

# bsi.



By Royal Charter

## EC Certificate - Full Quality Assurance System

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

No. CE 619995  
Issued To: **OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

In respect of:  
**Design, development, manufacture of sterile intravascular catheters, coronary stents and drug-eluting coronary stents.**

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 0086):

*J M Sra*  
Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2015-02-03**

Date: **2018-04-18**

Expiry Date: **2023-04-21**

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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 includes 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 may be issued electronically and is issued by the conditions of the contract.  
International and Contact: BSI, Marton Road, Watlington, Oxford, OX4 0DQ, UK. Tel: +44 (0)1865 909001  
BSI Customer Service Centre: BSI, Marton Road, Watlington, Oxford, OX4 0DQ, UK. Tel: +44 (0)1865 909001  
A member of BSI Group plc, Company No. 3090728, Registered in England, under number 2052321 at 205 Chiswick Road, London W4 4AL, UK.

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## EC Certificate - Full Quality Assurance System

Supplementary Information to CE 619995

Issued To: **OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

### Product

The following product families are listed in conjunction with EC Certificate CE 619995:

Sapphire II PRO Coronary Dilatation Catheter
JADE PTA Balloon Dilatation Catheter
Scoreflex PTA Balloon Dilatation Catheter
Scoreflex NC Coronary Dilatation Catheter
Sapphire II PRO PTA Balloon Dilatation Catheter
Combo Bio-Engineered Sirolimus Eluting Stent (Combo Stent)
COMBO™ Plus Dual Therapy Stent (COMBO Plus Stent)
Sapphire Coronary Dilatation Catheter
Azule CoCr Alloy Coronary Stent Delivery System
ScoreFlex Coronary Dilatation Catheter
Sapphire NC Coronary Dilatation Catheter
Sapphire II NC Coronary Dilatation Catheter
Sapphire™ II (RX) Coronary Dilatation Catheter
Teleport Microcatheter

First Issued: **2015-02-03**

Date: **2018-04-18**

Expiry Date: **2023-04-21**

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Page 2 of 2

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 includes 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 may be issued electronically and is issued by the conditions of the contract.  
International and Contact: BSI, Marton Road, Watlington, Oxford, OX4 0DQ, UK. Tel: +44 (0)1865 909001  
BSI Customer Service Centre: BSI, Marton Road, Watlington, Oxford, OX4 0DQ, UK. Tel: +44 (0)1865 909001  
A member of BSI Group plc, Company No. 3090728, Registered in England, under number 2052321 at 205 Chiswick Road, London W4 4AL, UK.



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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 619995**  
 Date: **2018-04-18**  
 Issued To: **OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

Subcontractor:	Service(s) supplied
Chunghwa Chemical Synthesis & Biotech Co., Ltd 1, Jung-Hsing St. Shu-Lin New Taipei City 23850 Taiwan	Crucial Supplier
Fujian Kerui Pharmaceutical Co., Ltd. Yuanzai Industrial Area Fujian Province, 350313 China	Crucial Supplier
Meko Laserstrahl-Materialbearbeitungen Im Kirchenfelde 12-14 Hannover D-31157 Sarstedt Germany	Manufacture

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Information and Contact: BSI, Attention: Enquiry Service, Kingston, Middlesex, UK. See: [www.bsi.com](http://www.bsi.com)  
 BSI Assurance UK Limited, registered in England, number 2762743, registered office: 1, 900 Crispin, High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.



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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 619995**  
 Date: **2018-04-18**  
 Issued To: **OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

Subcontractor:	Service(s) supplied
OrbusNeich Medical (Shenzhen) Co., Ltd. No. 1 Jinkui Road Futian Free Trade Zone Shenzhen 518038 China	Design Manufacture
OrbusNeich Medical, Inc. 5363 NW 35th Avenue Fort Lauderdale FL 33309 USA	Design Regulatory Compliance
Patheon, Inc. 201 College Rd E Princeton NJ 08540 USA	Crucial Supplier

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Information and Contact: BSI, Attention: Enquiry Service, Kingston, Middlesex, UK. See: [www.bsi.com](http://www.bsi.com)  
 BSI Assurance UK Limited, registered in England, number 2762743, registered office: 1, 900 Crispin, High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.



