306 ES-04730-D EU-12955-FE EU-15955-FE FR-12853-IP FR-15853-IP FR-12702-DP IT-04306-BE IT-14502-BE LA-14854 NL-12703-Fr NL-15703-ANNA SK-04701-BK SK-15802-BK SK-16702-BK UG-14703-C VI-15703
140	21-Mar-2019	Add catheter MC-14502-001F (CATHETER 2-L: 5Fr x 13cm) per ECR-034228/ECO-051383.

Rev. Level	Date	Description
141	25-Mar-2019	Added new procedure packs DE-15853-SHA2 and DE-15853-UKB as per ECR-035275/ECO-053166. (New EASK Finished goods for Germany) Added new procedure packs FR-12853-DPT, FR-12854-DPT, FR-12955-DPT, FR-15853-DPT and FR-15955-DPT as per ECR-035437/ECO-053529. (New EASK finished goods for France)
142	10-Apr-2019	Added new procedure pack DE-14703-KN1 as per ECR-035533/ECO-053692 (New EASK finished good for Germany) Added new procedure packs FR-12853-IPSE and FR-15853-IPSE as per ECR-035604/ECO-053819. (New EASK finished goods for France) Added new procedure packs DE-04701-SAN, DE-04706-SAN, DE-12702-SAN, DE-12853-SAN and DE-17702-SAN. (New EASK finished goods for Germany)
143	29-Apr-2019	Added new procedure packs NL-12854-AZIC, NL-12703-AZIC and NL-04706-AZIC as per ECR-035684/ECO-054010 (New EASK finished goods for the Netherlands) Added new procedure packs DE-15955-SAN, DE-15854-SAN, DE-15853-SAN, DE-12955-SAN and DE-12854-SAN as per ECR-035677/ECO-053994. (New EASK Finished goods for Germany). Updated Regulatory Affairs approver.
144	06-May-2019	Removed the following codes that were made obsolete per ECR-035840: MCZ-14702-001B, MCZ-12702-001B, MCZ-12702-002B, MCZ-17752-001B, MCZ-16702-001B, MCZ-51616-001B, MCZ-21814-002B, and MCZ-21418-001B
145	10-May-2019	Added new procedure pack DE-14854-RHE as per ECR-035771/ECO-054188 (New EASK Finished good for Germany)
146	05-Jun-2019	Added new procedure packs TR-12703-S1, TR-12853-S1 and TR-15703-S1 as per ECR-035817/ECO-054320 (New EASK Finished Good for Turkey)
147	02-Jul-2019	Added the following catheter part numbers with Mexico extrusions per BSI certificate reference number 9671921: HO-14702-001C, HO-14703-001C, K-04150-003B, K-04300-009B, K-04301-001B, K-04303-001A, K-04306-001B, K-04400-001B, K-04650-001B, K-04660-001B, K-50014-001B, K-50016-001B, LC-12703-001D, LC-15703-001C, LC-15703-001D, MC-12402-001I, MC-12402-001J, MC-12553-001G, MC-12702-007A, MC-12702-009A, MC-12703-003A, MC-14402-003E, MC-14402-003F, MC-14502-001G, MC-14502-003B, MC-14502-003C, MC-14553-002H, MC-14553-002I, MC-14702-004A, MC-14703-017E, MC-14703-017F, MC-15402-002J, MC-15402-002K, MC-15553-002H, MC-15553-002I, MC-15703-017A, MC-16402-002J, MC-16402-002K, MC-16553-002H, MC-16553-002I, MC-16553-003G, MC-16702-010B, MC-16702-012B, MC-17702-011B, MC-17702-011C, MC-17752-003B, MC-18703-004E, MC-18703-004F, MC-21814-002A, MC-40688-001D, MC-50688-001D, MC-51418-003A, P-04706-001B, S-04522-001B, S-04700-001B, S-04701-001B, S-04730-001D, S-04730-003B, SL-09803-001A, MC-12702-006A, and SS-14701-001A
148	05-Jul-2019	Added the following catheter part numbers with new BASF material juncture hub per BSI certificate reference number 9671921. MCZ-14703-002A and MCZ-12703-002A (ECO-053358), MCZ-15703-004A (ECO-053363), MCZ-18703-003A (ECO-053365), and MCZ-10703-001A (ECO-053926).
149	09-Jul-2019	Removed MCZ-15802-001C (ECR-036170). Catheter is being made obsolete due to having no inventory and not being used in any CE marked finished good.
150	10-Jul-2019	Added the following catheters per ECR-053486 (removal of injection site/dust caps on extension line hubs): MC-16402-002I
151	06-Aug-2019	Per ECO-055322 and ECO-054842 added the following catheter part numbers with the new BASF juncture hub material: MCZ-12702-004A, MCZ-12702-003A, MCZ-14702-002A, MCZ-17702-002A. Revised catheter table to list catheter part numbers individually on separate lines.
152	08-Aug-2019	ECR-035257 – remove SA-15855 from DOC as it is being made obsolete

Rev. Level	Date	Description
153	13-Aug-2019	ECO-054843 – Added new catheter MCZ-16702-003A with the new BASF juncture hub material
154	15-Aug-2019	ECO-055323 - Added new catheter MCZ-17752-002A with the new BASF juncture hub material
155	10-Sep-2019	Removed the following catheters based on not being used in CE marked finished goods or Production released finished goods: LC-12703-001B, LC-15703-001A, MC-15703-014, MC-16702-012, MC-51616-002, MCZ-15403-004, MCZ-15855-003, MCZ-16702-004B, and MCZ-18702-003
156	13-Sep-2019	ECO-055088: Added catheters MDZ-10802-002A, MCZ-15802-003A, and MCZ-12802-001C with the new BASF juncture hub material
157	10-Oct-2019	ECO-055055: Added catheter MCZ-12802-002A with the new BASF juncture hub material. ECO-054999: Added catheter MC-14702-003 without injection sites Added new procedure pack IE-12854-SJH as per ECR-036384/ECO-035373 (New finished goods for Ireland)
158	17-Oct-2019	Added catheter, K-04050-001B per ECR-035209/ECO-053934 (catheter with Mexico extrusions per BSI certificate reference number 9671921) Added catheters, MC-17702-011A and MC-17702-011C per ECO-054763 (injection site removal project)
159	30-Oct-2019	Added new procedure packs CH-04306-KSBL1, CH-12703-KSBL1 and CH-12712-KSBL1 as per ECR-036475/ECO-055812 (New finished goods for Switzerland)
160	05-Nov-2019	Changed Notified Body number from 086 to 2797 Added procedure packs FR-04301-IPSE, FR-12802-IPSE and FR-14702-IPSE as per ECR-036820/ECO-056461 (New EASK finished goods for France) Added procedure packs FR-14703-IPSE, FR-15854-IPSE, FR-17702-IPSE as per ECR-036820/ECO-056474 (New EASK finished goods for Fracne) Added procedure pack DE-15854-UG as per ECR-036819/ECO-056434 (New EASK finished good for Germany)
161	13-Nov-2019	Added procedure packs DE-15703-RKM, DE-04701-RKM and DE-15802-RKM as per ECR-036754/ECO-056326 (New EASK finished goods for Germany) Added procedure pack EU-15853-CVT as per ECR-036662/ECO-056132 (New EASK finished good for EU)
162	19-Nov-2019	Added procedure packs PL-12402-MSB, PL-15402-MSB, PL-15553-MSB and PL-16553-MSB as per ECR-036849/ECO-056544 (New EASK finished goods for Poland)
163	03-Feb-2020	Correction: HO-14702-001A, HO-14702-001B, and HO-14702-001C were inadvertently listed as 20cm and should be 30cm. They were changed to 30cm. Changed Quality approval from Taryn Kern to Matt Roberts.
164	25-Feb-2020	Changed GMDN code from 10729 to 61594
165	03-Mar-2020	Added procedure packs DE-04730-TS, DE-15802-TS and DE-15955-TS as per ECR-037105/ECO-057098 (New EASK finished good for Germany).
166	04-May-2020	Annual Review of DOC - Removed the following catheter part numbers due to being obsolete or not used in an CE marked kits: C-04401-001, HO-14702-001B, HO-14703-001B, K-04301-005, K-04303-001, K-04303-001A, K-04825-001A, L4-12703-001A, LC-12703-001D, M4-00703-001B, M4-12702-001B, M4-12702-002B, M4-12703-001B, M4-16702-001B, MCZ-16702-004B, M4-17702-003B, MCZ-17702-003B, M4-17752-001A, MCZ-36123-001B, M4-51616-001B, MC-16702-012, MC-12553-001E, MC-12702-007, MC-12702-007A, MC-12702-009, MC-12702-009A, MC-14402-003B, MC-14502-001G, MC-14702-004, MC-14702-004A, MC-14703-017C, MC-14703-017E, MC-14703-019B, MC-16553-003E, MC-16553-003G, MC-16702-010, MC-16702-010B, MC-17752-

<table>
<tr><th>Rev. Level</th><th>Date</th><th>Description</th></tr>
<tr><td></td><td></td><td>002, MC-17752-003A, MC-18703-004C, MC-18703-004E, MC-20688-001C, MC-21418-003, MC- 21814-002, MC-21814-002A, MC-40688-001C, MC-40688-001D, MC-50688-001C, MC-50688-001D, M4-12802-001A, MCZ-12802-001B, MCZ-12802-001C, MCZ-12855-002, M4-14703-003B, M4-14854-002A, MCZ-14854-005A, M4-15703-003B, M4-15802-001A, M4-15854-001A, MCZ-15854-003A, M4-20688-001B, M4-32123-001B, MCZ-32123-001B, MCZ-35123-001A, M4-36123-001A, MCZ-36123-001B, S-04730-003A, S4-14702-001A

