

**Manufacturer:**

Arrow International LLC  
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 3015 Carrington Mill Blvd.  
 Morrisville  
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 27560  
 USA

**European Representative:**

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Arrow International, Inc.  
 Subsidiary of Teleflex Incorporated  
 2400 Bernville Rd.  
 Reading, PA 19605  
 USA

<b>Product Name:</b>	<b>Arterial Catheterization Devices</b>		
<b>TECHNICAL FILE OR DESIGN DOSSIER #</b>	<b>T-BSI-015</b>	<b>Classification:</b>	<b>IIa</b>
<b>GMDN Code:</b>	<b>64575 Peripheral Artery Cannula</b>		

<b>GMDN Code:</b>	<b>64575 Peripheral Artery Cannula</b>	<b>Classification:</b>	<b>IIa</b>
<b>Arterial Finished Good Number</b>	<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
AD-04018	Arterial Catheterization Set 18 Ga. x 12 cm (5")	12- Apr-07	
AV-04020	Arterial/Venous Catheterization Set 20 Ga. x 4.45 cm (1-3/4")	12-Nov-98	
BB-01218	Arterial Catheterization Kit 18 Ga. x 12 cm (5")	21-Jun-06	
BB-04018	Arterial Catheterization Kit 18 Ga. x 12 cm (5")	06-Jan-00	
BB-04018-GH	Arterial Catheterization Kit 18 Ga. x 12 cm (5")	16-Jan-01	
CH-00820P-CSB	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	24-Nov-20	
CH-00820P-KM	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	25-Sep-18	
CK-04018	Arterial Catheterization Set 18 Ga. x 12 cm (5")	12-Apr-07	
DE-00820-BAB	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	30-May-17	
DE-00820-OLD	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	28-Oct-09	
DE-00820-EKBI	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	29-Aug-13	
DE-00820-MKHS	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	04-Jan-17	
DE-00820P-MKHS	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	08-Apr-20	
DE-00820-MSG	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	09-May-18	
DE-00820-UB	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	04-Jan-17	
DE-00820-VB	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	06-Apr-17	
DE-00820-WKKH	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	27-Mar-14	
DE-00820-WO1	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	12-May-17	
DE-00820P-BOT	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	12-Jul-18	
DE-00820P-ZNAN	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	10-Aug-20	
DE-01618-HZO	Arterial Catheterization Kit 18 Ga. x 16 cm (6-1/4")	11-Feb-11	
DE-01618-OLD	Arterial Catheterization Kit 18 Ga. x 16 cm (6-1/4")	13-Sep-17	
DE-01618-VB	Arterial Catheterization Kit 18 Ga. x 16 cm (6-1/4")	06-Apr-17	
DE-01618-ZB	Arterial Catheterization Set 18 Ga. x 16 cm (6-1/4")	06-Jan-10	
DE-01618P-ZNAN	Arterial Catheterization Kit 18 Ga. x 16 cm (6-1/4")	10-Aug-20	
FA-04016	Arterial/Venous Catheterization Set 16 Ga. x 17.8 cm (7")	02-Nov-98	
FA-04018	Arterial Catheterization Set 18 Ga. x 10.8 cm (4-1/4")	12-Apr-07	
FA-04020	Arterial Catheterization Set 20 Ga. x 10.8 cm (4-1/4")	02-Nov-98	