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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 619995**

Date: **2018-04-18**

Issued To:

**OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

Subcontractor:	Service(s) supplied
Quality First International Suites 317 & 318 Burford Business Centre 11 Burford Road London E15 2ST United Kingdom	EU Representative
Seens B.V. Panthoeon 1 7521 PR Enschede The Netherlands	Manufacture
Sterigenics Belgium (Pettit-Rechain) SA Zoning Industriel de Pettit Rechain Avenue Andre Ernst 21 Verriers B-4800 Belgium	ETO Sterilization

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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 619995**

Date: **2018-04-18**

Issued To:

**OrbusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

Subcontractor:	Service(s) supplied
SurfModics, Inc 9924 W. 74th Street Eden Prairie Minnesota 55344-3523 USA	Crucial Supplier
Synergy Health AST, Venlo Faurialaan 38 5928 RZ Venlo The Netherlands	ETO Sterilization

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619995**  
Date: **2018-04-18**  
Issued To: **OrbusNeich Medical B.V.,  
Drs. W.van Royenstraat 5  
3871 AN Hoevelaken  
The Netherlands**

Date	Reference Number	Action
03 February 2015	8224626	First issue.
24 January 2016	8443505	Add product names on page 2.
12 May 2016	8450798	Add Scoreflex NC to listed product families.
22 June 2016	8558739	Add Sapphire II PRO PTA Balloon Dilatation Catheter to listed product families.
22 July 2016	8481876	Transfer scope of "drug-eluting coronary stents" from another notified body. Alignment of expiration date with transferred certificate. Add COMBO stent and COMBO Plus stent to listed product families. Add significant subcontractors and crucial suppliers associated with transfer of COMBO product: OrbusNeich Medical Inc. (USA), Meko, Biolvent International AB, Pathneon Inc., Ssens B.V., Synergy Health Ede B.V., SurModics, Inc., Fujian Kerui.
16 December 2016	8604280	Add Sapphire Coronary Dilatation Catheter to listed product families; transfer from another notified body.
15 February 2017	8661882	Transfer scope of "coronary stents" from another Notified Body. Add Azule CoCr Alloy Coronary Stent Delivery System to listed product families.
28 April 2017	8726875	Add Chunghwa Chemical Synthesis & Biotech Co., Ltd as Crucial Supplier

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Page 1 of 2

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 is valid for 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.

For information and contact: BSI, Standards Central, 389, Chiswick Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1875 930100  
BSI Customer Services, 138, Blenheim Road, Bournemouth, Dorset, UK. Tel: +44 (0)1202 316100  
Fax: +44 (0)1202 316101  
Email: [bsi.enquiries@bsi.org.uk](mailto:bsi.enquiries@bsi.org.uk)

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619995**  
Date: **2018-04-18**  
Issued To: **OrbusNeich Medical B.V.,  
Drs. W.van Royenstraat 5  
3871 AN Hoevelaken  
The Netherlands**

Date	Reference Number	Action
19 May 2017	8604338	Add ScoreFlex Coronary Dilatation Catheter, Sapphire NC Coronary Dilatation Catheter, Sapphire II NC Coronary Dilatation Catheter, and Sapphire II (RX) Coronary Dilatation Catheter to listed product families; transfer from another notified body.
5 March 2018	8730349	Addition of Teleport Microcatheter to listed product families.
Current	8883580	Certificate Renewal. Remove supplier Biolvent International AB. Correction to name of Synergy Health AST, Venlo.

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Page 2 of 2

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 is valid for 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.

For information and contact: BSI, Standards Central, 389, Chiswick Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1875 930100  
BSI Customer Services, 138, Blenheim Road, Bournemouth, Dorset, UK. Tel: +44 (0)1202 316100  
Fax: +44 (0)1202 316101  
Email: [bsi.enquiries@bsi.org.uk](mailto:bsi.enquiries@bsi.org.uk)



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# EC Design-Examination Certificate

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

No. **CE 646780**  
Issued To: **OrthusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

In respect of:  
**Scoreflex NC Coronary Dilatation Catheter**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

**Frank Lee, EMEA Compliance & Risk Director**

First Issued: **12 May 2016**      Date: **31 January 2017**

Expiry Date: **11 May 2021**  
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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 certificate was issued directly into the certificate of the contract. For enquiries and contact, please contact BSI, 389 Chiswick Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1875 930100. BSI also provides the British Standard BS EN ISO 13485:2012 and BS EN ISO 13485:2012/1:2009. BSI is a member of the British Standards Institution.



