

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA

Holds Certificate No:

**FM 512674**

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

Please see scope page.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-12-19

Latest Revision Date: 2019-10-30

Effective Date: 2019-10-31

Expiry Date: 2021-10-30

Page: 1 of 5



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Certificate No: **FM 512674**

## Registered Scope:

Design, development, manufacture, servicing and distribution of the following catheters: intravascular, anesthesia, hemodialysis, abdominal, thoracic and pleural drainage, atherectomy, electrophysiology/pacing, transradial, thermolulution, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolectomy, vascular positioning system (VPS) stylets, consoles and accessories, plus components and accessories for the above product lines. Contract manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal. Design and development of needle sets, drivers, and accessories for intraosseous vascular access, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy, and pelvic stabilization device.

Devices include: Embolectomy Thrombectomy Rotational Catheters and rotor, vascular access, intravascular administration sets, intra-aortic balloon pumps, ultrasonic cardiac blood flow monitors, spring wire guides, percutaneous sheath introducers, intraosseous needle sets, drivers, and accessories, and pelvic stabilization device. Processing and packaging of sutures and the manufacturing of feeding tubes.



Original Registration Date: 2006-12-19

Latest Revision Date: 2019-10-30

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Expiry Date: 2021-10-30

Page: 2 of 5

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 512674**

Location	Registered Activities
Arrow International, Inc. (subsidiary of Teleflex, Incorporated) 2400 Bernville Road Reading Pennsylvania 19605 USA	<p>Design, development, manufacture, servicing and distribution of the following catheters: intravascular, anesthesia, hemodialysis, abdominal, thoracic and pleural drainage, atherectomy, electrophysiology/pacing, transradial, thermodilution, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolectomy, vascular positioning system (VPS) stylets, consoles and accessories, plus components and accessories for the above product lines. Contract manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal. Design and development of needle sets, drivers, and accessories for intraosseous vascular access, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy, and pelvic stabilization device.</p> <p>Devices include: Embolectomy Thrombectomy Rotational Catheters and rotor, vascular access, intravascular administration sets, intra-aortic balloon pumps, ultrasonic cardiac blood flow monitors, spring wire guides, percutaneous sheath introducers, intraosseous needle sets, drivers, and accessories, and pelvic stabilization device. Processing and packaging of sutures and the manufacturing of feeding tubes.</p>
Arrow International, Inc. 312 Commerce Place Asheboro North Carolina 27203 USA	<p>Kit packaging of anesthesia and interventional products, kit assembly for anesthesia and vascular products, sterilization, supporting laboratory testing, and distribution.</p>
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	<p>Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermodilution catheters, percutaneous sheath introducers, spring wire guides and related components and accessories for the above products. Contract manufacturing operations for Endobronchial Blocking Device and the Cardio Dynamic catheters.</p>

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Location	Registered Activities
Arrow Internacional de Chihuahua de S.A. de C.V. Ave. Washington 3701 Interior Circuito Industrial Alta Tecnología, Edificio 40 Col. Panamericana Chihuahua CP 31200 Mexico	Manufacture and distribution of intravascular catheters, transradial catheters, abdominal, thoracic and pleural drainage catheters, percutaneous sheath introducers, spring wire guides, and related components and accessories for the above product lines. Packaging and distribution of anesthesia catheters, hemodialysis catheters, transradial catheters, and intra-aortic balloon catheters and sutures.
Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701 Edificio 2 Col. Panamericana Chihuahua CP 31200 Mexico	Manufacture and distribution of intravascular catheters, abdominal, thoracic and pleural drainage catheters, hemodialysis catheters, Embolectomy Thrombectomy Rotational Catheters, percutaneous sheath introducers, spring wire guides, and related components and accessories for the above product lines and packing and distribution of anesthesia catheters, hemodialysis catheters.
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermodilution catheters, percutaneous sheath introducers, spring wire guides and related components and accessories for the above product lines. Contract manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal.
Arrow International, Inc. (subsidiary of Teleflex, Incorporated) 16 Elizabeth Drive Chelmsford Massachusetts 01824 USA	Design, development, manufacture and distribution of electrophysiology / pacing, thermodilution, angiography and wedge pressure catheters; intra-aortic balloons and pumps; and components and accessories for these product lines. Manufacture of cholangiography devices. Servicing of intra-aorticballoon pumps.
Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificio 4 Colonia Complejo Industrial Las Americas Chihuahua CP 31114 Mexico	Manufacture, packaging, and distribution of Intravascular catheters, anesthesia catheters, hemodialysis catheters, abdominal, thoracic and pleural drainage catheters, feeding tubes, embolectomy catheters, spring wire guides, and percutaneous sheath introducers, plus components and accessories for the above product lines.

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Location

Arrow Internacional de Chihuahua  
S.A. de C.V.  
Avenida Washington # 3701  
Edificio 36  
Colonia Complejo Industrial Las Americas  
Chihuahua  
CP 31114  
Mexico

Registered Activities

Manufacture and distribution of dilators, needles and syringes and components for the intravascular, anesthesia, hemodialysis, thoracic and pleural drainage, intra-aortic balloon, catheter kits.



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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

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

**No.** CE 511137  
**Issued To:** **Arrow International, Inc.**  
**(subsidiary of Teleflex, Incorporated)**  
**2400 Bernville Road**  
**Reading**  
**Pennsylvania**  
**19605**  
**USA**

In respect of:

**See certificate scope page.**

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-10-18**

Date: **2020-12-01**

Expiry Date: **2024-05-26**

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Page 1 of 7

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

This certificate was issued electronically and is bound by the conditions of the contract.



