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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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.

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Supplementary Information to CE 511137

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Number	Device Name	Intended purpose per IFU
Class III		
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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Number	Device Name	Intended purpose per IFU
Class III		
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
Class IIb		
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
Class IIa		
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
Class IIa		
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
Class Is		
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

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

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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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Subcontractor:	**Service(s) supplied**
Acme Monaco 75 Winchell Drive New Britain CT 06052 USA	**Manufacture**
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	**Manufacture** **Packaging**

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Subcontractor:	**Service(s) supplied**
Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificio 4 Colonia Complejo Industrial Las Americas Chihuahua Chihuahua CP 31114 Mexico	**Manufacture** **Packaging**
Arrow Internacional de Chihuahua SA de C.V Avenida Washington 3701, Edificio 36 Col. Complejo Industrial Las Américas Chihuahua Chihuahua CP 31114 Mexico	**Manufacture**

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

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

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

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

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Subcontractor:	**Service(s) supplied**
Heraeus Medical Components, SRL Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago 30106 Costa Rica	**Manufacture**
Hereaus Medical Components, LLC 5030 Centerville Road St Paul Minnesota 55127 USA	**Design**
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	**Manufacture** **Packaging**

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

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

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

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EC Certificate - Full Quality Assurance System Certificate History

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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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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 (edeficio 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 International 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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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.