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# EC Design-Examination Certificate

Supplementary Information to CE 646780

Issued To: **OrthusNeich Medical B.V.**  
**Drs. W.van Royenstraat 5**  
**3871 AN Hoevelaken**  
**The Netherlands**

## Scoreflex NC Coronary Dilatation Catheter

### List of Product Numbers

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
617-104-1	1.75	10
617-154-1	1.75	15
617-204-1	1.75	20
620-104-1	2.0	10
620-154-1	2.0	15
620-204-1	2.0	20
622-104-1	2.25	10
622-154-1	2.25	15
622-204-1	2.25	20
625-104-1	2.5	10
625-154-1	2.5	15
625-204-1	2.5	20
627-104-1	2.75	10
627-154-1	2.75	15
627-204-1	2.75	20
630-104-1	3.0	10

First Issued: **12 May 2016**

Date: **31 January 2017**

Expiry Date: **11 May 2021**  
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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 certificate was issued directly into the certificate of the contract. For enquiries and contact, please contact BSI, 389 Chiswick Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1875 930100. BSI also provides the British Standard BS EN ISO 13485:2012 and BS EN ISO 13485:2012/1:2009. BSI is a member of the British Standards Institution.



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## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

**OrbusNeich Medical B.V.**  
Drs. W.van Royenstraat 5  
3871 AN Hoevelaken  
The Netherlands

Holds Certificate Number:

MD 649583

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

Design, development, manufacture, inspection, and distribution of sterile coronary and peripheral stents, delivery systems, dilatation catheters, guiding catheters

For and on behalf of BSI:

*J M Brain*

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-01  
Latest Revision Date: 2018-06-06

Effective Date: 2018-06-08  
Expiry Date: 2021-06-07  
Page: 1 of 1



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## EC Declaration of Conformity

### JADE PTA Balloon Dilation Catheter

Product Name : JADE PTA Balloon Dilation Catheter  
 Classification : Class IIa (MDD Annex IX)  
 Conformity Assessment : MDD 93/42/EEC, Annex II

Manufacturer: ObusMehc Medical B.V.  
 Name: Drs. W. van Royenstraat 5  
 Address: 3871 AN Hoerjaken  
 The Netherlands

EU Authorized Representative: Quality First International Limited  
 Name: Suites 317-318  
 Address: Burford Business Centre  
 11 Burford Road  
 Stratford, London E15 2ST  
 United Kingdom

Notified Body: BSI Assurance UK Limited  
 Name: Klenmark Court, Davy Avenue  
 Address: Knockhill, Milton Keynes,  
 MK5 8PP  
 United Kingdom

Certificates: EC Certificate No.: CE 619995  
 Medical Device Directive: Council Directive 93/42/EEC of June 14<sup>th</sup>, 1993 concerning medical devices (MDD 93/42/EEC)

We hereby declare that the distributed CE marked products, as specified on the attached product schedule, are covered by the "CE Marking of Conformity Certificate", reference number CE 619995 and delivered by Notified Body "BSI Assurance UK Limited", Notified Body Identification Number 0086. All products on the attached schedule meet the provisions of the abovementioned EC Council Directives, and conform to the required technical documentation, in accordance with Annex II of the "EC-Directive", the "Council Directive 93/42/EEC of 14 June 1993, concerning medical devices".

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II (full quality assurance system) of the Council Directive 93/42/EEC. The conformity of the production quality assurance set out in Annex II, is confirmed in the said CE Marking of Conformity Certificate, issued and delivered by BSI Assurance UK Limited.

All supporting documentation, in evidence to the above, is retained on the premises of the manufacturer:

Authorized Representative: E.S. Henning  
 Signature: *[Signature]*  
 Title: *[Title]*  
 Signature: *[Signature]*  
 Place & Date: *[Signature]*  
 March 14, 2016

### Product Schedule:

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
515-015-41	1.5 mm	15 mm
515-020-41	1.5 mm	20 mm
515-040-41	1.5 mm	40 mm
515-080-41	1.5 mm	80 mm
515-120-41	1.5 mm	120 mm
520-015-41	2.0 mm	15 mm
520-020-41	2.0 mm	20 mm
520-040-41	2.0 mm	40 mm
520-080-41	2.0 mm	80 mm
520-120-41	2.0 mm	120 mm
525-020-41	2.5 mm	20 mm
525-040-41	2.5 mm	40 mm
525-080-41	2.5 mm	80 mm
525-120-41	2.5 mm	120 mm
530-015-41	3.0 mm	15 mm
530-020-41	3.0 mm	20 mm
530-040-41	3.0 mm	40 mm
530-080-41	3.0 mm	80 mm
530-120-41	3.0 mm	120 mm
535-020-41	3.5 mm	20 mm
535-040-41	3.5 mm	40 mm
535-080-41	3.5 mm	80 mm
535-120-41	3.5 mm	120 mm
540-015-41	4.0 mm	15 mm
540-020-41	4.0 mm	20 mm
540-040-41	4.0 mm	40 mm
540-080-41	4.0 mm	80 mm
540-120-41	4.0 mm	120 mm
545-020-41	4.5 mm	20 mm
545-040-41	4.5 mm	40 mm
545-080-41	4.5 mm	80 mm
545-120-41	4.5 mm	120 mm
550-015-41	5.0 mm	15 mm
550-020-41	5.0 mm	20 mm
550-040-41	5.0 mm	40 mm
550-080-41	5.0 mm	80 mm
550-120-41	5.0 mm	120 mm
555-020-41	5.5 mm	20 mm
555-040-41	5.5 mm	40 mm
555-080-41	5.5 mm	80 mm
560-015-41	6.0 mm	15 mm