Certificate No: CE 511137

## Certificate Scope:

**The design, development and manufacture of ARROWg+ard Blue Plus Central Venous Catheters (CVC); Arrowg+ard Blue CVCs, hemodialysis catheters and Percutaneous Sheath Introducers (PSI); non-coated CVC, PSI, hemodialysis catheters, Peripherally Inserted Central Catheters (PICCs), thermodilution catheters, intra-aortic balloon catheters, intra-aortic balloon pumps, angiographic catheters, balloon wedge pressure catheters, guidewires, anesthesia products, mid-line/peripheral vascular access catheters, Multi-Access Catheters (MAC), Emergency Infusion Devices (EID), Rapid Infusion Catheters (RIC), Trauma catheters, drainage catheters, Pneumothorax/ Thoracentesis products, arterial catheterization products, Percutaneous Thrombolytic Device (PTD), central catheters with Arrowg+ard Blue Advance Protection, sterile single-use Vascular Positioning System (VPS) convenience kits and non-sterile Vascular Positioning System (VPS) consoles, plus components and accessories for the above product lines; and procedure packs incorporating the above product lines.**

**Those aspects of Annex II concerned with securing and maintaining sterile conditions of VPS Rhythm ECG accessory packs, syringes, clamps, fasteners, anchoring devices, and catheter contamination shield.**

**Those aspects relating to obtaining and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.**

First Issued: **2006-10-18**Date: **2020-12-01**Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 511137

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**Arrow International, Inc.**  
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**2400 Bernville Road**  
**Reading**  
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**19605**  
**USA**

Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
MD 0102	ARROWg+ard Blue and ARROWg+ard Blue Plus Central Venous Catheters (containing chlorhexidine), Sets and Kits	See CE 511138
MD 0102	Single-Lumen and Multi-Lumen Central Venous Catheter Sets and Kits	See CE 512282
MD 0102	Arrow Single and Multiple Lumen Peripherally Inserted Central Catheters (PICC)	See CE 512292
MD 0102	Hemodialysis Two-Lumen Catheters, Kits and Sets	See CE 512295
MD 0102	ARROWg+ard Blue® 2-Lumen Hemodialysis Catheters, Kits and Sets	See CE 512296
MD 0102	ARROWg+ard Blue ® Percutaneous Sheath Introducers, Kits and Sets	See CE 512297
MD 0106	Spring Wire Guide/ Guidewire	See CE 512299
MD 0100	Non-Heparin Coated Thermodilution Catheters and Kits	See CE 512333

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.



# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 511137

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**19605**  
**USA**

Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
MD 0100	Berman Angiographic Balloon Catheters and Kits and Reverse Berman Angiographic Balloon Catheter and Kits	See CE 512337
MD 0100	Balloon Wedge Pressure Catheters and Kits	See CE 512338
MD 0100	Intra-Aortic Balloon Catheter Kits	See CE 556859
MD 0102	Arrow® PICC with Arrowg+ard Blue Advance™ Technology	See CE 589968
<b>Class IIb</b>		
MD 1101	AutoCAT3 Intra Aortic Balloon Pump	The AC3 Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions:  Acute Coronary Syndrome Cardiac and Non-Cardiac Surgery Complications of Heart Failure
MD 1101	Intra-Aortic Balloon Pump AutoCat 2	There are three primary indications for IABP use; Acute Coronary Syndrome Cardiac and Non-Cardiac Surgery Complications of Heart Failure

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0106	Access Product Accessories	N/A
MD 1202	VPS Rhythm Device with TipTracker Stylet (and accessories)	N/A
MD 0106	Spring Wire Guides/Guidewires	N/A
MD 0101	Epidural Needles	N/A
MD 0101	Peripheral Nerve Block	N/A
MD 0101	Epidural Catheters	N/A
MD 0102	Introducer & Injection Needles & Accessories	N/A
MD 0102	Introducer Catheter over Needle	N/A
MD 0106	Connectors and Accessories	N/A
MD 0102	Sheath Introducers (PSI), Multi-Access Catheters (MAC) and Accessories	N/A
MD 0106	Dilator	N/A
MD 0106	Syringes	N/A
MD 0102	Arterial Products	N/A
MD 0106	Pneumothorax/ Thoracentesis & Drainage Catheters	N/A
MD 0102	Cholangiography Sets	N/A

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0102	TwinCath and Midline Peripheral Catheter Products	N/A
MD 0102	Peel Away Introducer Assemblies	N/A
MD 0106	Filter	N/A
MD 0102	Transradial Catheters	N/A
MD 0106	Scalpels (includes stitch cutter)	N/A
MD 0106	Staple Anchoring Device	N/A
MD 0106	Sutures	N/A
MD 1104	Percutaneous Thrombolytic Device (PTD)	N/A
MD 0106	Arrow Raulerson Syringe and Pressure Transduction Probe	N/A
MD 0106	Arrow-Johans ECG Adapter	N/A
MD 0106	IAB Accessories	N/A
MD 0106	Catheter Adaptors	N/A
MD 0102	Emergency Infusion Devices (EID)	N/A
MD 0102	Rapid Infusion Catheters (RIC)	N/A
MD 0102	Trauma Catheters	N/A

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Number	Device Name	Intended purpose per IFU
<b>Class Is</b>		
MD 1100	VPS Rhythm ECG Accessory Pack	N/A
MD 0102	Cath-Gard	N/A
MD 0106	Loss of Resistance (LOR) Syringe	N/A
MD 0302	Catheter Clamp and Fastener and Skin Adherent Anchoring Devices	N/A

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date: **2020-12-01**  
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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Acme Monaco 75 Winchell Drive New Britain CT 06052 USA	<b>Manufacture</b>
Arrow Internacional de Chihuahua S.A. de C.V. Ave Washington 3701 Interior Circuito Industrial Alta Tecnologica Edificio 40 Colonia Panamerica Chihuahua Chihuahua CP 31200 Mexico	<b>Manufacture Packaging</b>

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Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificio 4 Colonia Complejo Industrial Las Americas Chihuahua Chihuahua CP 31114 Mexico	<b>Manufacture Packaging</b>
Arrow Internacional de Chihuahua SA de C.V Avenida Washington 3701, Edificio 36 Col. Complejo Industrial Las Américas Chihuahua Chihuahua CP 31114 Mexico	<b>Manufacture</b>