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<b>GMDN Code:</b>	<b>64575 Peripheral Artery Cannula</b>	<b>Classification:</b>	<b>IIa</b>
<b>Arterial Finished Good Number</b>	<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
GH-04120	Radial Artery Catheterization Set 20 Ga. x 6.35 cm (2-1/2")	04-Feb-98	
GH-04120-E	Radial Artery Catheterization Set 20 Ga. x 7.78 cm (3-1/16")	03-Mar-98	
GH-04122	Radial Artery Catheterization Set 20 Ga. x 3.49 cm (1.37")	04-Feb-98	
GH-04125	Arterial Catheterization Set 20 Ga. x 7.78 cm (3-1/16")	03-Mar-98	
GH-04150	Femoral Artery Catheterization Set 20 Ga. x 20 cm (8")	02-Mar-98	
MONZINO-00818	Arterial Catheterization Set 18 Ga. x 8 cm (3.14")	11-Apr-07	
NL-00520-CZE	Arterial Catheterization Set 20 Ga. x 5 cm (1.90")	10-Oct-16	
NL-00520-HMC	Arterial Catheterization Kit 20 Ga. x 5 cm (1.90")	29-May-18	
NL-00520-MUMC	Arterial Catheterization Kit 20 Ga. x 5 cm (1.90")	29-Feb-16	
NL-00822P-LZR	Arterial Catheterization Kit 22 Ga. x 8 cm (3.14")	24-Nov-20	
NL-00820-ZUY	Arterial Catheterization Kit 20 Ga. x 8 cm (3.14")	27-May-16	
NL-01618-CZE	Femoral Artery Catheterization Set 18 Ga. x 16 cm (6-1/4")	10-Oct-16	
NL-01618-HMC	Femoral Artery Catheterization Kit 18 Ga. x 16 cm (6-1/4")	29-May-18	
NL-01618-ZUY	Femoral Artery Catheterization Kit 18 Ga. x 16 cm (6-1/4")	27-May-16	
OY-04022	Radial Artery Catheterization Set 22 Ga. x 4.45 cm (1-3/4")	14-Mar-02	
RA-04018	Radial Artery Catheterization Set 18 Ga. x 4.45 cm (1-3/4")	16-Jun-05	
RA-04020	Radial Artery Catheterization Set 20 Ga. x 4.45 cm (1-3/4")	12-Oct-04	
RA-04022	Radial Artery Catheterization Set 22 Ga. x 4.45 cm (1-3/4")	31-Jul-06	
RA-04120	Radial Artery Catheterization Set 20 Ga. x 3.81 cm (1-1/2")	11-Nov-04	
RA-04122	Radial Artery Catheterization Set 22 Ga. x 3.49 cm (1-3/8")	12-Oct-04	
RA-04220	QuickFlash Set 20 Ga. x 3.81 cm (1-1/2")	11-Nov-04	
RA-04220-W	QuickFlash Set 20 Ga. x 3.81 cm (1-1/2")	01-Apr-04	
TI-00820-IR	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	21-Nov-20	
ZB-00820	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	06-Jun-06	
SAC-00324	Arterial Catheterization Set 24 Ga. x 2.5 cm (1")	11-Nov-08	
SAC-00520	Arterial Catheterization Set 20 Ga. x 5 cm (2")	08-Jan-04	
SAC-00522	Arterial Catheterization Set 22 Ga. x 5 cm (2")	03-Jul-04	
SAC-00524	Arterial Catheterization Set 24 Ga. x 5 cm (2")	20-Nov-08	
SAC-00818	Arterial Catheterization Set 18 Ga. x 8 cm (3.14")	08-Jan-04	
SAC-00820	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	20-Nov-08	
SAC-00822	Arterial Catheterization Set 22 Ga. x 8 cm (3-1/8")	15-Mar-05	
SAC-01218	Arterial Catheterization Set 18 Ga. x 12 cm (5")	20-Dec-04	
SAC-01220	Arterial Catheterization Set 20 Ga. x 12 cm (5")	16-Mar-05	
SAC-01222	Arterial Catheterization Set 22 Ga. x 12 cm (5")	16-Mar-05	
SAC-01618	Arterial Catheterization Set 18 Ga. x 16 cm (6-1/4")	16-Mar-05	
SAC-01620	Arterial Catheterization Set 20 Ga. x 16 cm (6-1/4")	16-Mar-05	
SAC-02318	Arterial Catheterization Set 18 Ga. x 23 cm (9-1/4")	08-Jan-04	
SAC-00324-PBX	Arterial Catheterization Set 24 Ga. x 2.5 cm (1")	01-Dec-16	
SAC-00520-PBX	Arterial Catheterization Set 20 Ga. x 5 cm (2")	01-Dec-16	
SAC-00522-PBX	Arterial Catheterization Set 22 Ga. x 5 cm (2")	01-Dec-16	
SAC-00524-PBX	Arterial Catheterization Set 24 Ga. x 5 cm (2")	01-Dec-16	
SAC-00818-PBX	Arterial Catheterization Set 18 Ga. x 8 cm (3.14")	01-Dec-16	
SAC-00820-PBX	Arterial Catheterization Set 20 Ga. x 8 cm (3-1/8")	01-Dec-16	
SAC-00822-PBX	Arterial Catheterization Set 22 Ga. x 8 cm (3-1/8")	01-Dec-16	
SAC-01218-PBX	Arterial Catheterization Set 18 Ga. x 12 cm (5")	01-Dec-16	
SAC-01220-PBX	Arterial Catheterization Set 20 Ga. x 12 cm (5")	01-Dec-16	
SAC-01222-PBX	Arterial Catheterization Set 22 Ga. x 12 cm (5")	01-Dec-16	