DC-0021 Rev 02

DCN: 180042  
EFF DATE: 09/12/06  
Page 3 of 3

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
560-020-41	6.0 mm	20 mm
560-040-41	6.0 mm	40 mm
560-080-41	6.0 mm	80 mm

## EC Declaration of Conformity

### Scoreflex NC Coronary Dilatation Catheter

Product Name : Scoreflex NC Coronary Dilatation Catheter  
 Classification : Class III (MDD Annex IX)  
 Conformity Assessment : MDD 93/42/EEC, Annex II  
 Manufacturer: ObusNatch Medical, B.V.  
 Address: Drs. W. van Royenstraat 5  
 3871 AN Heerhaleken  
 The Netherlands

EU Authorized Representative:

Name: Quality First International Limited  
 Address: Suites 317-318  
 Burford Business Centre  
 11 Burford Road  
 Stratford, London E15 2ST  
 United Kingdom

Notified Body:

Name: BSI Assurance UK Limited  
 Address: Kitemark Court, Davy Avenue,  
 Knowlhill, Milton Keynes,  
 MK5 8PP,  
 United Kingdom

Certificates:

EC Certificate No.: CE 619995  
 EC Design Examination Certificate No.: CE 646780

General Applicable Directives

Medical Device Directive: Council Directive 93/42/EEC of June  
 14<sup>th</sup>, 1993 concerning medical devices (MDD 93/42/EEC)

We hereby declare that the distributed CE marked products, as specified on the attached product schedule, are covered by the "CE Marking of Conformity Certificate", and delivered by Notified Body "BSI Assurance UK Limited", Notified Body Identification Number: 0086. All products on the attached schedule meet the provisions of the abovementioned EC Council Directives, and conform to the required technical documentation, in accordance with Annex II of the "EC-Directive", the "Council Directive 93/42/EEC of 14 June 1993, concerning medical devices".

This declaration is based on the application of the Quality System approved for the design manufacture and final inspection of the products concerned, in accordance with Annex II (Full quality assurance system) of the Council Directive 93/42/EEC. The conformity of the production quality assurance set out in Annex II, is confirmed in the said CE Marking of Conformity Certificate, issued and delivered by BSI Assurance UK Limited.

All supporting documentation, in evidence to the above, is retained on the premises of the manufacturer.

Authorized Representative:

*EJ Tennant*  
 Signature  
 Sales Manager Q&A (RF)

Title:

Signature:

*Trudisha THA Haveland*  
 Signature  
 September 9, 2016

Place & Date:

Product Schedule:

Catalog Number	Scoreflex NC Coronary Dilatation Catheter	
	Balloon Diameter (mm)	Balloon Length (mm)
617-104-1	1.75	10
617-154-1	1.75	15
617-204-1	1.75	20
620-104-1	2.0	10
620-154-1	2.0	15
620-204-1	2.0	20
622-104-1	2.25	10
622-154-1	2.25	15
622-204-1	2.25	20
625-104-1	2.5	10
625-154-1	2.5	15
625-204-1	2.5	20
627-104-1	2.75	10
627-154-1	2.75	15
627-204-1	2.75	20
630-104-1	3.0	10
630-154-1	3.0	15
630-204-1	3.0	20
635-104-1	3.5	10
635-154-1	3.5	15
635-204-1	3.5	20
640-104-1	4.0	10
640-154-1	4.0	15
640-204-1	4.0	20

**EC Declaration of Conformity**

**Scoreflex PTA Balloon Dilatation Catheter**

Product Name : Scoreflex PTA Balloon Dilatation Catheter  
 Classification : Class IIIa (MDD Annex IX)  
 Conformity Assessment : MDD 93/42/EEC Annex II

Manufacturer: **OnlusNebich Medical, B.V.**  
 Name: Drs. V. van Royenstraat 5  
 Address: 3871 AN Horevalken  
 The Netherlands