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Arrow Internacional de Chihuahua SA de C.V. Ave Washington 3701 Edificio 2 Colonia Panamerica Chihuahua Chihuahua CP 31200 Mexico	<b>Manufacture</b> <b>Packaging</b>
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	<b>Design</b> <b>Manufacture</b>
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	<b>Design</b> <b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Arrow International LLC (subsidiary of Teleflex, Incorporated) 16 Elizabeth Drive Chelmsford Massachusetts 01824 USA	<b>Design</b> <b>Manufacture</b>
Arrow International LLC 312 Commerce Place Asheboro North Carolina 27203 USA	<b>ETO Sterilization</b> <b>Manufacture</b>
Arrow International LLC Subsidiary of Teleflex Incorporated 35 Innovation Way Wyomissing Pennsylvania 19610 USA	<b>Design</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Arrow International LLC Subsidiary of Teleflex Incorporated 3015 Carrington Mill Blvd. Morrisville North Carolina 24560 USA	<b>Design</b> <b>Manufacture</b>
Brivant Ltd Parkmore West Business Park Galway Ireland	<b>Manufacture</b>
Celestica Oregon LLC 18870 NE Riverside Parkway Portland OR 97230 USA	<b>Crucial Supplier</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Custom Wire Technologies, Inc. 1123 Mineral Springs Drive Port Washington WI 53074 USA	<b>Crucial Supplier</b>
EPflex Feinwerktechnik GmbH Im Schwöllbogen 24 Dettingen an der Erms 72581 Germany	<b>Manufacture</b>
Galt Medical Corp 2220 Merritt Drive Garland, TX 75041 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Heraeus Medical Components, SRL Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago 30106 Costa Rica	<b>Manufacture</b>
Heraeus Medical Components, LLC 5030 Centerville Road St Paul Minnesota 55127 USA	<b>Design</b>
Hudson Respiratory Care Tecate S. de R.L de C.V. (A Teleflex Medical Company) Prolongacion Mision Eusebio Kino No. 1316, Rancho El Descanso Tecate, B.C., C.P., 21478 Mexico	<b>Manufacture Packaging</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Lake Region Medical 304 Lake Hazeltine Drive Chaska Minnesota 55318 USA	<b>Manufacture</b>
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	<b>Manufacture</b>
LEK a Sandoz Company Verovskova 57 SI - 1526 Ljubljana Slovenia	<b>Crucial Supplier</b>
Medichem, S.A. Poligono industrial Celra 17460, Celra. Girona Spain	<b>Crucial Supplier</b>

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
SaFeMed spol.s.r.o. Trabantska 292 19015 Praha 9 Czech Republic	<b>Manufacture Packaging</b>
sfm medical devices GmbH Brückenstrasse 5 63607 Wächtersbach Germany	<b>ETO Sterilization Manufacture Packaging</b>
Sterigenics 2400 Airport Road Santa Teresa New Mexico 88008 USA	<b>ETO Sterilization</b>

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 511137**  
 Date: **2020-12-01**  
 Issued To: **Arrow International, Inc.**  
**(subsidiary of Teleflex, Incorporated)**  
**2400 Bernville Road**  
**Reading**  
**Pennsylvania**  
**19605**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics, Inc. (Sterigenics US, LLC) 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	<b>ETO Sterilization</b>
STERIS AST CZ s.r.o. Prumyslova Zona Kosikov Velka Bites 595 01 Czech Republic	<b>ETO Sterilization</b> <b>Other Critical Processes</b>
Teleflex Medical Europe Ltd. IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath Ireland	<b>Control of Sterilization</b> <b>EU Representative</b> <b>Manufacture</b>

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 511137**  
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**(subsidiary of Teleflex, Incorporated)**  
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**Reading**  
**Pennsylvania**  
**19605**  
**USA**

Date	Reference Number	Action
18 October 2006		First Issue.
28 March 2007		Re-issue due to extension to scope, addition of manufacturing locations and an alternative subcontractor for sterilization.
18 May 2010	7522899	Re-issue due to clarify previously supplied information to the company's name at three locations and extend the scope to cover "Intra-Aortic Balloon Pumps." Added Arrow at Jamska as a subcontractor. Removed Arrow International, Inc, Wyomissing Pennsylvania from the list of significant subcontractors. Added Teleflex Medical as EU Representative to the list of significant subcontractors.
29 September 2010	7572925	Addition of alternative sterilization site, Sterigenics in Charlotte, North Carolina, for production from all Arrow North America manufacturing facilities. Correction to add Sterigenics sterilization site in Santa Teresa, New Mexico that was inadvertently omitted. Clarification of Arrow Chihuahua facility addresses. Arrow has two manufacturing facilities in Chihuahua, Mexico in the same office park that were previously listed as one address.

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Page 1 of 5

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



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Date	Reference Number	Action
30 June 2011	7689688	Approval of new subcontractor Teleflex Medical, Ireland for manufacture and control of sterilisation.
12 October 2011	7731342	Certificate Renewal. Removal of subcontractor Arrow Internacional de Chihuahua, Carmargo, Mexico. Clarification in scope wording.
15 May 2012	7828408	Scope extension to include procedure packs under Article 12. Updated ER representative address.
16 August 2012	7878198	EpFlex Feinwerktechnik, Acme Monaco, Galt Medical, Lake Region Medical (USA and Ireland), Brivant and NeoMetrics added to the list of significant subcontractors.
15 May 2013	7944946	Addition of significant subcontractors SFM and SaFeMed spol. s.r.o. Update of Arrow International de Chihuahua S.A. de C.V. and Teleflex Medical addresses.
16 November 2013	8080642	Arrow International (Mount Holly) removed and Arrow International (Chelmsford) added to the list of subcontractors.
16 June 2014	8166172	Hudson Respiratory Care Tecate and Teleflex Medical (North Carolina) added to the list of subcontractors.

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Date	Reference Number	Action
12 August 2015	8373794	Update certificate scope to add: central catheters with Chlorag+ard technology, and Change: "mid-line catheters" to "mid-line/peripheral vascular access catheters". Arrow Internacional de Chihuahua (edificio 4), and Teleflex Medical (Morrisville) added to the list of subcontractors, and Teleflex Medical Durham removed. Corrected Edificio 2 and 40 address typos for these 2 ARROW Internacional de Chihuahua facilities.
26 August 2015	8332115	Scope extension to include the Vascular Positioning System (VPS). Introduction of Sterigenics (Willowbrook) as a significant subcontractor.
29 July 2016	8534169	Addition of Celestica Oregon LLC and Custom Wire Technologies, Inc. as significant subcontractors.
13 October 2016	8562443	Certificate Renewal. Corrected EBSTER s.r.o address.
27 April 2017	8718569	Add Packaging services to Edificio 4, 40 and 2 Chihuahua locations per pervious review SMO 8405167 & EQ 1015720
11 July 2017	8750813	Removed Arrow Interventional Everett, MA from list of subcontractors and changed subcontractor name from "Ebster s.r.o." to STERIS AST CZ s.r.o."