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GMDN Code:	64575 Peripheral Artery Cannula	Classification:	Iia
Arterial Finished Good Number	Device Description	Date CE Mark First Affixed	
SAC-01618-PBX	Arterial Catheterization Set 18 Ga. x 16 cm (6-1/4")	01-Dec-16	
SAC-01620-PBX	Arterial Catheterization Set 20 Ga. x 16 cm (6-1/4")	01-Dec-16	
SAC-02318-PBX	Arterial Catheterization Set 18 Ga. x 23 cm (9-1/4")	01-Dec-16	
UK-00820P-ART	Arterial Catheterization Kit 20 Ga. x 8 cm (3-1/8")	20-Jun-18	

Arterial Part # (if applicable)	Device Description
A-04016-015	Catheter: 16 Ga. x 17.8 cm (7") over 19 Ga. Introducer Needle
A-04018-005	Catheter: 18 Ga. x 4.45 cm (1-3/4") over 20 Ga. Introducer Needle with Integral 0.64mm (.025") dia. Spring-Wire Guide
A-04018-009	Catheter: 18 Ga. x 10.8 cm (4-1/4") over 20 Ga. Introducer Needle
A-04020-011A	Catheter: 18 Ga. x 10.8 cm (4-1/4") over 20 Ga. Introducer Needle
A-04022-001	Catheter: 22 Ga. x 4.45 cm (1-3/4") over 25 Ga. Introducer Needle
A-04120-012A	Catheter: 20 Ga. x 3.81 cm (1-1/2") over 22 Ga. Needle with Integral 0.46 mm (.018") dia. Spring-Wire Guide
A-04122-010	Catheter: 22 Ga. x 3.49 cm (1-3/8")
A-04122-012	Catheter: 22 Ga. x 3.49 cm (1-3/8") over 23 Ga. Introducer Needle
A-04220-009C	QuickFlash Catheter: 20 Ga. x 3.81 cm (1-1/2") over 21 Ga. Needle with Integral 0.46 mm (.018") dia. Spring-Wire Guide
H-04120-003B	Catheter: 20 Ga. x 6.35 cm (2-1/2")
H-04120-005	Catheter: 20 Ga. x 7.78 cm (3-1/16")
H-04125-001	Catheter: 20 Ga. x 7.78 cm (3-1/16")
H-04150-004	Catheter: 20 Ga. x 20 cm (8")
K-04018-001B	Catheter: 18 Ga. x 12 cm (5")
K-04124-001	Catheter: 24 Ga. x 4 cm (1-5/8")
K-04220-003A	Catheter: 20 Ga. x 3.81 cm (1-1/2") over 21 Ga. Introducer Needle with Integral 0.46 mm (.018") dia. Spring-Wire Guide
K-14402-003	Catheter: 22 Ga. x 4.45 cm (1-3/4") over 25 Ga. Introducer Needle
P-04020-005C	Catheter: 20 Ga. x 4.45 cm (1-3/4") over 22 Ga. Introducer Needle
P-04020-007A	Catheter: 20 Ga. x 4.45 cm (1-3/4") over 22 Ga. Introducer Needle with Integral 0.46 mm (.018") dia. Spring-Wire Guide
PCZ-00324-001	Hydrophilic Catheter: 24 Ga. x 2.5 cm (1")
PCZ-00324-002	Hydrophilic Catheter: 24 Ga. x 2.5 cm (1")
PCZ-00520-001	Hydrophilic Catheter: 20 Ga. x 5 cm (2")
PCZ-00520-001A	Hydrophilic Catheter: 20 Ga. x 5 cm (2")
PCZ-00520-002	Hydrophilic Catheter: 20 Ga. x 5 cm (2")
PCZ-00522-001	Hydrophilic Catheter: 22 Ga. x 5 cm (2")
PCZ-00522-002	Hydrophilic Catheter: 22 Ga. x 5 cm (2")
PCZ-00524-001	Hydrophilic Catheter: 24 Ga. x 5 cm (2")
PCZ-00524-002	Hydrophilic Catheter: 24 Ga. x 5 cm (2")
PCZ-00818-001	Hydrophilic Catheter: 18 Ga. x 8 cm (3-1/8")
PCZ-00818-002	Hydrophilic Catheter: 18 Ga. x 8 cm (3-1/8")
PCZ-00820-001	Hydrophilic Catheter: 20 Ga. x 8 cm (3-1/8")
PCZ-00820-001A	Hydrophilic Catheter: 20 Ga. x 8 cm (3-1/8")
PCZ-00820-002	Hydrophilic Catheter: 20 Ga. x 8 cm (3-1/8")
PCZ-00822-001	Hydrophilic Catheter: 22 Ga. x 8 cm (3-1/8")