Removed Finished Goods ID-04200 and ID-04700 due to being inactive.</td></tr>
<tr><td>167</td><td>31-Jul-2020</td><td>Updated to add the new name and legal manufacturer address, Arrow International LLC/Morrisville and added reference to the mirrored certificate that was created for the new legal manufacturer. Changed regulatory designees' approval to Christine Ford and QA to Angel Diaz. Added reference to the 2007 MDD amendment under DIRECTIVES AND STANDARDS.</td></tr>
<tr><td>168</td><td>07-Aug-2020</td><td>Added procedure pack DE-12123-TS per ECR-038284/ ECO-059915 (New EASK finished good for Germany)</td></tr>
<tr><td>169</td><td>28-Oct-2020</td><td>Added the following EASK kits:
<table>
<tr><th>Part number (Country)</th><th>ECR/ECO</th><th>Added components are CE marked?</th><th>Mutual Compatibility of new components confirmed, if applicable?</th></tr>
<tr><td>DE-14703-UMZ</td><td>ECR-038555/ ECO-060764</td><td>Yes</td><td>Yes</td></tr>
<tr><td>DE-14955-UMZ</td><td>ECR-038555/ ECO-060764</td><td>Yes</td><td>Yes</td></tr>
</table>
Changed RA approver from Christine Ford to Krista Hughes</td></tr>
<tr><td>170</td><td>19-Nov-2020</td><td>Per ECR-038322/ECO-060566, added catheter MLB-32123-001 (equivalent to MCZ-32123-002), MLB-35123-001 (equivalent to MCZ-35123-002), and MLB-36123-001 (equivalent to MCZ-36123-001C). ARROW printed on extension lines removed.</td></tr>
<tr><td>171</td><td>14-Jan-2021</td><td>Per ECO-061585, added catheters MC-17752-003A, HO-14702-001B, and HO-14703-001B (removal of the injection sites).</td></tr>
<tr><td>172</td><td>10-Mar-2021</td><td>Added the following EASK kits:
<table>
<tr><th>Part number (Country)</th><th>ECR/ECO</th><th>Added components are CE marked?</th><th>Mutual Compatibility of new components confirmed, if applicable?</th></tr>
<tr><td>UK-12854-MRI</td><td>ECR-039173/ ECO-062314</td><td>Yes</td><td>Yes</td></tr>
</table></td></tr>
<tr><td>173</td><td>20-Apr-2021</td><td>Added the following EASK kits:
<table>
<tr><th>Part number (Country)</th><th>ECR/ECO</th><th>Added components are CE marked?</th><th>Mutual Compatibility of new components confirmed, if applicable?</th></tr>
<tr><td>DE-14403-UB</td><td>ECR-039688 / ECO-064180</td><td>Yes</td><td>Yes</td></tr>
</table></td></tr>
</table>

Rev. Level	Date	Description
		DE-16553-UB | ECR-039688 / ECO-064180 | Yes | Yes
174	02-Jun-2021	ECO-065107 Added the following catheter part numbers: MCZ-12853-008B (Same catheter variant as MCZ-12853-008A but with BASF juncture hub material) MCZ-15853-008B (Same catheter variant as MCZ-15853-008A but with BASF juncture hub material) Juncture hub material change was approved by BSI 1-July-2019 reference number 9671921.
175	10-Jun-2021	ECO-065106 Added MCZ-10853-005B (Same catheter as MCZ-10853-005A but with BASF juncture hub material) ECO-055826 Added MCZ-14853-004B (Same as MCZ-14853-004A but with BASF juncture hub material) Juncture hub material change was approved by BSI 1-July-2019 reference number 9671921.

EC CERTIFICATE
Full Quality Assurance System

Certificate No.:
10144-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-13237-2007-PRC-RGC

Valid until:
27 May 2024

This is to certify that the quality system of:

Bioteque Corporation

5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C.

For design, production and final product inspection/testing of:

Sterile Medical Suction, Infusion and Drainage Systems

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 21 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 91617-2011-CE-RGC-NA Rev. 3.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	18-05-2017
1.0	**Recertification**	**21-05-2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Medical Suction, Infusion and Drainage Systems	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula - BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series, Ureteral Stent Set and Accessories, including Guidewire - BT-DJ-30 series, BT-DJ-40 series, BT-DJ-48 series, BT-DJ-50 series, BT-DJ-60 series, BT-DJ-70 series, BT-DJ-80 series,BT-DJ-30 series-SC, BT-DJ-40 series-SC, BT-DJ-48 series-SC, BT-DJ-50 series-SC, BT-DJ-60 series-SC, BT-DJ-70 series-SC, BT-DJ-80 series-SC Guide Wire - GW-S-series, GW-J-series	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Head office	5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C.
Taiwan Factory	No. 5, Chung Cheng Road, Su-Ao Cheng, I-Lan, Taiwan, R.O.C.

EU Representative

Name	Address
MedNet EC-REP GmbH	Borkstrasse 10, 48163 Muenster, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

CE SERTIFIKATAS

Visiškos kokybės užtikrinimo sistema

Sertifikato Nr.:
10144-2017-CE-RGC-NA-PS Rev. 1.0

Projekto Nr.:
PRJC-13237-2007-KLR-RGC

Galioja iki:
2024 m. gegužės 27 d.

Patvirtinama, kad žemiau nurodytos įmonės kokybės sistema:

Bioteque korporacija

5F-6, Nr. 23, Sek. 1, Chang-An E. Road, Taipėjus 104, Taivanas, R.O.C.

Projektuojant, gaminant ir galutinai tikrinant ir (arba) bandant žemiau nurodytą gaminį:

Sterilios medicininės siurbimo, infuzijos ir drenažo sistemos

Buvo įvertinta pagal:

Medicininių prietaisų direktyvos 93/42/EEB II priede, išskyrus 4 dalį, aprašytą atitikties įvertinimo tvarką

ir nustatyta, kad ji atitinka

Išsamesnė informacija apie produktą (-us) ir sertifikavimo sąlygas pateikiama toliau.

Vieta ir data:
Høvik, 2021 m. gegužės 21

Išdavusiai įstaigai:
d. Notifikuota įstaiga 2460
DNV produkto garantija AS

Jeremijasenas

Pastaba: sertifikatui taikomos sertifikavimo sutartyje nustatytos sąlygos. Nesilaikant šio sertifikato gali tapti negaliojančiu.

Jurisdikcija

1993 m. birželio 14 d. Direktyvą 93/42/EEB Norvegijos sveikatos ir priežiūros paslaugų ministerija priėmė kaip „Forskrift om Medisinsk Utstyr“.

Sertifikatų istorija:

Peržiūra	Apibūdinimas	Išdavimo data
0.0	Pakeičia sertifikatą 91617-2011-CE-RGC-NA Rev. 3.0 (NB 0434) po notifikuotos įstaigos funkcijų perdavimo DNV GL NEMKO Presafe AS (NB 2460).	18-05-2017
1.0	**Pakartotinis sertifikatų išdavimas**	**21-05-2021**

Produktai, kuriems taikomas šis sertifikatas:

Produkto aprašymas	Produkto pavadinimas	Klasė
Sterilios medicininės siurbimo, infuzijos ir drenažo sistemos	Drenažo kateterio rinkinys ir priedai, įskaitant jungiamąjį vamzdį ir lanksčią standinančią kaniulę - BT-PD0 serija, BT-PD1 serija, BT-PD2 serija, BT-PD4 serija, BT-PDS serija, Ureterinių stentų rinkinys ir priedai, įskaitant nukreipiančiąją vielą - BT-DJ-30 serija, BT-DJ-40 serija, BT-DJ-48 serija, BT-DJ-50 serija, BT-DJ-60 serija, BT-DJ-70 serija, BT-DJ-80 serija, BT-DJ-30 serija-SC, BT-DJ-40 serija-SC, BT-DJ-48 serija-SC, BT-DJ-50 serija-SC, BT-DJ-60 serija-SC, BT-DJ-70 serija-SC, BT-DJ-80 serija-SC Nukreipiančioji viela - GW-S serija, GW-J serija	IIa

Visas prietaisų sąrašas pateikiamas notifikuotai įstaigai

Vietos, kurioms taikomas šis sertifikatas

Vietos pavadinimas	adresas
Pagrindinė buveinė	5F-6, Nr. 23, Sek. 1, Chang-An E. Road, Taipėjus 104, Taivanas, R.O.C.
Taivano gamykla	Nr. 5, Chung Cheng Road, Su-Ao Cheng, I-Lan, Taivanas, R.O.C.

ES atstovas

Pavadinimas	**Adresas**
MedNet EC-REP GmbH	Borkstrasse 10, 48163 Muenster, Vokietija

Terminai ir sąlygos

Sertifikatui taikomos šios sąlygos:

- Bet kuris gamintojas (žr. tikslų apibrėžimą žr. 2001/95/EB) atsako už žalą, atsiradusią dėl jo gaminio (-ų) defekto pagal Direktyvą 85/374/EEB (su atnaujinimais) dėl atsakomybės už gaminius su trūkumais.
- Sertifikatas galioja tik anksčiau išvardintoms produkto ir (arba) gamybos patalpoms.
- Gamintojas vykdo įsipareigojimus, susijusius su patvirtinta kokybės sistema, ir užtikrina, kad ji išliktų tinkama ir veiksminga.
- Gamintojas informuoja notifikuotąją įstaigą apie bet kokį ketinamą kokybės sistemos atnaujinimą, o notifikuota įstaiga įvertins pakeitimus ir nuspręs, ar sertifikatas tebegalioja.
- Bus atliekami periodiniai auditai, siekiant patikrinti, ar gamintojas prižiūri ir taiko kokybės sistemą. Notifikuota įstaiga pasilieka teisę atlikti patikrinimus iš anksto nepranešus, jeigu kyla įtarimų dėl tinkamo kokybės sistemos taikymo.