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Date	Reference Number	Action
15 January 2018	8857195	Adding Arrow Internacional de Chihuahua, Edificio 36 as manufacturing subcontractor. Remove information from Arrow Internacional de Chihuahua, Edificio 2 address to match their ISO:13485 certificate.
17 August 2018	8951723	Change of coating name from Chlorag+ard Technology to Arrowg+ard Blue Advance Protection. Add design services to Arrow International at Chelmsford site and the Hradec Kralove site.
15 February 2019	7780599	Traceable to NB 0086.

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**Reading**  
**Pennsylvania**  
**19605**  
**USA**

Date	Reference Number	Action
Current	9731526	Certificate Renewal. Change NeoMetrics, Inc to Heraeus Medical Components, LLC due to the acquisition; address also changed from Plymouth, MN to St Paul, MN. Remove "Vysocina" from address of STERIS AST CZ s.r.o. Add "(subsidiary of Teleflex, Incorporated)" to the Arrow International, Inc subcontractor in Chelmsford, MA. Change "Teleflex Medical" in Morrisville, NC to "Arrow International LLC Subsidiary of Teleflex Incorporated" and added Manufacture to services supplied to the same site. Remove Sterigenics in Willowbrook, IL. Added Device Tables. Added Class Is devices specifically to the scope statement. Added EID, RIC, and trauma catheters to scope and Class IIa device table. Changed Celestica Oregon LLC and Custom Wire Technologies from critical subcontractors to crucial suppliers. Added LEK a Sandoz company and Medichem SA as crucial suppliers.

<p><b>Manufacturer:</b>                  Arrow International LLC                  Subsidiary of Teleflex Incorporated                  3015 Carrington Mill Blvd.                  Morrisville                  North Carolina                  27560                  USA</p> <p>Arrow International, Inc.                  Subsidiary of Teleflex Incorporated                  2400 Bernville Rd.                  Reading, PA 19605                  USA</p>	<p><b>European Representative:</b>                  Teleflex Medical                  IDA Business and Technology Park                  Dublin Road                  Athlone, Co. Westmeath, Ireland</p>
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<b>Product Name:</b>	<b>Sheath Introducers, Multi-Access Catheters (MAC) and Accessories</b>	<b>Technical file #:</b>	<b>T-BSI-008</b>
<b>GMDN Code:</b>	<b>58865 Vascular catheter introduction kit</b>	<b>Classification:</b>	<b>IIa</b>
	<b>46505 – Instrument guard, single-use</b>	<b>Classification:</b>	<b>Is**</b>

<b>GMDN Code:</b>	<b>58865 Vascular catheter introduction kit</b>	<b>Classification</b>	<b>IIa</b>
<b>PSI Finished Goods #</b>	<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
AD-09801	Percutaneous Sheath Introducer Set: 8.5 Fr. x 7 cm (2-5/8")	9-Mar-98	
AD-09903	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	9-Mar-98	
AD-09903-S	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	9-Mar-98	
AK-09601	Percutaneous Sheath Introducer Kit: 6 Fr. x 10 cm (4")	14-Mar-03	
AK-09701	Percutaneous Sheath Introducer Kit: 7 Fr. x 10 cm (4")	14-Mar-03	
AK-09800-AC	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	19-Dec-2019	
AK-09801	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	22-Dec-98	
AK-09801-A	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	9-Nov-01	
AT-09875-E	Percutaneous Sheath Introducer Set: 8.5 FR x 10 cm (4")	21-Dec-15	
BR-09903-S	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	29-Jul-03	
CA-09801-SB	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	23-May-00	
CA-09886	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	23-May-03	
CI-09600	Percutaneous Sheath Introducer Set: 6 Fr. x 10 cm (4")	10-Dec-97	
CI-09800	Percutaneous Sheath Introducer Set: 8.5. Fr. x 10 cm (4")	28-Jul-03	
CI-09800-SB	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	9-Mar-98	
CI-09803	Percutaneous Sheath Introducer Set: 8 Fr. x 10 cm (4")	25-Aug-02	
CL-07011	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-07024	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 24 cm (9-3/8")	25-Mar-98	
CL-07035	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 35 cm (13-3/4")	25-Mar-98	
CL-07045	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 45 cm (17-3/4")	25-Mar-98	
CL-07065	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07080	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 80 cm (31-1/2")	9-Mar-98	
CL-07511	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 11cm (4-3/8")	25-Mar-98	
CL-07524	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 24 cm (9-3/8")	25-Mar-98	
CL-07545	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 45 cm (17-3/4")	25-Mar-98	
CL-07565	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07590	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 90 cm (35-1/2")	25-Mar-98	
CL-07611	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-07624	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 24 cm (9-3/8")	25-Mar-98	