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Arterial Part # (if applicable)	Device Description
PCZ-00822-002	Hydrophilic Catheter: 22 Ga. x 8 cm (3-1/8")
PCZ-01218-001	Hydrophilic Catheter: 18 Ga. x 12 cm (5")
PCZ-01218-002	Hydrophilic Catheter: 18 Ga. x 12 cm (5")
PCZ-01220-001	Hydrophilic Catheter: 20 Ga. x 12 cm (5")
PCZ-01220-001A	Hydrophilic Catheter: 20 Ga. x 12 cm (5")
PCZ-01220-002	Hydrophilic Catheter: 20 Ga. x 12 cm (5")
PCZ-01222-001	Hydrophilic Catheter: 22 Ga. x 12 cm (5")
PCZ-01222-002	Hydrophilic Catheter: 22 Ga. x 12 cm (5")
PCZ-01618-001	Hydrophilic Catheter: 18 Ga. x 16 cm (6-1/2")
PCZ-01618-002	Hydrophilic Catheter: 18 Ga. x 16 cm (6-1/2")
PCZ-01620-001	Hydrophilic Catheter: 20 Ga. x 16 cm (6-1/2")
PCZ-01620-001A	Hydrophilic Catheter: 20 Ga. x 16 cm (6-1/2")
PCZ-01620-002	Hydrophilic Catheter: 20 Ga. x 16 cm (6-1/2")
PCZ-02318-001	Hydrophilic Catheter: 18 Ga. x 23 cm (9-1/4")
PCZ-02318-002	Hydrophilic Catheter: 18 Ga. x 23 cm (9-1/4")
PZ-00818-002	Hydrophilic Catheter: 18 Ga. x 8 cm (3-1/8")
PZ-00820-002	Hydrophilic Catheter: 20 Ga. x 8 cm (3-1/8")
PZ-00820-002A	Hydrophilic Catheter: 20 Ga. x 8 cm (3-1/8")
PZ-01218-002	Hydrophilic Catheter: 18 Ga. x 12 cm (5")

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 05 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).