Šis sertifikatas gali tapti negaliojančiu, kai:

- Atsiranda kokybės sistemos pokyčių, turinčių įtakos gamybai.
- Periodiniai auditai nėra atliekami per leistiną laikotarpį.

Gaminio atitikties deklaracija ir ženklinimas

Laikydamasis aukščiau nurodytų sąlygų, gamintojas gali parengti EB atitikties deklaraciją ir teisiškai naudoti CE ženklą kartu su notifikuotos įstaigos identifikaciniu numeriu.

Sertifikato
pabaiga

EC CERTIFICATE
Full Quality Assurance System

Certificate No.:
10144-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-13237-2007-PRC-RGC

Valid until:
27 May 2024

This is to certify that the quality system of:

Bioteque Corporation

5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C.

For design, production and final product inspection/testing of:

Sterile Medical Suction, Infusion and Drainage Systems

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 21 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 91617-2011-CE-RGC-NA Rev. 3.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	18-05-2017
1.0	**Recertification**	**21-05-2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Medical Suction, Infusion and Drainage Systems	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula - BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series, Ureteral Stent Set and Accessories, including Guidewire - BT-DJ-30 series, BT-DJ-40 series, BT-DJ-48 series, BT-DJ-50 series, BT-DJ-60 series, BT-DJ-70 series, BT-DJ-80 series,BT-DJ-30 series-SC, BT-DJ-40 series-SC, BT-DJ-48 series-SC, BT-DJ-50 series-SC, BT-DJ-60 series-SC, BT-DJ-70 series-SC, BT-DJ-80 series-SC Guide Wire - GW-S-series, GW-J-series	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Head office	5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C.
Taiwan Factory	No. 5, Chung Cheng Road, Su-Ao Cheng, I-Lan, Taiwan, R.O.C.

EU Representative

Name	Address
MedNet EC-REP GmbH	Borkstrasse 10, 48163 Muenster, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Notified Body Confirmation Letter Reference: C657576

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has 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 following manufacturer:

Bioteque Corporation
5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C.

SRN Number: TW-MF-000015568

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under 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 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, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2024/02/22

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
'way

André Fernandes
Management Representative

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Closed Suction Catheter Set-Closed Suction Catheter / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460
Closed Suction Catheter Set-Wedge / 471988267CSCRN	Is	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460
Closed Suction Catheter Set-Breathing Tube (Flexible Tube) / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460
Closed Suction Catheter Set-Y connector (pediatric) / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460
Drainage Catheter Set-Drainage Catheter / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		series	
Drainage Catheter Set- Split Straighter / 471988271PDZG	Is	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460
Drainage Catheter Set- Puncture Needle (Trocar Stylet and Trocar Needle) / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460
Drainage Catheter Set- Flexible Stiffening Cannula / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460
Drainage Catheter Set- Metal Stiffening Cannula / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460
Drainage Catheter Set-Connecting Tube / 471988271PDZG	Is	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/22	C657576	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Bioteque Corporation
Manufacturer address and contact details	5F-6, No. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan
Single Registration Number (SRN) (if available)	TW-MF-000015568

Authorised Representative name (if applicable)	MedNet EC-REP GmbH
Authorised Representative address and contact details	Borkstrasse 10, 48163 Muenster, Germany
Single Registration Number (SRN) (if available)	DE-AR-000000002

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☑ Expired/expires *after* 20 March 2023:

☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*
  - ☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
  - ☐ A QMS in accordance with Article 10(9) MDR is in place.
  - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Con

Location

Signatur

DNV

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Closed Suction Catheter Set-Closed Suction Catheter / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 16/April/2023	**31/Dec/2028**
Closed Suction Catheter Set-Wedge / 471988267CSCRN	Is	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 16/April/2023	**31/Dec/2028**
Closed Suction Catheter Set-Breathing Tube (Flexible Tube) / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 16/April/2023	**31/Dec/2028**
Closed Suction Catheter Set-Y connector (pediatric) / 471988267CSCRN	IIa	Closed Suction Catheter Set BT-SC Series	Certificate number: 10133-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 16/April/2023	**31/Dec/2028**
Drainage Catheter Set-Drainage Catheter / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**

		BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series			
Drainage Catheter Set- Split Straighter / 471988271PDZG	Is	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**
Drainage Catheter Set- Puncture Needle (Trocar Stylet and Trocar Needle) / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**
Drainage Catheter Set- Flexible Stiffening Cannula / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**

Drainage Catheter Set- Metal Stiffening Cannula / 471988271PDZG	IIa	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**
Drainage Catheter Set-Connecting Tube / 471988271PDZG	Is	Drainage Catheter Set and Accessory, including Connecting Tube and Flexible Stiffening Cannula BT-PD0-series, BT-PD1-series, BT-PD2-series, BT-PD4-series, BT-PDS-series	Certificate number: 10144-2017-CE-RGC-NA-PS NB number NB 2460	Expiry date 27/May/2024	**31/Dec/2028**

EC Certificate

Certificate Number: DGM – 410

Presafe
A DNV & NEMKO COMPANY

Patvirtiname, kad žemiau nurodytos įmonės kokybės sistema

Coloplast A/S
Holtedam 1
3050 Humlebaek
Danija

atitinka žemiau nurodytos direktyvos reikalavimus

Priedas II pilna kokybės užtikrinimo sistema

Tarybos direktyva 93/42/EEB dėl medicinos priemonių pagal Danijos įstatymų pataisas ir transpozicijas, išskyrus II priedo, 4 skyrių

Sertifikavimo sritis:

Chirurginių tinklelių, pravedėjų, ostomijos, žaizdų ir odos priežiūros, drenavimo, chirurgijos, urologijos, ginekologijos ir inkontinencijos priežiūros produktų kūrimas, vystymas ir gamyba, I klasė sterili, IIa klasė, IIb klasė ir III klasė

CE sertifikatas galioja tol, kol įdiegta kokybės sistema atitinka sukščiau paminėtus reikalavimus, atsižvelgiant į tai, jog įmonė neatliko jokių reikšmingų kokybės sistemos pokyčių be sertifikavimo įstaigos Presafe Denmark A/S sutikimo. CE sertifikavimas išduodamas pagal Presafe Denmark A/S taisykles, taikomas medicininių priemonių sertifikavimui, ir leidžia šio sertifikato savininkui žymėti prekes CE ženklu.

/parašas/	Išleidimo data:	2018-09-21
Heidi Jorgensen	Galioja iki:	2023-09-21
	Pirmoji leidimo data:	2003-04-30
Presafe Denmark A/S	Nuoroda:	aur2a1809v1260f492

Presafe Denmark A/S
Notifikuota įstaiga, identifikacijos Nr. 0543
Tuborg Parkvej 8, 2900 Helleruo, Danija

Šis sertifikatas skirtas ir sekančioms veiklos sritims:

Danijoje:

Coloplast
Industrivej 7
7700 Thisted

Coloplast
Holtedam 1 ir 3
3050 Humlebaek

Coloplast A/S
Aa. Louis-Hansens Alle 15
Mordrup
3060 Espergaerde

Prancūzijoje**:**
Coloplast Manufacturing France SA
Le Pontet, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SA
Lieaudit La Boursidiere
Centre d'Affaires
92350 Le Plessis Robinson

Coloplast Manufacturing France SA
Madrazes, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SA
ZAC du Clotais
2b, Route du Chemin Blanc
91160 Champlan

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Vengrijoje:

Coloplast Vengrija KFT
Búzavirág út 15
2800 Tatabánya

Coloplast Vengrija KFT
Coloplast utca 2
4300 Nyirbátor

Coloplast Vengrija KFT
Barina g. 1
2890 Tata

JAV:

Coloplast Corporation
1601 West River Road North
Mineapolis, MN 55411

Coloplast Manufacturing US, LLC
1601 West River Road North
Mineapolis, MN 55411

Coloplast Manufacturing US, LLC
1940 Commerce Dr.
North Mankato, MN 56003

Kinija:

Coloplast (Kinija) Ltd.
Bao Cheng Rd.
Zhuhai Free Trade Zone
Zhuhai 519030 Guangdong

Coloplast (Kinija) Ltd.
3F, Nr. 1, Bldg, Honda Road
Nanping Industrial park
Zhuhai miestas 519060

Sertifikatas taikomas šioms III klasės medicininėms priemonės:

Antibakteriniai putų tvarsčiai (DGM – 529)
Antibakteriniai pleistrai žaizdoms (DGM – 530)
IBU putų tvarsčiai (DGM – 528)

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Sertifikatas taikomas šioms IIb klasės medicininėms priemonėms:

Alginate tvarsčiai
Biatain putų tvarsčiai
Comfeel žaizdų tvarsčiai
Conseal ostomijos tamponai
Hidrokapiliariniai tvarsčiai
Izorinai
Varpos implantai
Implantai varpos tvirtumui
Peristeen analiniai tamponai
Physiotulle tvarsčiai
Purilon gelis
Chirurginiai priedai
Chirurginiai tinkleliai
Sėklidžių protezai
Šlapimo kateteriai
Šlapimo/perkutaniniai kateteriai
Šlapimo/suprapubiniai kateteriai
Urologiniai implantai
Vaginaliniai stentai

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

Sertifikatas taikomas šioms IIa klasės medicininėms priemonėms:

Ostomijos lazdelė
Akmenų ištraukėjai
Chirurginiai priedai
Chirurginio drenavimo priemonės
Siūlų/adatų pravedėjai
Šlapimo kateteriai
Šlapimo/perkutaniniai kateteriai
Urodinaminiai priedai
Urodinaminiai kateteriai
Urologiniai priedai
Urologiniai implantai

Sertifikatas taikomas šioms I klasės medicininėms priemonėms:

Kateterių praplovimo tirpalai (sterilūs)
Drenavimo maišeliai (sterilūs)
Ostomijos pooperaciniai rinkiniai (sterilūs)
Chirurginiai priedai (sterilūs)
Šlapimo kateteriai protarpiniam naudojimui (sterilūs)
Šlapimo maišeliai (sterilūs)
Urologiniai priedai (sterilūs)
Urologiniai kateteriai (sterilūs)

Sertifikato numeris: DGM-410
Sertifikato rūšis: CE sertifikatas

Išleidimo data: 2018-09-21
Galioja iki: 2023-09-21
Pirminio leidimo data: 2003-04-30
Nuoroda: aur2a1809v1260f492

EC Certificate

Certificate Number: DGM – 410

This is to certify that the quality system of:

Coloplast A/S
Holtedam 1
3050 Humlebaek
Denmark
has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design, development and manufacture of surgical meshes, guidewires, ostomy, wound and skin care, drainage, surgery, urology, gynaecology and continence care products in class I sterile, class IIa, class IIb and class III

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.

Authorized person

For Presafe Denmark A/S

Date of issue:	2018-09-21
Expires:	2023-09-21
Initial date of issue:	2003-04-30
Reference:	Aur2a1809v1260f492

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

The following sites are covered by the certificate:

With the following sites in Denmark:

Coloplast A/S
Industrivej 7
7700 Thisted

Coloplast A/S
Holtedam 1 and 3
3050 Humlebaek

Coloplast A/S
Aa. Louis-Hansens Allé 15
Mørdrup
3060 Espergaerde

With the following sites in France:

Coloplast Manufacturing France SAS
Le Pontet, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SAS
Lieudit La Boursidière
Centre d'Affaires
92350 Le Plessis Robinson

Coloplast Manufacturing France SAS
Madrazès, BP89
24203 Sarlat Cedex

Coloplast Manufacturing France SAS
ZAC du Clotais
2b, Route du Chemin Blanc
91160 Champlan

With the following sites in Hungary:

Coloplast Hungary KFT
Búzavirág út 15
2800 Tatabánya

Coloplast Hungary KFT
Coloplast utca 2
4300 Nyírbátor

Coloplast Hungary KFT
Kerék utca 3
2800 Tatabánya

With the following sites in the USA:

Coloplast Corporation
1601 West River Road North
Minneapolis, MN 55411

Coloplast Manufacturing US, LLC
1601 West River Road North
Minneapolis, MN 55411

Coloplast Manufacturing US, LLC
1940 Commerce Dr.
North Mankato, MN 56003

With the following site in the People's Republic of China:

Coloplast (China) Ltd.
No. 202, Baocheng Rd
Xiangzhou District
Zhuhai 519030

Coloplast (China) Ltd.
No. 18 Pingbei Er Rd.
Nanping Industrial Park
Zhuhai City 519060

Certificate number: DGM – 410
Certificate type: EC Certificate

Date of issue: 2018-09-21
Expires: 2023-09-21
Initial date of issue: 2003-04-30
Reference: Aur2a1809v1260f492

The following product families in class III are covered by the certificate and by Design Examination certificates as specified below:

Antibacterial Foam Dressings (DGM – 529)
Antibacterial Wound Contact Layer (DGM – 530)
Ibu Foam Dressings (DGM – 528)

The following product families in class IIb are covered by the certificate:

Alginate Dressings
Biatain Foam Dressings
Comfeel Wound Dressings
Conseal Ostomy Plugs
Hydrocapillary Dressings
Isorins
Penile Inflatable Implants
Penile Rigidity Implants
Peristeen Anal Plugs
Physiotulle Dressings
Purilon Gel
Surgical Accessories
Surgical meshes
Testicular Prostheses
Urinary Indwelling Catheters
Urinary/Percutaneous Indwelling Catheters
Urinary/Suprapubic Indwelling Catheters
Urological Implants
Vaginal Stents

Certificate number: DGM – 410
Certificate type: EC Certificate

Date of issue: 2018-09-21
Expires: 2023-09-21
Initial date of issue: 2003-04-30
Reference: Aur2a1809v1260f492

The following product families in class IIa are covered by the certificate:

Ostomy Rod
Stone Extractors
Surgical Accessories
Surgical Drainage
Suture/Needle passer
Urinary Indwelling Catheters
Urinary/Percutaneous Indwelling Catheters
Urodynamic Accessories
Urodynamic Catheters
Urological Accessories
Urological Implants

The following sterile product families in class I are covered by the certificate:

Catheter Irrigation Solutions (sterile)
Drainage Bags (sterile)
Ostomy Post-Operative Sets (sterile)
Surgical Accessories (sterile)
Urinary Catheters for Intermittent Use (sterile)
Urine Bags (sterile)
Urological Accessories (sterile)
Urological Catheters (sterile)

Certificate number:	DGM – 410	Date of issue:	2018-09-21
Certificate type:	EC Certificate	Expires:	2023-09-21
		Initial date of issue:	2003-04-30
		Reference:	Aur2a1809v1260f492

DNV Product Assurance AS
Medical Devices
Veritasveien 3, 1363 Høvik
Postal address: P.O. Box 116, N-1300 Sandvika, Norway
Tel: +47 67 57 88 00
Enterprise No: NO 997 067 401

Date:
30 August 2023

Dear Hassan

We confirm that the products listed in table 1 will be continued to be under MDD surveillance by DNV according to the framework agreement signed 2021-03-26 until the certificate expiration on 26 May 2024 according to Regulation (EU) 2023 / 607.

Sincerely
for DNV Product Assurance AS

Palani Damodharan
Certification Manager

Cc: DNV Business Assurance Korea office

Table 1: List of Coloplast devices which will not upgrade under MDR.

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Easivac system for collecting pieces of tissue after TURP 570893263589799	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
CystoCare post operative urine bags 57089329106137D	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostatectomy catheter siliconised semi-rigid latex 570893263588796	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostaflow prostatectomy catheter 57089326358908T	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Prostatectomy catheter siliconised	Class IIa	NA	1000041028 2-PA-NA-	Expiry date: 21	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
reinforced latex 57089326358918V			DNK NB number: NB 2460 DNV Product Assurance AS	Sep 2023	
Prostatic special catheters – latex 5708932115290438JL	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Urospiral 2 - Prostatic stent	Class IIb implantable	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
In-Ka for Percutaneous Nephrolithotomy 57089326358668W	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
In-Ka ureteral balloon dilatation catheter 57089326358678Y	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			AS		
Conical connector for ureteric catheter to urine bag latex 57089326358598Z	Class Is	TPE connectors 5708932122590763 K9 (Class Is)	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Orchestra hydrophilic guidewire 57089326358438J	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Drain for nephrostomy with malleable blunt needle (PCN Drainage - Gil-Vernet) 57089326358618L	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Amplatz sheath 57089326358658U	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Vortek percutaneous nephrostomy catheter cumming-malecot	Class IIb	NA	1000041028 2-PA-NA-DNK NB number:	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			NB 2460 DNV Product Assurance AS		
Percutaneous nephrostomy set with silicone balloon catheter (Kolibri - Silicone nephrostomy balloon catheter set) 57089326358548P	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Dormia stone extractor 570893263586892	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Steerable radiopaque pusher	Class IIa	ORX tip steerable radiopaque pusher	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Dormia biliary stone extractor 570893263590187	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Kehr T-drain latex 57089326359038B	Class IIa	NA	1000041028 2-PA-NA-	Expiry date: 21	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
& Abdominal irrigation-lavage drain 57089326359088M & Drain with controlled aspiration 570893263591088 & Flat suction drain silicone 57089326359118A			DNK NB number: NB 2460 DNV Product Assurance AS	Sep 2023	
Bulb for drain 57089326359128C	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Folatex silicone coated latex urinary catheter (Folatex soft latex catheter) 57089326358718P	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Releen InLine urinary indwelling drainage catheter 570893229781599	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Multi-organ procurement catheter	Class IIa	NA	1000041028 2-PA-NA-DNK	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
57089326358999D			NB number: NB 2460 DNV Product Assurance AS		
DIABOLO® Urethral Stent	Class IIb implantable	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Foley catheters - Semi-rigid latex: Foley catheter straight tip 57089326358728R & Foley catheter coudé tip 57089326358738T	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Soft latex Rusch	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Biosoft minute stent	Class IIb implantable	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Pezzer & Malécot Catheters	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
S.P.E.C. 10® Emergency supra-pubic set	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
PVC Bougies	Class Is	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Urodynamic catheters	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Cobra Single Use Biopsy Gun	Class IIa	NA	1000041028 2-PA-NA-DNK NB number: NB 2460	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
			DNV Product Assurance AS		
Gastro-Intestinal Tubes	Class IIb	NA	100004102822-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Oesophageal Bougies	Class Is	NA	100004102822-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Larget Rod	Class IIa	NA	100004102822-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Biatain Soft-Hold foam dressing	Class IIb	NA	100004102822-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024
Comfeel Plus Transparent hydrocolloid	Class IIb	NA	100004102822-PA-NA-DNK	Expiry date: 21 Sep 2023	26 May 2024