**\*Confidential\***

The footer information below is for reference only



GMDN Code:	58865 Vascular catheter introduction kit	Classification	IIa
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
CL-07635	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 35 cm (13-3/4")	25-Mar-98	
CL-07645	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 45 cm (17-3/4")	25-Mar-98	
CL-07665	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07690	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 90 cm (35-1/2")	25-Mar-98	
CL-07700	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 100 cm (39-3/8")	25-Mar-98	
CL-07711	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-07724	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 24 cm (9-3/8")	25-Mar-98	
CL-07735	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 35 cm (13-3/4")	25-Mar-98	
CL-07745	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 45 cm (17-3/4")	25-Mar-98	
CL-07765	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07780	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 80 cm (31-1/2")	25-Mar-98	
CL-07790-R	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 90 cm (35-1/2")	23-Nov-98	
CL-07800	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 100 cm (39-3/8")	23-Nov-98	
CL-07811	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-07824	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 24 cm (9-3/8")	25-Mar-98	
CL-07835	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 35 cm (13-3/4")	25-Mar-98	
CL-07845	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 45 cm (17-3/4")	25-Mar-98	
CL-07865	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07880	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 80 cm (31-1/2")	25-Mar-98	
CL-07900	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 100 cm (39-3/8")	25-Mar-98	
CL-07911	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-07924	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 24 cm (9-3/8")	25-Mar-98	
CL-07965	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-07980	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 80 cm (31-1/2")	25-Mar-98	
CL-08403	Cath Lab PSI: 4 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CL-08403-A	Cath Lab PSI: 4 Fr. x 11 cm (4-3/8")	26-May-98	
CL-08503	Cath Lab PSI: 5 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CL-08503-A	Cath Lab PSI: 5 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-08505	Cath Lab PSI: 5 Fr. x 5 cm (2")	25-Mar-98	
CL-08603	Cath Lab PSI: 6 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-08605	Cath Lab PSI: 6 Fr. x 5 cm (2")	25-Mar-98	
CL-08605-HF	High-Flow Cath Lab PSI: 6 Fr. x 5 cm (2")	24-Jan-01	
CL-08703	Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-08705-HF	High-Flow Cath Lab PSI: 7 Fr. x 5 cm (2")	25-Mar-98	
CL-08803	Cath Lab PSI: 8 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-08903	Cath Lab PSI: 9 Fr. x 11 cm (4-3/8")	25-Mar-98	
CL-71165	Super Arrow-Flex Cath Lab PSI: 11 Fr. x 65 cm (25-5/8")	25-Mar-98	
CL-71180	Super Arrow-Flex Cath Lab PSI: 11 Fr. x 80 cm (31-1/2")	25-Mar-98	
CP-07011	Super Arrow-Flex Cath Lab PSI: 10 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-07511	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-07511-P	Super Arrow-Flex Cath Lab PSI: 5 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CP-07611	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-07611-P	Super Arrow-Flex Cath Lab PSI: 6 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CP-07711	Super Arrow-Flex Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-07811	Super Arrow-Flex Cath Lab PSI: 8 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-07911	Super Arrow-Flex Cath Lab PSI: 9 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-08403	Cath Lab PSI: 4 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CP-08503	Cath Lab PSI: 5 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CP-08503-A	Cath Lab PSI: 5 Fr. x 11 cm (4-3/8")	25-Mar-98	

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GMDN Code:	58865 Vascular catheter introduction kit	Classification	IIa
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
CP-08603	Cath Lab PSI: 6 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-08603-P	Cath Lab PSI: 6 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CP-08703	Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-08803	Cath Lab PSI: 8 Fr. x 11 cm (4-3/8")	25-Mar-98	
CP-08903	Cath Lab PSI: 9 Fr. x 11 cm (4-3/8")	25-Mar-98	
CR-07645	Super Arrow Flex PSI: 6 Fr. x 45 cm (17-3/4")	19-Feb-99	
CR-07745	Super Arrow Flex PSI: 7 Fr. x 45 cm (17-3/4")	30-Jun-98	
CR-07745-NT	Super Arrow Flex PSI: 7 Fr. x 45 cm (17-3/4")	21-Jul-99	
CT-07860	Super Arrow Flex PSI: 8 Fr. x 60 cm (24-1/8")	25-Mar-98	
CW-08403	Cath Lab PSI: 4 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CW-08503	Cath Lab PSI: 5 Fr. x 7.5 cm (2-15/16")	25-Mar-98	
CW-08503-A	Cath Lab PSI: 5 Fr. x 11 cm (4-3/8")	3-Feb-99	
CW-08603	Cath Lab PSI: 6 Fr. x 11 cm (4-3/8")	25-Mar-98	
CW-08703	Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	25-Mar-98	
CW-08803	Cath Lab PSI: 8 Fr. x 11 cm (4-3/8")	25-Mar-98	
CW-08903	Cath Lab PSI: 9 Fr. x 11 cm (4-3/8")	25-Mar-98	
DE-09600-UNH	Percutaneous Sheath Introducer Set: 6 Fr. x 10 cm (4")	13-Sep-17	
DE-09801-HZM	Percutaneous Sheath Introducer Kit: 8.5 Fr x 7 cm (2-5/8")	24-Oct-18	
DE-09875-HZO1	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 10 cm (4")	14-Sep-17	
DM-09875	Percutaneous Sheath Introducer Kit: 9 Fr. x 10 cm (4")	30-Mar-98	
GR-08403	Percutaneous Sheath Introducer Set: 4Fr. x 11 cm (4-3/8")	17-Feb-12	
GR-08503-A	Cath Lab PSI: 5 Fr. x 11 cm (4-3/8")	21-Oct-10	
GR-08603	Cath Lab PSI: 6 Fr., 11 cm (4-3/8")	21-Oct-10	
GR-08703	Cath Lab PSI: 7 Fr. x 11 cm (4-3/8")	21-Oct-10	
HK-09903-S	Percutaneous Sheath Introducer Kit: 9 Fr. x 10 cm (4")	14-May-99	
HZ-09801	Percutaneous Sheath Introducer Kit: 8.5 Fr. x 7 cm (2-5/8")	08-April-98	
IK-09600	Percutaneous Sheath Introducer Kit: 6 Fr. x 10 cm (4")	5-Aug-05	
SG-09903	Percutaneous Sheath Introducer Kit: 9 Fr. x 10 cm (4")	10-Dec-97	
SI-09600	Percutaneous Sheath Introducer Set: 6 Fr. x 10 cm (4")	16-Jun-08	
SI-09600-LJ	Percutaneous Sheath Introducer Set: 6 Fr. x 10 cm (4")	25-Mar-98	
SI-09700	Percutaneous Sheath Introducer Set: 7 Fr. x 10 cm (4")	19-Dec-97	
SI-09700-LJ	Percutaneous Sheath Introducer Set: 7 Fr. x 10 cm (4")	12-Mar-08	
SI-09803-CV	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	21-Aug-98	
SI-09806	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	9-Mar-98	
SI-09808	Percutaneous Sheath Introducer Set: 8 Fr. x 10 cm (4")	10-Dec-97	
SI-09808-LJ	Percutaneous Sheath Introducer Set: 8 Fr. x 10 cm (4")	14-Mar-08	
SI-09870-E	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	10-Dec-97	
SI-09875-E	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	10-Dec-97	
SI-09875-EANG	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	11-Apr-05	
SI-09875-ESB	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	17-Jun-02	
SI-09880	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	10-Dec-97	
SI-09880-LF	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	14-Jan-00	
SI-09880-QE	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	15-Dec-03	
SI-09880-SB	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	17-Jun-02	
SI-09880-SE	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	9-Mar-98	
SI-09903-E	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	10-Dec-97	
SS-09903-S	Radiopaque Polyurethane Sheath/Dilator: 9 Fr. x 7 cm (2-5/8")	17-Oct-07	
SU-09903-C	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	3-Apr-07	