Other: \_\_\_\_\_

**CERTIFICATE NUMBERS:**

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

Annex II.4 Certificate (Class III products only) **N/A**

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

Arrow International, Inc./Arrow International LLC

**Krista Hughes** 

Regulatory Management or Designee (Print and Sign)

**24-NOV-2020**

Date

**Angel Diaz** 

Senior Manager Quality Assurance or Designee (Print and Sign)

**23 Nov 2020**

Date

**REVISION HISTORY:**

Rev Level	Date	Description

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Rev Level	Date	Description
0	10 Nov-2009	Original issue (Created Declaration of Conformity for Arterial Catheterization Devices from DC-BSI-024, DC-BSI-045, and DC-BSI-046).
1	07 Jan- 2010	Addition of DE-01618-ZB.
2	7- Mar- 2011	Addition of new SAC kit: DE-00820-RB
3	22-Jun-2011	Declaration of Conformity updated to new format, Addition of new Transradial artery access kits: AA-10607-1, AA-10611-1, AA-10624-1
4	1-Sep-2011	Addition of new TransRadial Artery Access kits AA-10407-1, AA-10507-1 and AA-10511-1. Added GMDN Codes. Added GH-04120, GH-04120-E, GH-04122, GH-04124, GH-04125 and GH-04150 back to DC; they were erroneously removed from the DC from Rev 0 to Rev 1.
5	22-Nov-2011	Addition of new finished good DE-01618-HZO per ECR-013872. This product is EASK for Germany.
6	20-Dec-2011	Added finished good AA-10607-1D.
7	4-Sep-2012	Added new finished goods AA-10411-1, AA-10524-1, AA-15511-3, AA-15611-3, AA-20407-1, AA-20411-1, AA-20507-1, AA-20511-1, AA-20524-1, AA-20607-1, AA-20611-1, AA-20624-1, AA-30407-1, AA-30411-1, AA-30507-1, AA-30511-1, AA-30524-1, AA-30607-1, AA-30611-1, AA-30624-1 per ECR-016326.
8	29-Aug-2013	Added component part numbers to support the procedure pack initiative. Removed the following product codes that have been made inactive/obsolete: AA-10607-1D, UN-00820, UW-04120-C, and ZB-01618. Added DE-00820-EKBI per ECR-017888.
9	10-Mar-2014	Added TI-00820-IR per ECR-016488. Removed KZ-04120-001, KZ-04018-001, KZ-041124-001, KZ-014402-008 per ECR-019142. Based on previous EASK usage added PCZ-00520-001, PCZ-00522-001, PCZ-00818-001, PCZ-00822-001, PCZ-01218-001, PCZ-01220-001, PCZ-01222-001, and PCZ-02318-001. Added UK-00820-ART per ECR-020804.
10	1-Apr-2014	Update format to indicate market specific codes. Added DE-00820-WKKH per ECR-021128.
11	19-Oct-2015	Updated components to include A-04122-012 used in RA-04122, updated GMDN code due to obsolete code and separated finished goods and components by GMDN codes.
12	29-Feb-16	Moved Transradial to new technical file T-BSI-058 and products to DC-T-BSI-058. Added NL-00520-MUMC per ECR-027174/ECO-038149
13	27-May-2016	Added NL-00820-ZUY and NL-01618-ZUY per ECR-027939
14	10-Oct-2016	Added NL-01618-CZE and NL-00520-CZE per ECR-028596
15	01-Dec-2016	Added PCZ-00324-002, PCZ-00520-002, PCZ-00522-002, PCZ-00524-002, PCZ-00818-002, PCZ-00820-002, PCZ-00822-002, PCZ-01218-002, PCZ-01220-002, PCZ-01222-002, PCZ-01618-002, PCZ-01620-002, PCZ-02318-002, SAC-00818-PBX, SAC-01218-PBX, SAC-01618-PBX, SAC-02318-PBX, SAC-00520-PBX, SAC-00820-PBX, SAC-01220-PBX, SAC-01620-PBX, SAC-00522-PBX, SAC-00822-PBX, SAC-01222-PBX, SAC-00324-PBX, and SAC-00524-PBX per ERC-028490. Added DE-00820-MKHS, DE-00820-UB and DE-00820-WO per ECR-029803
16	17-Feb-2017	Removed procedure pack # under the product name section as it is not applicable.
17	07-Apr-2017	Added DE-00820-VB and DE-01618-VB as per ECR-030402
18	1-Jun-2017	Added DE-00820-BAB per ECR-030971
19	22-Sep-2017	Added DE-01618-OLD per ECR-031771
20	14-Dec-2017	Added DE-00820-WO1 as per ECR-032501.
21	21-Mar-2018	Added DE-01618-UMA for a custom EASK kit configuration request that uses the same catheter as the already CE marked SAC-01618, as per ECR-032997. Corrected Finished Good Number PCZ-01618-001, previously erroneously written as PCZ-01681-001.
22	15-May-2018	Added DE-00820-MSG for a custom EASK kit configuration request that uses the same catheter as the already CE marked SAC-00820, as per ECR-033342.
23	20-Jun-2018	Added NL-00520-HMC and NL-01618-HMC for a custom EASK kit configuration request that uses the same catheter as the already CE marked SAC-00520 and SAC-01618, as per ECR-033524. Added UK-00820P-ART for a custom EASK Kit configuration request that uses already CE marked catheter PCZ-00820-001, as per ECR-033708/ECO-050149.