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
dressing old generation			NB number: NB 2460 DNV Product Assurance AS		
Comfeel Plus hydrocolloid dressing old generation	Class IIb	NA	1000041028 2-PA-NA-DNK NB number: NB 2460 DNV Product Assurance AS	Expiry date: 21 Sep 2023	26 May 2024

Notified Body Confirmation Letter Reference: C627818

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has 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 following manufacturer:

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark

SRN Number: DK-MF-000025526

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under 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 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, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2023.09.20

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Biatain Ibu Non-Adhesive foam dressing 57089322853047J	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no: 10000410284-PA-NA-DNK
Biatain Ibu Soft-Hold foam dressing 57089322853057L	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no: 10000410284-PA-NA-DNK
InterDry wicking fabric 57089322853167R	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460 EC Design Examination Certificate no.: 10000423479-PA-NA-DNK
Comfeel Plus hydrocolloid dressing 57089322853067N	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Comfeel Plus Transparent hydrocolloid dressing 57089322853077Q	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Comfeel Plus Contour hydrocolloid dressing	Class IIb	NA	10000410282-PA-NA-DNK

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
57089322853097U			NB Number: NB 2460
Biatain Super Adhesive dressing 57089322853117F	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Super Non-Adhesive dressing 57089322853107D	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Adhesive foam dressing 57089322852988G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Non-Adhesive foam dressing 57089322852978E	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone foam dressing 57089322853027E	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone Lite foam dressing 57089322853037G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone Non-Border foam dressing 570893260292393Q2	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Silicone against pressure injuries 57089322853017C	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Purilon Gel 57089322853157P	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biatain Fiber dressing 57089322853147M	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conseal Plug 5708932117220516H4	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Peristeen Anal Plug and accessories 57089322978619G	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Baby flex ostomy bag 2-piece open 570893229756497	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Baby flex ostomy baseplate 570893229760892	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Alprep Pad 57089322853207G	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Assura/Alterna Post op ostomy bag 1-piece sterile 570893229762592	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Post op ostomy bag 1-piece sterile 57089322976228U	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura drainable ostomy bag 1-piece open sterile 570893299814023VL	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SenSura Mio Post op ostomy bag 1-piece sterile 57089322976208Q	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Coloplast Drainage bag 1-piece open sterile 5708932117046058HZ	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath/SureCath Set urinary intermittent drainage catheter with integrated urine bag 57089322978199H	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath catheter urinary intermittent drainage catheter 57089322978169B	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Self-Cath urinary intermittent drainage catheter 570893229782296	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Control urinary intermittent drainage catheter 57089322978289J	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Standard urinary intermittent drainage catheter 57089322978269E	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact Eve urinary intermittent drainage catheter 57089322978349D	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact female/female plus urinary intermittent drainage catheter 57089322978339B	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact male urinary intermittent drainage catheter 570893229783197	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Compact Set female urinary intermittent drainage catheter with integrated urine bag	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
57089322978369H			
SpeediCath Compact Set Male urinary intermittent drainage catheter with integrated urine bag 57089322978359F	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Flex urinary intermittent drainage catheter 57089322978379K	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Flex Set urinary intermittent drainage catheter with integrated urine bag 5708932117288128LH	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Navi urinary intermittent drainage catheter 57089322978399P	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
SpeediCath Soft urinary intermittent drainage catheter 570893261193271PW	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath Dilatation urinary intermittent dilatation catheter 57089322978179D	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
EasiCath Luerlock urinary intermittent infusion and drainage catheter 57089322978189F	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ bedside drainage bag sterile drainable sample port 57089322978919R	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus bedside drainage bag sterile drainable sample port 57089322978929T	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile bedside drainage bag sterile EtO drainable sample port 57089322978939V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile bedside drainage bag sterile Irradiation drainable sample port 5708932117311270H4	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla S4 bedside drainage bag sterile drainable sample port 5708932297896A3	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla S5 bedside drainage bag sterile drainable sample port	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
5708932297897A5			
Conveen Standard combi bag sterile drainable 5708932297899A9	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Contour leg bag sterile drainable sample port 57089322978709H	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ leg bag sterile drainable 57089322978749R	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Conveen Security+ leg bag sterile drainable sample port 57089322978739P	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Freedom Triform leg bag sterile drainable sample port 57089322978769V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus leg bag sterile drainable sample port 57089322978779X	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Plus Syphon leg bag sterile drainable sample port 57089322978789Z	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Simpla Profile leg bag sterile drainable sample port 57089322978819N	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Titan Inflatable Penile Prosthesis 570893291871755U9	Class IIb	Titan Inflatable Penile Prosthesis	10000410282-PA-NA-DNK NB Number: NB 2460
Titan Inflatable Penile Prosthesis Accessories 5708932110370449FT	Class IIb	Titan Inflatable Penile Prosthesis Accessories	10000410282-PA-NA-DNK NB Number: NB 2460
Genesis Malleable Penile Prosthesis 570893255573908T9	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Virtue Male Sling System 570893255591814T7	Class III	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Aris Introducers 570893255591823T8	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Furlow Insertion Tool 570893255573897TV	Class Ir	Furlow Insertion Tool	N/A - Device did not require a Notified Body certificate under Directives
Rossello Dilator Set	Class Ir	NA	N/A - Device did not

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
570893255573898TX			require a Notified Body certificate under Directives
Brooks Dilator Set 5708932121570220GP	Class Ir	Brooks Dilator Set	N/A - Device did not require a Notified Body certificate under Directives
Hydro X-Flow catheter silicone with hydrogel coating 57089326358899A	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
X-Flow prostatectomy catheter 570893263588898	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Freudenberg introducer 570893263589697	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Connector for tubes 57089326358608J	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer connector to syringe PVC 57089326358588X	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer lock connector for ureteric catheter to syringe polyamide 57089326358578V	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tuohy borst adapter 57089326358568T	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent set in polyamide 570893262832628RL	Class IIb Implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent set in polyurethane 570893262832633RD	Class IIb Implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Detour subcutaneous ureteral bypass 57089326358478S	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Guidewire stainless steel without coating 57089326358468Q	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Stainless steel PTFE coated guidewire 57089326358458N	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy guidewire 57089326358448L	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Luer connector for urine bag 57089326358648S	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek J percutaneous	Class IIb	NA	10000410282-PA-NA-

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
nephrostomy catheter 57089326358628N			DNK NB Number: NB 2460
Vortek malecot percutaneous nephrostomy catheter 570893262832582RM	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Balloon nephrostomy catheter short term (Silicone nephrostomy balloon catheters) 57089326358498W	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy dilator 57089326358518H	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous puncture needle 57089326358508F	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Direct puncture set 57089326358538M	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Percutaneous nephrostomy set with simple loop vortek catheter 570893262832546RH	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Dormia No-Tip / N-Stone 570893263586994	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biosoft duo double loop ureteral stent 57089326358348H	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Biosoft duo multilength hydro-coated ureteral stent 570893262832542R9	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop in rigid polyurethane 57089326358278L	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop in soft polyurethane 57089326358268J	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone 57089326358298Q	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent silicone hydrogel 57089326358328D	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone with partial reinforcement 570893263583089	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Double loop ureteral stent in silicone with total reinforcement	Class IIb implantable	NA	10000410282-PA-NA-DNK

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
57089326358318B			NB Number: NB 2460
Single loop ureteral stent 57089326358228A	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tumor Stent double loop ureteral stent 57089326358258G	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek double loop ureteral stent 57089326358248E	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Vortek hydro-coated double loop ureteral stent with hydrogel coating 57089326358238C	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Non steerable pusher 570893262832532R6	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Non steerable radiopaque pusher 570893262832531R4	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Steerable pusher 570893262832522R3	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric drainage catheter in neoplex 57089326358368M	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric drainage catheter in polyamide 57089326358378P	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Floppy tip hydro-coated ureteric catheter 57089326358408C	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric interventional catheter 57089326358398T	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteric catheter for retrograde uretero-pyelography 57089326358388R	Class Is	Ureteric catheter for retrograde uretero-pyelography	10000410282-PA-NA-DNK NB Number: NB 2460
Retrace ureteral access sheath 57089326358418E	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureteral dilator 57089326358428G	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Short term enterocystoplasty catheter 57089326358088G	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Short term uretero-sigmoidostomy catheter	Class IIa	NA	10000410282-PA-NA-DNK

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
57089326358078E			NB Number: NB 2460
Single loop ureterostomy catheter 570893263581083	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Ureterostomy catheter 57089326358098J	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Elefant suction-irrigation device 570893263590085	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Escat transcystic drains in PVC 57089326359058F	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Pedinielli transcystic drains in PVC 57089326359048D	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Coeliodrain for cholangiography 570893263590289	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Delbet drains 57089326359078K	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Multitubular drain silicone 57089326359068H	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Tubular drains silicone 570893262838040RN	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Multi-perforated tubular drain silicone radiopaque 57089326359098P	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Bonee needle for bladder injection 570893263588694	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Neoplex catheters without balloon 570893263587793	Class IIa	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Catheter valve 57089326358768Z	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Folysil silicone catheter 57089326358748V	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Folysil silicone catheter - Long-term 57089326358758X	Class IIb implantable	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Cystodrain supra-pubic drainage set with silicone J tip catheter 57089326358808Q	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Cystodrain supra-pubic puncture set with polyurethane J tip catheter	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
570893263588185			
Cystodrain integral set for supra-pubic drainage 570893263588285	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Supraflow supra-pubic drainage set with silicone balloon catheter 570893263588592	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Uristil suprapubic drainage set in silicone 570893263588387	Class IIb	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Bougie neoplex for routine urethral dilation 570893263587997	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460
Filiform bougie neoplex 570893263587895	Class Is	NA	10000410282-PA-NA-DNK NB Number: NB 2460

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/20	C627818	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe

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 033038 0037 Rev. 00

Manufacturer:

Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Product Category(ies):

Disposable devices and accessories for use in vascular, urological, gastroenterological pulmonary procedures (class IIa and IIb) including catheters, introducers, wires and drainage sets, electrosurgical and non-active instruments, stents and stent grafts, needles, cannulae and connecting tubes. Vascular stents and delivery systems.