**\*Confidential\***

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GMDN Code:	58865 Vascular catheter introduction kit	Classification	IIa
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
UB-09903-C	Percutaneous Sheath Introducer Kit: 9 Fr. x 10 cm (4")	30-Oct-01	
UE-09800	Percutaneous Sheath Introducer Set: 8.5 Fr. x 10 cm (4")	13-Feb-01	
UK-09903	Percutaneous Sheath Introducer Set: 9 Fr. x 10 cm (4")	24-Oct-08	
UR-09880-LF	Percutaneous Sheath Introducer Set: 8.5 FR x 10 cm (4")	4-Dec-02	

PSI Part # (if applicable)	Device Description
K-09601-014	Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 10 cm (4")
K-09701-005	Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 10 cm (4")
K-09808-005	Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 10 cm (4")
K-09880-012	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
K-09880-012B	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
K-09880-015	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
L-07011-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 11 cm (4-3/8")
L-07024-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 24 cm (9-3/8")
L-07035-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 35 cm (13-3/4")
L-07045-001E	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 45 cm (17-3/4")
L-07065-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 65 cm (25-5/8")
L-07080-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 10 Fr. x 80 cm (31-1/2")
L-07511-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 11cm (4-3/8")
L-07524-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 24 cm (9-3/8")
L-07545-001D	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 45 cm (17-3/4")
L-07565-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 65 cm (25-5/8")
L-07590-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 90 cm (35-1/2")
L-07611-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 11 cm (4-3/8")
L-07624-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 24 cm (9-3/8")
L-07635-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 35 cm (13-3/4")
L-07645-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: : 6 Fr. x 45 cm (17-3/4")
L-07665-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 65 cm (25-5/8")
L-07690-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 90 cm (35-1/2")
L-07700-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 100 cm (39-3/8")
L-07711-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 11 cm (4-3/8")
L-07724-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 24 cm (9-3/8")
L-07735-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 35 cm (13-3/4")
L-07745-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 45 cm (17-3/4")
L-07765-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 65 cm (25-5/8")
L-07780-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 80 cm (31-1/2")
L-07800-001D	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 100 cm (39-3/8")
L-07811-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 11 cm (4-3/8")
L-07824-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 24 cm (9-3/8")
L-07835-004	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 35 cm (13-3/4")
L-07845-001D	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 45 cm (17-3/4")
L-07865-001D	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 65 cm (25-5/8")
L-07880-001D	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 80 cm (31-1/2")
L-07900-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 100 cm (39-3/8")
L-07911-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 11 cm (4-3/8")
L-07924-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 24 cm (9-3/8")
L-07965-001C	Super Arrow-Flex Sheath Ext Assy w/Dilator: : 9 Fr. x 65 cm (25-5/8")
L-07980-001B	Super Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 80 cm (31-1/2")

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PSI Part # (if applicable)	Device Description
L-08705-003A	High-Flow Cath Lab Sheath Ext Assy w/Dilator: 7 Fr. x 5 cm (2")
L-09807-002	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
L-09807-002A	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
L-71165-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 11 Fr. x 65 cm (25-5/8")
L-71180-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 11 Fr. x 80 cm (31-1/2")
LF-09803-006	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
LF-09803-006A	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
LF-09803-009	Arrow-Flex Sheath Ext Assy w/Dilator: 8.5 Fr. x 10 cm (4")
LF-09804-007A	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 7 cm (2-5/8")
LF-09875-001	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 10 cm (4")
LF-09903-008	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 10 cm (4")
LF-09903-008B	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 10 cm (4")
LF-09903-009	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 10 cm (4")
LF-09903-009A	Arrow-Flex Sheath Ext Assy w/Dilator: 9 Fr. x 10 cm (4")
P-07511-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 5 Fr. x 7.5 cm (2-15/16")
P-07611-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 7.5 cm (2-15/16")
R-07645-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 6 Fr. x 45 cm (17-3/4")
R-07745-001A	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 45 cm (17-3/4")
R-07745-007	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 45 cm (17-3/4")
R-07790-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 7 Fr. x 90 cm (35-1/2")
T-01000-033A	High-Flow Cath Lab Sheath Ext Assy w/Dilator: 6 Fr. x 5 cm (2")
T-07860-001	Super Arrow-Flex Sheath Ext Assy w/Dilator: 8 Fr. x 60 cm (24-1/8")
T-45509-010A	Cath-Lab Sheath Ext Assy w/Dilator: 6 Fr. x 5 cm (2")
T-45509-013A	Cath-Lab Sheath Ext Assy w/Dilator: 5 Fr. x 5 cm (2")
W-08403-012D	Cath-Lab Sheath Ext Assy w/Dilator: 4 Fr. x 7.5 cm (2-15/16")
W-08403-014	Cath-Lab Sheath Ext Assy w/Dilator: 4 Fr. x 11 cm (4-3/8")
W-08503-005C	Cath-Lab Sheath Ext Assy w/Dilator: 5 Fr. x 7.5 cm (2-15/16")
W-08513-004B	Cath-Lab Sheath Ext Assy w/Dilator: 5 Fr. x 11 cm (4-3/8")
W-08603-005D	Cath-Lab Sheath Ext Assy w/Dilator: 6 Fr. x 11 cm (4-3/8")
W-08613-004C	Cath-Lab Sheath Ext Assy w/Dilator: 6 Fr. x 7.5 cm (2-15/16")
W-08703-006C	Cath-Lab Sheath Ext Assy w/Dilator: 7 Fr. x 11 cm (4-3/8")
W-08803-014C	Cath-Lab Sheath Ext Assy w/Dilator: 8 Fr. x 11 cm (4-3/8")
W-08903-005C	Cath-Lab Sheath Ext Assy w/Dilator: 9 Fr. x 11 cm (4-3/8")
Z-09800-008A	Arrow-Flex Sheath Ext Assy w/ Dilator: 8.5 Fr. x 7 cm (2-5/8")