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Rev Level	Date	Description
24	12-Jul-2018	Added DE-00820P-BOT for a custom EASK Kit configuration request that uses already CE marked catheter PCZ-00820-002, as per ECR-033450/ECO-049547.
25	25-Sep-2018	Added CH-00820P-KM for a custom EASK Kit configuration request that uses already CE marked catheter PCZ-00820-002 and all already production components, as per ECR-034241/ECO-050912. Updated revision of document from rev 7 to rev 8.
26	21-Mar-2019	Removed AA-15511-S, a transradial product, and K-15511-001, used only in transradial products. Removed AG-04120, HZ-04125-001, AZ-04022-001, PC-00520-001, PC-00522-001, PC-00818-001, PC-00820-001, PC-00822-001, PC-01218-001, PC-01220-001, PC-01618-001, PC-01620-001, PC-02318-001 due to being obsolete. Added A-04220-009C, P-04020-005C, PCZ-00820-001A, PCZ-00520-001A, P-04020-007A, A-04018-005, PZ-00820-002A due to them being used in a CE marked FG, but was not previously listed on this DOC. Removed A-04122-003B, A-04220-009B, P-04020-005A, P-04020-007, due to not being used in any CE marked kits.
27	09-Jan-2020	Updated GMDN codes, due to previous code becoming obsolete.
28	02-Apr-2020	Updated representatives to be current. Updated notified body number from 0086 to 2797 due to transition of FQA certificate from BSI UK to BSI Netherlands.
29	24-Apr-2020	Added DE-00820P-MKHS for a custom EASK Kit configuration request that is based on CE marked DE-00820-MKHS but will use the Pebax SAC catheter that is also already CE marked PCZ-00820-002, per ECR-037538/ECO-058152. Removed A-04014-015, PZ-01218-003 due to not being used in any CE marked production lifecycle FGs.
30	10-Aug-2020	Added DE-00820P-ZNAN and DE-01618P-ZNAN that are based on CE marked DE-00820-UB. DE-00820P-ZNAN will contain CE marked catheter PCZ-00820-002 and CE marked drape K-12703-001 (DC-T-BSI-039) and DE-01618P-ZNAN will use CE marked catheter PCZ-01618-002, SWG ATZ-02545-001 (DC-T-BSI-057), introducer needle K-00718-001A (DC-T-BSI-003), and drape K-12703-001 (DC-T-BSI-039) as per ECR-037560/ECO-058221. 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.
31	24-Nov-2020	Removed AE-04018, BB-04018-C, DE-00820-RB, DE-00820-WO, DE-01618-UMA, FA-04014, GH-04124, and UK-00820-ART due to being inactive with no inventory. Added NL-00822P-LZR (Netherlands), based on SAC-00822-PBX with additional CE marked kit components such as additional drape and needle, and CH-00820P-CSB (Switzerland), based on SAC-00822-PBX with additional CE marked kit components such as additional drape and needle, as per ECR-038516/ ECO-060664. The components added to both NL-00822P-LZR and CH-00820P-CSB are all CE marked and the mutual compatibility of the new components has been confirmed.

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