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.: 75941443_CN

Valid from: 2020-03-04
Valid until: 2024-05-26

Date, 2020-03-04

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

TÜV®

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

KOPIJA

ZLG-BS-244.10.08

Product Service

CE Sertifikatas

Produkto kokybės užtikrinimo sistema
Medicinos prietaisų Direktyva 93/42/EEC, Priedas II, išskyrus (4)
(IIa, IIb ar III klasės prietaisai)

No. G1 033038 0037 Perž. 00

Gamintojas: **Cook Ireland Limited**
O'Halloran kelias
National Technology Park
Limerick
Airija

Produkto kategorija (-os):

Vienkartiniai prietaisai ir jų priedai kraujagyslių, urologijos, gastroenterologijos, plaučių procedūrose (IIa ir IIb klasė), įskaitant kateterius, introdiuserius, vielas ir drenavimo rinkinius, elektrochirurginius ir neaktyvius instrumentus, stentus, stentgraftus, adatas, kaniules ir jungiamuosius vamzdelius. Kraujagyslių stentus ir įvedimo sistemas.

Notifikuotoji įstaiga TUV SUD Product Service GmbH pareiškia, kad anksčiau minėtas gamintojas įdiegė produktų dizaino, gamybos ir galutinio atitinkamų prietaisų patikrinimo kokybės užtikrinimo sistemą, pagal Direktyvos II priedą. Ši kokybės Sistema apima prietaisų periodinių patikrinimų aspektus, kaip nurodyta Direktyvoje. III klasės prietaisų prekybai papildomai yra privalomas Direktyvos II priedo (4) sertifikatas. Žiūrėti pastabas kitoje pusėje.

Ataskaita Nr.: 75941443_CN

Galioja nuo: 2020-03-04
Galioja iki: 2024-05-26

Data, 2020-03-04

Notifikuotosios įstaigos vadovas

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Cook Ireland Limited
O'Halloran Road
National Technology Park
LIMERICK
IRELAND

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
33038	713212698 Ruairi McCaul	+353 (0) 860 755843 ruairi.mccaul@tuvsud.com	-	2024-01-26	1 of 24

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 033038 0059 Rev. 00

Reference: **713212698 | 713233811 | 713254205 | 713255917 | 713260952 | 713222487 | 713222510 | 713228654 | 713252400 | 713258121 | 713260959 | 713260960 | 713260963 | 713261373 | 713270171 | 713270207**

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: IE-MF-000001530

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.

Product Service

- 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 033038 0059 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-01-26

TÜV SÜD Product Service GmbH Medical and Health Services	TÜV SÜD Product Service GmbH Medical and Health Services
Ruairi Confo Assessment Responsible (CARE)	Application Reviewer

Product Service

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
BUDI-DI: **0827002CIRL202007067008E6** **Article Numbers:** RMS-060012-R RMS-060014-R RMS-060016-R RMS-060018-R RMS-060020-R RMS-060022-R RMS-060024-R RMS-060026-R RMS-060028-R RMS-060030-R	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202007008009CD** **Article Numbers:** USI-500 USI-500-B USI-500-B-T USI-500-LP USI-500-R USI-500-RPC USI-512 USI-512-CE USI-512-LP USI-512-RPC USI-514 USI-514-RPC USI-516 USI-516-LP USI-518 USI-520 USI-520-B USI-520-LP USI-520-R USI-520-RPC USI-522 USI-522-B USI-522-CE USI-522-LP USI-522-R USI-522-RPC USI-524 USI-524-B USI-524-CE USI-524-LP USI-524-R USI-524-RPC USI-526 USI-526-B USI-526-CE USI-526-CE-B USI-526-CE-LP USI-526-CE-R USI-526-LP USI-526-R USI-526-RPC USI-526-RPC-LP	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#

Product Service

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
USI-528 USI-528-B USI-528-CE USI-528-CE-B USI-528-LP USI-528-R USI-528-RPC USI-530 USI-530-B USI-530-LP USI-530-R USI-530-RPC USI-600 USI-600-B USI-600-B-T USI-600-CE USI-600-LP USI-600-R USI-600-RPC USI-600-RPC-T USI-600-R-T USI-600-T USI-612 USI-614 USI-614-RPC-T USI-616 USI-616-RPC USI-618 USI-620 USI-620-B USI-620-LP USI-620-R USI-620-RPC USI-622 USI-622-B USI-622-CE USI-622-LP USI-622-R USI-622-RPC USI-622-RPC-LP USI-624 USI-624-B USI-624-CE USI-624-CE-LP USI-624-CE-R USI-624-LP USI-624-R USI-624-RPC USI-624-RPC-LP USI-624-RPC-T USI-624-R-T USI-624-T USI-626 USI-626-B USI-626-CE USI-626-CE-B USI-626-CE-LP USI-626-CE-R USI-626-CE-RPC-T USI-626-LP USI-626-R USI-626-RPC USI-626-RPC-LP USI-626-RPC-T USI-626-R-T USI-626-T USI-628 USI-628-B USI-628-CE USI-628-CE-B USI-628-CE-LP USI-628-LP			

Product Service

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
USI-628-LP-PD USI-628-R USI-628-RPC USI-628-RPC-LP USI-628-RPC-T USI-628-R-T USI-628-T USI-630 USI-630-B USI-630-LP USI-630-R USI-630-RPC USI-700 USI-700-B USI-700-LP USI-700-R USI-700-RPC USI-700-RPC-T USI-700-R-T USI-712 USI-714 USI-716 USI-716-B USI-718 USI-718-P USI-720 USI-720-B USI-720-LP USI-720-R USI-720-RPC USI-722 USI-722-B USI-722-CE USI-722-LP USI-722-P USI-722-R USI-722-RPC USI-724 USI-724-B USI-724-CE USI-724-LP USI-724-P USI-724-R USI-724-RPC USI-724-RPC-LP USI-724-RPC-T USI-724-R-T USI-726 USI-726-B USI-726-CE USI-726-CE-B USI-726-CE-LP USI-726-LP USI-726-P USI-726-R USI-726-RPC USI-726-RPC-LP USI-726-RPC-T USI-726-R-T USI-728 USI-728-B USI-728-CE USI-728-CE-B USI-728-CE-LP USI-728-LP USI-728-LP-PD USI-728-P USI-728-R USI-728-RPC USI-728-RPC-LP USI-728-RPC-T USI-728-R-T			

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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
USI-728-T USI-730 USI-730-B USI-730-LP USI-730-R USI-730-RPC USI-800 USI-800-B USI-800-R USI-800-R-P USI-800-RPC USI-822 USI-822-B USI-822-R USI-822-RPC USI-824 USI-824-B USI-824-CE USI-824-R USI-824-RPC USI-826 USI-826-B USI-826-CE USI-826-R USI-826-RPC USI-828 USI-828-B USI-828-CE USI-828-R USI-828-RPC USI-830 USI-830-B USI-830-R USI-830-RPC			
BUDI-DI: **0827002CIRL202007020003AX** **Article Numbers:** GEPD-10-12 GEPD-10-15 GEPD-10-3 GEPD-10-5 GEPD-10-7 GEPD-10-9 GEPD-11.5-6 GEPD-11.5-8 GEPD-11.5-10 GEPD-11.5-12 GEPD-3-10 GEPD-3-11 GEPD-3-12 GEPD-3-13 GEPD-3-14 GEPD-3-15 GEPD-3-3 GEPD-3-4 GEPD-3-5 GEPD-3-6 GEPD-3-7 GEPD-3-8 GEPD-3-9 GEPD-5-10 GEPD-5-11 GEPD-5-12 GEPD-5-13 GEPD-5-14 GEPD-5-15 GEPD-5-2	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#

Product Service

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
GEPD-5-3 GEPD-5-4 GEPD-5-5 GEPD-5-6 GEPD-5-7 GEPD-5-8 GEPD-5-9 GEPD-7-10 GEPD-7-11 GEPD-7-12 GEPD-7-13 GEPD-7-14 GEPD-7-15 GEPD-7-3 GEPD-7-4 GEPD-7-5 GEPD-7-6 GEPD-7-7 GEPD-7-8 GEPD-7-9 GEPD-8.5-12 GEPD-8.5-3 GEPD-8.5-5 GEPD-8.5-7 GEPD-8.5-9 GPDS-5-15 GPDS-5-2 GPDS-5-12 GPDS-5-3 GPDS-5-5 GPDS-5-7 GPDS-5-9 GPDS-7-3 GPDS-7-12 GPDS-7-5 GPDS-7-7 GPDS-7-9 GPSO-7-20 GPSO-10-2 GPSO-10-10 GPSO-10-12 GPSO-10-15 GPSO-10-3 GPSO-10-5 GPSO-10-7 GPSO-10-9 GPSO-3-2 GPSO-3-10 GPSO-3-11 GPSO-3-12 GPSO-3-13 GPSO-3-14 GPSO-3-15 GPSO-3-3 GPSO-3-4 GPSO-3-5 GPSO-3-6 GPSO-3-7 GPSO-3-8 GPSO-3-9 GPSO-4-2 GPSO-4-5 GPSO-4-7 GPSO-4-9 GPSO-5-2 GPSO-5-9 GPSO-5-10 GPSO-5-11 GPSO-5-12 GPSO-5-13 GPSO-5-14 GPSO-5-15			