GMDN Code:	46505 – Instrument guard, single-use	Classification	Is**
Cath-Gard Finished Good #	Device Description	Date CE Mark First Affixed	
AI-08803	Cath-Gard: 5-6 Fr X 30 cm (12")	22-May-98	
SA-09847	Sheath Adapter with Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2") w/TB Adapt	17-Oct-02	
ST-09807	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2") w/TB Adapt	22-May-98	
ST-09870	TwistLock Cath-Gard: 7 Fr x 80 cm (31-1/2")	22-May-98	
ST-09875	TwistLock Cath-Gard: 7.5 Fr x 80 cm (31-1/2")	22-May-98	
ST-09880	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2")	22-May-98	
ST-09885	TwistLock Cath-Gard: 8.5 Fr x 80 cm (31-1/2") w/TB Adapt	01-Feb-00	
EU-00001-ST	TwistLock Cath-Gard: 5 Fr x 80 cm (31-1/2") w/TB Adapt	21-Mar-14	

Cath-Gard Part # (if applicable)	Device Description
A-09880-001	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2") w/TB Adapt

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AI-08803-002	Cath-Gard: 5-6 Fr x 30 cm (12")
B001-0010-001	IAB Cath-Gard: 34 cm (13-1/3")
I-09800-004A	TwistLock Cath-Gard: 7.5 Fr x 80 cm (31-1/2")
I-09880-001A	TwistLock Cath-Gard: 7 Fr x 80 cm (31-1/2")
I-09885-001	TwistLock Cath-Gard: 8.5 Fr x 80 cm (31-1/2") w/TB Adapt
P-00001-002	Cath-Gard: 5-6 Fr x 80 cm (31-1/2") w/TB Adapt
P-09806-003	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2") w/TB Adapt
P-09806-014	Cath-Gard Pkgd: 7-7.5 Fr x 80 cm (31-1/2") w/TB Adapt
PZ-00001-003	TwistLock Cath-Gard: 5 Fr x 80 cm (31-1/2") w/TB Adapt
ST-09600-003	Cath-Gard: 5-6 Fr x 30.5 cm (12")
ST-09600-004	Cath-Gard Pkgd: 5-6 Fr x 30.5 cm (12")
ST-09680-002	Cath-Gard: 5-6 Fr x 80 cm (31-1/2")
ST-09870-001	TwistLock Cath-Gard Pkgd: 7 Fr x 80 cm (31-1/2")
ST-09875-001	TwistLock Cath-Gard Pkgd: 7.5 Fr x 80 cm (31-1/2")
ST-09880-004	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2")
ST-09880-005	Cath-Gard: 7-7.5 Fr x 80 cm (31-1/2")
ST-09885-001	TwistLock Cath-Gard Pkgd: 8.5 Fr x 80 cm (31-1/2")
T-09800-009A	TwistLock Cath-Gard: 7.5 Fr x 112 cm (44")
T-09880-012A	TwistLock Cath-Gard: 7 Fr x 112 cm (44")
T-14703-002	TwistLock Cath-Gard: 7 Fr x 33 cm (13")
T-14703-002A	TwistLock Cath-Gard: 7 Fr x 33 cm (13")
TZ-05050-005	TwistLock Cath-Gard: 7.5 Fr x 112 cm (44")

GMDN Code:	58865 Vascular catheter introduction kit	Classification	Ia
Trauma Finished Goods Product #	Device Description	Date CE Mark First Affixed	
EI-04060	EID 6 Fr x 3.81 cm (1-1/2")	17-June-98	
EI-04080	EID 8.5 Fr x 8.9 cm (3-1/2")	17-June-98	
RC-05801	Trauma Kit 8.5 Fr x 8.89 cm (3-1/2")	24-June-02	
RC-09700	RIC Exchange Set 7 Fr x 5.08 cm (2")	16-June-98	
RC-09850	RIC Exchange Set 8.5 Fr x 6.04 cm (2-1/2")	16-June-98	

Trauma Part # (if applicable)	Device Description
I-04060-001	EID Sheath: 6 F. x 3.81 cm (1-1/2")w/ Dilator over 20 Ga. TW Needle
I-04080-017B	EID ArrowFlex Sheath 8.5 Fr x 8.9 cm (3-1/2") w/Dilator over 17 Ga. x 14 cm (5-1/2") TW Needle
S-09850-001A	ArrowFlex Sheath: 8.5 Fr x 8.89 cm (3-1/2") w/ Dilator
C-09700-001	ArrowFlex Sheath: 7 Fr x 5.08 cm (2") w/ Dilator
C-09850-001A	ArrowFlex Sheath: 8.5 Fr x 6.04 cm (2-1/2") w/ Dilator

GMDN Code:	58865 Vascular catheter introduction kit	Classification	Ia
MAC Finished Good #	Device Description	Date CE Mark First Affixed	
CA-11142	MAC 2-L 9 Fr x 10 cm (4")	22-June-01	
CA-11142-A	MAC 2-L 9 Fr x 10 cm (4")	19-Dec-2019	
CH-11242-ISB	MAC 2-L 9 Fr x 11.5 cm (4-1/2")	30-May-17	
DE-11142-TZU	MAC 2-L 9 Fr x 10 cm (4")	26-Feb-19	
DM-11142-TS	MAC 2-L 9 Fr x 10 cm (4")	12-Dec-06	
NL-11142-AMP	MAC 2-L 9 Fr x 10 cm (4")	29-Aug-13	

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<b>GMDN Code:</b>	<b>58865 Vascular catheter introduction kit</b>	<b>Classification</b>	<b>IIa</b>
<b>MAC Finished Good #</b>	<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
NL-11142-MUMC	MAC 2-L 9 Fr x 10 cm (4")	02-Dec-15	
SI-11142	MAC 2-L 9 Fr x 10 cm (4")	06-July-00	
SI-11142-S	MAC 2-L 9 Fr x 10 cm (4")	21-May-03	
SI-11242	MAC 2-L 9 Fr x 11.5 cm (4-1/2")	19-Feb-02	

