EC Certificate - Full Quality Assurance System

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

No. **CE 699333**

Issued To: **Arrow International LLC**
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd.
Morrisville
North Carolina
27560
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: **2020-06-11** Date: **2020-12-01** Expiry Date: **2024-05-26**

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Certificate No: CE 699333

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: **2020-06-11** Date: **2020-12-01** Expiry Date: **2024-05-26**

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Supplementary Information to CE 699333

Issued To:

Arrow International LLC
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd.
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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 699338
MD 0102	Single-Lumen and Multi-Lumen Central Venous Catheter Sets and Kits	See CE 699342
MD 0102	Arrow Single and Multiple Lumen Peripherally Inserted Central Catheters (PICC)	See CE 699339
MD 0102	Hemodialysis Two-Lumen Catheters, Kits and Sets	See CE 699348
MD 0102	ARROWg+ard Blue® 2-Lumen Hemodialysis Catheters, Kits and Sets	See CE 699355
MD 0102	ARROWg+ard Blue ® Percutaneous Sheath Introducers, Kits and Sets	See CE 699356
MD 0106	Spring Wire Guide/ Guidewire	See CE 699363
MD 0100	Non-Heparin Coated Thermodilution Catheters and Kits	See CE 699364

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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 699365
MD 0100	Balloon Wedge Pressure Catheters and Kits	See CE 699366
MD 0100	Intra-Aortic Balloon Catheter Kits	See CE 699367
MD 0102	Arrow® PICC with Arrowg+ard Blue Advance™ Technology	See CE 699337
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: **2020-06-11** Date: **2020-12-01** Expiry Date: **2024-05-26**

By Royal Charter

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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**
Brivant Ltd Parkmore West Business Park Galway Ireland	**Manufacture**
Celestica Oregon LLC 18870 NE Riverside Parkway Portland OR 97230 USA	**Crucial Supplier**
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**

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Subcontractor:	**Service(s) supplied**
Galt Medical Corp 2220 Merritt Drive Garland, TX 75041 USA	**Manufacture**
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**

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Subcontractor:	**Service(s) supplied**
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**
Lake Region Medical 304 Lake Hazeltine Drive Chaska Minnesota 55318 USA	**Manufacture**
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	**Manufacture**

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Subcontractor:	**Service(s) supplied**
LEK a Sandoz Company Verovskova 57 SI - 1526 Ljubljana Slovenia	**Crucial Supplier**
Medichem, S.A. Poligono industrial Celra 17460, Celra. Girona Spain	**Crucial Supplier**
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**

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Subcontractor:	**Service(s) supplied**
Sterigenics 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**
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**

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Subcontractor:	**Service(s) supplied**
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

Certificate No: **CE 699333**

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Date	Reference Number	Action
11 June 2020	9645608	First Issue. Mirror certificate to CE 511137.
Current	9731526	Certificate Renewal. Removed Stitch cutter, dressing commercial, drapes and ultrasound covers, surgical instruments, surgical apparel, cables, controlled stroke syringe, gauze pads, and sponges from Class Is device table as they are not CE marked separately. Added Class Is devices specifically to the scope statement. Added EID, RIC, and trauma catheters to scope and Class IIa device table. Change Celestica Oregon LLC and Custom Wire Technologies to crucial suppliers. Add LEK a Sandoz Company and Medichem S.A. as crucial suppliers.