

bsi.



Certificate

Full Quality Assurance



No. CE 511137

Issued to:

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

In respect of:

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), thermolulution catheters, intra-aortic balloon catheters, intra-aortic balloon pumps, angiographic catheters, balloon wedge pressure catheters, guidewires, anesthesia products, mid-line catheters, Multi-Access Catheters (MAC), drainage catheters, Pneumothorax/ Thoracentesis products, arterial catheterization products, Percutaneous Thrombolytic Device (PTD), plus components and accessories for the above product lines; and procedure packs incorporating the above product lines.

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

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **18 Oct 2006**

Date: **16 Nov 2013**

Expiration Date: **17 Oct 2016**

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

...making excellence a habit.™



List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Arrow International, Inc. 16 Elizabeth Drive Chelmsford Massachusetts 01824 USA	Manufacture
Acme Monaco Corporation 75 Winchell Drive New Britain CT 06052 USA	Manufacture
EPflex Feinwerktechnik GmbH Im Schwöllbogen 24 72581 Dettingen/Erms Germany	Manufacture
Galt Medical Corp 2220 Merritt Drive Garland TX 75041 USA	Manufacture



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Subcontractor	Service(s) supplied
Lake Region Medical 340 Lake Hazeltine Dr. Chaska MN 55318 USA	Manufacture
Brivant Ltd Parkmore West Business Park Galway Ireland	Manufacture
Lake Region Medical Ltd. Butlersland New Ross Co. Wexford Ireland	Manufacture
NeoMetrics Inc. 2605 Fernbrook Lane- Suite J Plymouth MN 55447 USA	Manufacture



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Subcontractor	Service(s) supplied
SFM Medical Devices GmbH Suddeutsche Feinmechanik GmbH Brückenstraße 5, 63607 Wächtersbach Germany	Manufacture Packaging Sterilization
SaFeMed spol.s.r.o. Trabantska 292 19015 Praha 9/Satalice, Czech Republic	Manufacture Packaging
Arrow Internacional de Chihuahua S.A. de C.V. Ave Washington 3701 Edificio 2 Colonia Panamericana Chihuahua, Chihuahua 31200 Mexico	Manufacture
Arrow International, Inc. 312 Commerce Place Asheboro North Carolina 27203 USA	Manufacture ETO Sterilization



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Subcontractor	Service(s) supplied
Ebster s.r.o. Průmyslová Zóna Košikov 59501 Velká Bíteš Czech Republic	ETO Sterilization Microbiology Service
Arrow Interventional, Inc. (subsidiary of Arrow Int, Inc) 9 Plymouth Street Everett Massachusetts 02149 USA	Manufacture
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	Manufacture



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Subcontractor	Service(s) supplied
Arrow Internacional de Chihuahua S.A. de C.V. Ave Washington 3701 Interior Circuito Industrial Alta Tecnologia Edificio 40 Colonia Panamericana Chihuahua, Chihuahua 31200 Mexico	Manufacture
Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath Ireland	EU Representative Control of Sterilization Manufacture
Sterigenics 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization



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Subcontractor	Service(s) supplied
Sterigenics 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization
Arrow International CR, a.s. Jamska 2359/47 Zdar nad Sazavou 59101 Czech Republic	Manufacture

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History of Quality Assurance Certificate

Certificate No: CE 511137
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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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30 Jun 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 EU representative address.
16 August 2012	7878198	EpFlex Feinwerktechnik, Acme Moncaco, 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.