<b>MAC Part # (if applicable)</b>	<b>Device Description</b>
K-11142-004C	Sheath Ext Assy: 2-L 9 Fr x 10 cm (4")
K-11142-011	Sheath Ext Assy: 2-L 9 Fr x 10 cm (4")
K-11142-011A	Sheath Ext Assy: 2-L 9 Fr x 10 cm (4")
K-11242-001A	Sheath Ext Assy: 2-L 9 Fr x 11.5 cm (4-1/2")
K-11242-008	Sheath Ext Assy: 2-L 9 Fr x 11.5 cm (4-1/2")
K-11242-008A	Sheath Ext Assy: 2-L 9 Fr x 11.5 cm (4-1/2")
KZ-11142-001B	Sheath Ext Assy: 2-L 9 Fr. x 10 cm (4")
KZ-11242-001A	Sheath Ext Assy: 2-L 9 Fr. x 11.5 cm (4-1/2")

Arrow International, Inc./Arrow International LLC 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).
- 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)** \*\* for those aspects related to sterility of the Class Is devices  
 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**

<b>Krista Hughes</b>	<i>Krista Hughes</i>
Regulatory Affairs Representative (Print and Sign)	02 Dec 2020 Date
<b>Angel Diaz</b>	<i>Angel Diaz</i>
Quality Assurance Representative (Print and Sign)	02 Dec 2020 Date

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Rev Level	Date	Description
0	04-Nov-2010	Original issue of DC-T-BSI-008 in new DC format – Replaces DC-BSI-018. Refer to DC-BSI-018 for revision history of previous DOC. Added GR-08503-A, GR-08603, and GR-08703 per ECR-011057, ECR-011058, and ECR-011056 respectively. Removed the following obsolete Finished Goods: BB-09903-NA, KK-09903-C, SI-09908-E.
1	21-Dec-2011	Added DE-09803-HZO to Declaration per ECR-014307.
2	17-Feb-2012	Added GR-08403 per ECR-014519.
3	11-Jun-2012	Added DE-09875-HZO to Declaration per ECR-015641. Update DOC with GMDN.
4	28-Feb-2014	Added component part numbers to support the Procedure Pack initiative. Added GMDN code. Added NL-09801-MUMC per ECR 018256, Removed DE-09803-HZO per ECR-ECR-016026. Per ECR-019142 removed KZ-09601, KZ-09701-001, KZ-09701-005, KZ-09800-001, KZ-09808-004, KZ-09880-002, KZ-09880-004, LFZ-09803-001, LFZ-09803-002, LFZ-09875-00, LFZ-09903-004, LFZ-09903-005, LFZ-09903-006, WZ-08403-001, WZ-08513-001, WZ-08603-001, and WZ-08703-001.
5	18-Mar-2015	Added BB-09903-AG per ECO-024121. Added K-11242-008, K-11142-011 per ECO-029601. Update format to indicate market specific codes. Merged DOC's DC-T-BSI-020 MAC, DC-T-BSI-026 Cath-Gard Products and T-BSI-029 Trauma to file consolidation
6	18-Dec-2015	Added NL-11142-MUMC per ECR-026233/ECO-036641.
7	21-Dec-2015	Added AT-09875-E per ECR-026737/ECO-037472
8	25-Jan-2016	Updated GMDN codes
9	28-Feb-2017	Administrative change: BB-09903-AG is appropriately included on DC-D-BSI-016 and is not covered by DC-T-BSI-018; removed BB-09903-AG .
10	1-Jun-2017	Added CH-11242-ISB per ECR-030828.
11	21-Sep-2017	Added DE-09600-UNH per ECR-031362
12	25-Oct-2017	Added DE-09875-HZO1 per ECR-032009. Updated product description for code EU-00001-ST per ECR-032020.
13	20-Jun-2018	Updated classification for GMDM code 46505, Instrument guard, from “Class I” to “Class Is” because they are provided sterile. Added cath-gard T-14703-002A; which is identical to T-14703-002, but will use the adhesive VC-2, that is utilized in T-09880-012A, instead of RP-5 for performance purposes per ECR-031879. Updated the Quality Assurance Representative to the appropriate personnel.
14	12-Oct-2018	Removed AH-09801 and WH-09800-T due to the product being obsolete. Added MAC catheter part numbers K11142-011A, K-11242-008A, K-11142-009A, and K11242-006A that includes the new juncture hub material per ECO-049109
15	24-Oct-2018	Added MAC catheter assemblies KZ-11142-001B, KZ-11242-001A, K-11142-012A, K-11142-013A, and K-11242-009A that include the new juncture hub material
16	28-Feb-2019	Addition of DE-09801-HZM, based off already CE marked DE-S22855-HZM and using all already CE marked components, as per ECR-034406/ECO-051266 for new EASK Finished Good (Code removed from DoC in error). Added DE-11142-TZU, based off already CE marked SI-11142, and using all already CE marked components, as per ECR-035249/ECO-053097 for new EASK Finished Good. Removed W-08503-004B, CL-08403-AE and LZ-09807-002 due to being obsolete. Added L-07880-001D, P-07611-001, and L-71165-001 due to them being the assembly used in CE marked FGs but not being listed on the DOC previously. Removed K-09800-008 due to gauze pads not needing to be on this DOC. Updated Doc from rev 7 to rev 8.

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17	02-Oct-2019	Added LF-09803-006A, L-09807-002A, K-09880-012B, LF-09903-008B per ECR-034762/ECO-052530. Added LF-09804-007A per ECR-035486/ECO-053337. Added LF-09903-009A per ECR-035486/ECO-053264. Added Z-09800-008A per ECR-035486/ECO-053483. The codes are identical to other already CE marked codes and the new part numbers are being added as a result of the transfer activities.
18	19-Dec-2019	Added EASK finished goods AK-09800-AC and CA-11142-A as per ECR-036727/ECO-055455.
19	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.
20	24-Apr-2020	K-09701-004, LF-09903-017, K-11142-009A, K-11242-006A, K-11142-012A, K-11142-013A, K-11242-009A due to not being used in any CE marked production FGs.
21	10-Aug-2020	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.
22	02-Dec-2020	Removed BB-09903-C, CK-09850, DE-09875-HZO, DE-S22855-HZM, HP-09903, LU-09903, MS-07803, MS-09600, NL-09801-MUMC, Z-09800-008, and LF-09804-007 due to being inactive/obsolete with no inventory. Updated RA representative from Christine Ford to Krista Hughes. Clarified that only those aspects related to sterility of the Class Is devices apply for class Is devices.

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