Product Service

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
GPSO-5-18 GPSO-5-3 GPSO-5-4 GPSO-5-5 GPSO-5-6 GPSO-5-7 GPSO-5-8 GPSO-6-2 GPSO-6-3 GPSO-6-5 GPSO-6-7 GPSO-6-9 GPSO-6-12 GPSO-6-15 GPSO-7-2 GPSO-7-10 GPSO-7-11 GPSO-7-12 GPSO-7-13 GPSO-7-14 GPSO-7-15 GPSO-7-18 GPSO-7-3 GPSO-7-4 GPSO-7-5 GPSO-7-6 GPSO-7-7 GPSO-7-8 GPSO-7-9 GPSO-8.5-12 GPSO-8.5-15 GPSO-8.5-3 GPSO-8.5-5 GPSO-8.5-7 GPSO-8.5-9 GPSOS-5-2 GPSOS-5-3 GPSOS-5-4 GPSOS-5-5 GPSOS-5-7 GPSOS-5-9 GPSOS-5-12 GPSOS-5-15 GPSOS-7-2 GPSOS-7-3 GPSOS-7-5 GPSOS-7-7 GPSOS-7-9 GPSOS-7-10 GPSOS-7-12 GPSOS-7-15 SPSOF-10-10 SPSOF-10-12 SPSOF-10-15 SPSOF-10-3 SPSOF-10-4 SPSOF-10-5 SPSOF-10-6 SPSOF-10-7 SPSOF-10-8 SPSOF-4-2 SPSOF-4-4 SPSOF-4-6 SPSOF-4-8 SPSOF-4-10 SPSOF-4-12 SPSOF-4-15 SPSOF-4-18 SPSOF-5-9 SPSOF-5-10 SPSOF-5-11 SPSOF-5-12			

Product Service

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
SPSOF-5-15 SPSOF-5-2 SPSOF-5-2.5 SPSOF-5-3 SPSOF-5-4 SPSOF-5-5 SPSOF-5-6 SPSOF-5-7 SPSOF-5-8 SPSOF-6-2 SPSOF-6-2.5 SPSOF-6-4 SPSOF-6-6 SPSOF-6-8 SPSOF-6-10 SPSOF-6-12 SPSOF-6-15 SPSOF-7-10 SPSOF-7-11 SPSOF-7-12 SPSOF-7-15 SPSOF-7-16 SPSOF-7-18 SPSOF-7-2 SPSOF-7-2.5 SPSOF-7-3 SPSOF-7-4 SPSOF-7-5 SPSOF-7-6 SPSOF-7-7 SPSOF-7-8 SPSOF-7-9 SPSOF-8.5-10 SPSOF-8.5-12 SPSOF-8.5-7 SPSOS-3-10-N SPSOS-3-12-N SPSOS-3-18-N SPSOS-3-4-N SPSOS-3-6-N SPSOS-3-8-N SPSOS-5-3 SPSOS-5-5 SPSOS-5-7 SPSOS-7-3 SPSOS-7-5 ZEPDF-5-9 ZEPDF-7-9 ZEPDF-5-10 ZEPDF-5-12 ZEPDF-5-2 ZEPDF-5-4 ZEPDF-5-5 ZEPDF-5-6 ZEPDF-5-7 ZEPDF-5-8 ZEPDF-7-10 ZEPDF-7-12 ZEPDF-7-15 ZEPDF-7-2 ZEPDF-7-4 ZEPDF-7-5 ZEPDF-7-6 ZEPDF-7-7 ZEPDF-7-8 ZEPDS-5-10 ZEPDS-5-12 ZEPDS-5-2 ZEPDS-5-4 ZEPDS-5-6 ZEPDS-5-8 ZEPDS-7-10			

Product Service

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ZEPDS-7-12 ZEPDS-7-4 ZEPDS-7-6 ZEPDS-7-8 ZPSOF-5-10 ZPSOF-5-12 ZPSOF-5-15 ZPSOF-5-2 ZPSOF-5-3 ZPSOF-5-4 ZPSOF-5-5 ZPSOF-5-6 ZPSOF-5-7 ZPSOF-5-8 ZPSOF-5-9 ZPSOF-7-10 ZPSOF-7-12 ZPSOF-7-15 ZPSOF-7-4 ZPSOF-7-6 ZPSOF-7-7 ZPSOF-7-8 ZPSOF-7-2 ZPSOF-7-9 ZPSOS-5-12 ZPSOS-5-3 ZPSOS-5-5 ZPSOS-5-7 ZPSOS-5-9 ZPSOS-7-10 ZPSOS-7-12 ZPSOS-7-4 ZPSOS-7-6 ZPSOS-7-25-NP ZPSOS-7-8 JPWS-8.5-10 JPWS-8.5-22 JPWS-8.5-12 JPWS-8.5-14 JPWS-8.5-16 JPWS-8.5-18 JPWS-8.5-20 JPWS-10-10 JPWS-10-12 JPWS-10-14 JPWS-10-16 JPWS-10-18 JPWS-10-20 JPWS-10-8 JPWS-8.5-8 JPWS-10-22 GPSO-SF-5-3 GPSO-SF-5-5 GPSO-SF-5-7 GPSO-SF-5-9 GPSO-SF-5-12 GPSOS-SF-5-3 GPSOS-SF-5-5 GPSOS-SF-5-7 GPSOS-SF-5-9 GPSOS-SF-5-12			

Product Service

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
BUDI-DI: **0827002CIRL202009051015DG** **Article Numbers:** ZVT7-35-80-14-6.0 ZVT7-35-80-14-10.0 ZVT7-35-80-14-14.0 ZVT7-35-80-16-6.0 ZVT7-35-80-16-10.0 ZVT7-35-80-16-14.0 ZVT7-35-120-14-6.0 ZVT7-35-120-14-10.0 ZVT7-35-120-14-14.0 ZVT7-35-120-16-6.0 ZVT7-35-120-16-10.0 ZVT7-35-120-16-14.0	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202011049017BC** **Article Numbers:** EVO-22-27-12-D EVO-22-27-6-D EVO-22-27-9-D	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL2020110500249M** **Article Numbers:** ZIB6-40-8-4.0 ZIB6-40-8-6.0 ZIB6-40-8-8.0 ZIB6-40-9-4.0 ZIB6-40-9-6.0 ZIB6-40-9-8.0 ZIB6-40-10-4.0 ZIB6-40-10-6.0 ZIB6-40-10-8.0 ZIB6-40-12-4.0 ZIB6-40-12-6.0 ZIB6-40-12-8.0 ZIB6-40-14-4.0 ZIB6-40-14-6.0 ZIB6-40-14-8.0 ZIB6-40-6-4.0 ZIB6-40-6-6.0 ZIB6-40-6-8.0	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202011055020AG** **Article Numbers:** ZFV6-125-5-2.0 ZFV6-125-5-3.0	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or

Product Service

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ZFV6-125-5-4.0 ZFV6-125-5-6.0 ZFV6-125-5-8.0 ZFV6-125-5-10.0 ZFV6-125-5-12.0 ZFV6-125-5-14.0 ZFV6-125-5-17.0 ZFV6-125-6-2.0 ZFV6-125-6-3.0 ZFV6-125-6-4.0 ZFV6-125-6-6.0 ZFV6-125-6-8.0 ZFV6-125-6-10.0 ZFV6-125-6-12.0 ZFV6-125-6-14.0 ZFV6-125-7-2.0 ZFV6-125-7-3.0 ZFV6-125-7-4.0 ZFV6-125-7-6.0 ZFV6-125-7-8.0 ZFV6-125-7-10.0 ZFV6-125-7-12.0 ZFV6-125-7-14.0 ZFV6-125-8-2.0 ZFV6-125-8-3.0 ZFV6-125-8-4.0 ZFV6-125-8-6.0 ZFV6-125-8-8.0 ZFV6-125-8-10.0 ZFV6-125-8-12.0 ZFV6-125-8-14.0 ZFV6-125-9-2.0 ZFV6-125-9-3.0 ZFV6-125-9-4.0 ZFV6-125-9-6.0 ZFV6-125-9-8.0 ZFV6-125-9-10.0 ZFV6-125-9-12.0 ZFV6-125-9-14.0 ZFV6-125-10-2.0 ZFV6-125-10-3.0 ZFV6-125-10-4.0 ZFV6-125-10-6.0 ZFV6-125-10-8.0 ZFV6-125-10-10.0 ZFV6-125-10-12.0 ZFV6-125-10-14.0 ZFV6-125-5-20.0 ZFV6-125-6-17.0 ZFV6-125-6-20.0 ZFV6-125-7-17.0 ZFV6-125-7-20.0 ZFV6-125-8-17.0 ZFV6-125-8-20.0 ZFV6-80-5-2.0 ZFV6-80-5-3.0 ZFV6-80-5-4.0 ZFV6-80-5-6.0 ZFV6-80-5-8.0 ZFV6-80-5-10.0 ZFV6-80-5-12.0 ZFV6-80-5-14.0 ZFV6-80-6-2.0 ZFV6-80-6-3.0 ZFV6-80-6-4.0 ZFV6-80-6-6.0 ZFV6-80-6-8.0 ZFV6-80-6-10.0 ZFV6-80-6-12.0 ZFV6-80-6-14.0 ZFV6-80-7-2.0 ZFV6-80-7-3.0	☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☐ 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#

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ZFV6-80-7-4.0 ZFV6-80-7-6.0 ZFV6-80-7-8.0 ZFV6-80-7-10.0 ZFV6-80-7-12.0 ZFV6-80-7-14.0 ZFV6-80-8-2.0 ZFV6-80-8-3.0 ZFV6-80-8-4.0 ZFV6-80-8-6.0 ZFV6-80-8-8.0 ZFV6-80-8-10.0 ZFV6-80-8-12.0 ZFV6-80-8-14.0 ZFV6-80-9-2.0 ZFV6-80-9-3.0 ZFV6-80-9-4.0 ZFV6-80-9-6.0 ZFV6-80-9-8.0 ZFV6-80-9-10.0 ZFV6-80-9-12.0 ZFV6-80-9-14.0 ZFV6-80-10-10.0 ZFV6-80-10-12.0 ZFV6-80-10-14.0 ZFV6-80-10-2.0 ZFV6-80-10-3.0 ZFV6-80-10-4.0 ZFV6-80-10-6.0 ZFV6-80-10-8.0 ZFV6-80-5-17.0 ZFV6-80-5-20.0 ZFV6-80-6-17.0 ZFV6-80-6-20.0 ZFV6-80-7-17.0 ZFV6-80-8-17.0 ZFV6-80-8-20.0 ZFV6-80-7-20.0			
BUDI-DI: **0827002CIRL202011056021AR** **Article Numbers:** ZIV5-80-4-2.0 ZIV5-80-4-3.0 ZIV5-80-4-4.0 ZIV5-80-4-6.0 ZIV5-80-4-8.0 ZIV5-80-5-2.0 ZIV5-80-5-3.0 ZIV5-80-5-4.0 ZIV5-80-5-6.0 ZIV5-80-5-8.0 ZIV5-80-6-2.0 ZIV5-80-6-3.0 ZIV5-80-6-4.0 ZIV5-80-6-6.0 ZIV5-80-6-8.0 ZIV5-80-7-2.0 ZIV5-80-7-3.0 ZIV5-80-7-4.0 ZIV5-80-7-6.0 ZIV5-80-7-8.0 ZIV5-80-8-2.0 ZIV5-80-8-3.0 ZIV5-80-8-4.0 ZIV5-80-8-6.0 ZIV5-80-8-8.0 ZIV5-80-9-2.0 ZIV5-80-9-3.0 ZIV5-80-9-4.0	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#

Product Service

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
ZIV5-80-9-6.0 ZIV5-80-9-8.0 ZIV5-80-10-2.0 ZIV5-80-10-3.0 ZIV5-80-10-4.0 ZIV5-80-10-6.0 ZIV5-80-10-8.0 ZIV5-125-4-2.0 ZIV5-125-4-3.0 ZIV5-125-4-4.0 ZIV5-125-4-6.0 ZIV5-125-4-8.0 ZIV5-125-5-2.0 ZIV5-125-5-3.0 ZIV5-125-5-4.0 ZIV5-125-5-6.0 ZIV5-125-5-8.0 ZIV5-125-6-2.0 ZIV5-125-6-3.0 ZIV5-125-6-4.0 ZIV5-125-6-6.0 ZIV5-125-6-8.0 ZIV5-125-7-2.0 ZIV5-125-7-3.0 ZIV5-125-7-4.0 ZIV5-125-7-6.0 ZIV5-125-7-8.0 ZIV5-125-8-2.0 ZIV5-125-8-3.0 ZIV5-125-8-4.0 ZIV5-125-8-6.0 ZIV5-125-8-8.0 ZIV5-125-9-2.0 ZIV5-125-9-3.0 ZIV5-125-9-4.0 ZIV5-125-9-6.0 ZIV5-125-9-8.0 ZIV5-125-10-2.0 ZIV5-125-10-3.0 ZIV5-125-10-4.0 ZIV5-125-10-6.0 ZIV5-125-10-8.0 ZIV6-80-5-2.0 ZIV6-80-5-3.0 ZIV6-80-5-4.0 ZIV6-80-5-6.0 ZIV6-80-5-8.0 ZIV6-80-6-2.0 ZIV6-80-6-3.0 ZIV6-80-6-4.0 ZIV6-80-6-6.0 ZIV6-80-6-8.0 ZIV6-80-7-2.0 ZIV6-80-7-3.0 ZIV6-80-7-4.0 ZIV6-80-7-6.0 ZIV6-80-7-8.0 ZIV6-80-8-2.0 ZIV6-80-8-3.0 ZIV6-80-8-4.0 ZIV6-80-8-6.0 ZIV6-80-8-8.0 ZIV6-80-9-2.0 ZIV6-80-9-3.0 ZIV6-80-9-4.0 ZIV6-80-9-6.0 ZIV6-80-9-8.0 ZIV6-80-10-2.0 ZIV6-80-10-3.0 ZIV6-80-10-4.0 ZIV6-80-10-6.0 ZIV6-80-10-8.0			

Product Service

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
ZIV6-80-12-3.0 ZIV6-80-12-4.0 ZIV6-80-12-6.0 ZIV6-80-12-8.0 ZIV6-80-14-3.0 ZIV6-80-14-4.0 ZIV6-80-14-6.0 ZIV6-80-14-8.0 ZIV6-125-5-2.0 ZIV6-125-5-3.0 ZIV6-125-5-4.0 ZIV6-125-5-6.0 ZIV6-125-5-8.0 ZIV6-125-6-2.0 ZIV6-125-6-3.0 ZIV6-125-6-4.0 ZIV6-125-6-6.0 ZIV6-125-6-8.0 ZIV6-125-7-2.0 ZIV6-125-7-3.0 ZIV6-125-7-4.0 ZIV6-125-7-6.0 ZIV6-125-7-8.0 ZIV6-125-8-2.0 ZIV6-125-8-3.0 ZIV6-125-8-4.0 ZIV6-125-8-6.0 ZIV6-125-8-8.0 ZIV6-125-9-2.0 ZIV6-125-9-3.0 ZIV6-125-9-4.0 ZIV6-125-9-6.0 ZIV6-125-9-8.0 ZIV6-125-10-2.0 ZIV6-125-10-3.0 ZIV6-125-10-4.0 ZIV6-125-10-6.0 ZIV6-125-10-8.0 ZIV6-125-12-3.0 ZIV6-125-12-4.0 ZIV6-125-12-6.0 ZIV6-125-12-8.0 ZIV6-125-14-3.0 ZIV6-125-14-4.0 ZIV6-125-14-6.0 ZIV6-125-14-8.0			
BUDI-DI: **0827002CIRL202011064022AQ** **Article Numbers:** EVO-PC-8-9-6-B EVO-PC-8-9-8-B EVO-PC-10-11-4-B EVO-PC-10-11-6-B EVO-PC-10-11-8-B EVO-FC-8-9-6-B EVO-FC-8-9-8-B EVO-FC-10-11-4-B EVO-FC-10-11-6-B EVO-FC-10-11-8-B	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202309008036FP** **Article Numbers:** UFI-522	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or

Product Service

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
UFI-524 UFI-526 UFI-528 UFI-530 UFI-622 UFI-624 UFI-626 UFI-628 UFI-630 UFI-722 UFI-724 UFI-726 UFI-728 UFI-822 UFI-824 UFI-826 UFI-828 UFI-500 UFI-600 UFI-700 UFI-522-R UFI-524-R UFI-526-R UFI-528-R UFI-622-R UFI-624-R UFI-626-R UFI-628-R UFI-722-R UFI-724-R UFI-726-R UFI-728-R UFI-822-R UFI-824-R UFI-826-R UFI-828-R UFI-500-R UFI-600-R UFI-700-R UFI-622-B UFI-624-B UFI-626-B UFI-726-B UFI-500-B UFI-600-B UFI-700-B UFI-522-RPC-LP UFI-524-RPC-LP UFI-526-RPC-LP UFI-528-RPC-LP UFI-622-RPC-LP UFI-624-RPC-LP UFI-626-RPC-LP UFI-628-RPC-LP UFI-722-RPC-LP UFI-724-RPC-LP UFI-726-RPC-LP UFI-728-RPC-LP UFI-500-RPC-LP UFI-600-RPC-LP UFI-700-RPC-LP UFI-626-LP UFI-724-LP UFI-726-P UFI-728-P UFI-626-P UFI-628-P UFI-500-LP UFI-600-LP UFI-700-LP	☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☐ 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#

Product Service

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
BUDI-DI: **0827002CIRL202011065016B4** **Article Numbers:** EVO-8-9-4-B EVO-8-9-6-B EVO-8-9-8-B EVO-8-9-10-B EVO-10-11-4-B EVO-10-11-6-B EVO-10-11-8-B EVO-10-11-10-B	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202011063030AG** **Article Numbers:** ZILBS-635-10-4 ZILBS-635-10-6 ZILBS-635-10-8 ZILBS-635-6-4 ZILBS-635-6-6 ZILBS-635-6-8 ZILBS-635-8-4 ZILBS-635-8-6 ZILBS-635-8-8 ZILBS-635-10-10 ZILBS-635-10-12 ZILBS-635-8-10 ZILBS-635-8-12 ZILBS-635-6-10 ZILBS-635-6-12	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202011068027BW** **Article Numbers:** EVO-25-30-10-C EVO-25-30-6-C EVO-25-30-8-C	☐ 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: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; 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#
BUDI-DI: **0827002CIRL202011069028C7** **Article Numbers:** EVO-20-25-10-E EVO-20-25-12.5-E EVO-20-25-15-E EVO-20-25-8-E EVO-FC-18-23-10-E EVO-FC-18-23-12-E EVO-FC-18-23-8-E	☐ Class III ☒ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: N\A	☒ Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or ☐ Evidence that a competent authority of a Member State