EU Authorized Representative: **Quality First International Limited**  
 Name: Suijter 317-318  
 Address: Burford Business Centre  
 11 Burford Road  
 Swafford, London E15 2ST  
 United Kingdom

Notified Body: **BSI Assurance UK Limited**  
 Name: Kiermark Court, Davy Avenue,  
 Address: Kewstall, Milton Keynes,  
 MK5 8PP,  
 United Kingdom

Certificates: **EC Certificate No.: CE 619995**

General Applicable Directives **Medical Device Directive: Council Directive 93/42/EEC of June 14<sup>th</sup>, 1993 concerning medical devices (MDD 93/42/EEC)**

We hereby declare that the distributed CE marked products, as specified on the attached product schedule, are covered by the "CE Marking of Conformity Certificate" reference number CE 619995 and delivered by Notified Body "BSI Assurance UK Limited", Notified Body Identification Number: 0086. All products on the attached schedule meet the provisions of the abovementioned EC Council Directives, and conform to the required technical documentation, in accordance with Annex II of the "EC-Directive", the "Council Directive 93/42/EEC of 14 June 1993, concerning medical devices".

This declaration is based on the application of the Quality System approved for the design manufacture and final inspection of the products concerned, in accordance with Annex II (full quality assurance system) of the Council Directive 93/42/EEC. The conformity of the production quality assurance set out in Annex II, is confirmed in the said CE Marking of Conformity Certificate, issued and delivered by BSI Assurance UK Limited.

All supporting documentation, in evidence to the above, is retained on the premises of the manufacturer.

Authorized Representative: **E.J. Hennink**  
 Title: **SE Manager QIA mms VCA**  
 Signature: *[Handwritten Signature]*  
 Place & Date: **Horevalken, THE NETHERLANDS**  
**March 14, 2016**

**Product Schedule:**

Scoreflex PTA 14 series (0.014" guidewire compatible), Coil Version

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
640F-20A-31	4.0	20
640F-40A-31	4.0	40
650F-20A-31	5.0	20
650F-40A-31	5.0	40
660F-20A-31	6.0	20
660F-40A-31	6.0	40
620F-20B-31	2.0	20
620F-40B-31	2.0	40
625F-20B-31	2.5	20
625F-40B-31	2.5	40
630F-20B-31	3.0	20
630F-40B-31	3.0	40
635F-20B-31	3.5	20
635F-40B-31	3.5	40
640F-20B-31	4.0	20
640F-40B-31	4.0	40
645F-20B-31	4.5	20
645F-40B-31	4.5	40
650F-20B-31	5.0	20
650F-40B-31	5.0	40
655F-20B-31	5.5	20
655F-40B-31	5.5	40
660F-20B-31	6.0	20
660F-40B-31	6.0	40
620F-15X-31	2.0	15
620F-20X-31	2.0	20
620F-40X-31	2.0	40
625F-15X-31	2.5	15
625F-20X-31	2.5	20
625F-40X-31	2.5	40
630F-15X-31	3.0	15
630F-20X-31	3.0	20
630F-40X-31	3.0	40
635F-15X-31	3.5	15
635F-20X-31	3.5	20
635F-40X-31	3.5	40
640F-15X-31	4.0	15
640F-20X-31	4.0	20
640F-40X-31	4.0	40
645F-15X-31	4.5	15
645F-20X-31	4.5	20
645F-40X-31	4.5	40
650F-15X-31	5.0	15
650F-20X-31	5.0	20
650F-40X-31	5.0	40
655F-15X-31	5.5	15
655F-20X-31	5.5	20
655F-40X-31	5.5	40
660F-15X-31	6.0	15
660F-20X-31	6.0	20
660F-40X-31	6.0	40

Scoreflex PTA 14 series (0.014" guidewire compatible), No-Coil Version

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
620F-15N-31	2.0	15
620F-20N-31	2.0	20
620F-40N-31	2.0	40
625F-15N-31	2.5	15
625F-20N-31	2.5	20
625F-40N-31	2.5	40
630F-15N-31	3.0	15
630F-20N-31	3.0	20
630F-40N-31	3.0	40
635F-15N-31	3.5	15
635F-20N-31	3.5	20
635F-40N-31	3.5	40
640F-15N-31	4.0	15
640F-20N-31	4.0	20
640F-40N-31	4.0	40

Scoreflex PTA 18 series (0.018" guidewire compatible), Coil Version Only

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
640E-40A-31	4.0	20
640E-40B-31	4.0	40
650E-20A-31	5.0	20
650E-40A-31	5.0	40
650E-20B-31	6.0	20
650E-40A-31	6.0	40
620E-20B-31	2.0	20
620E-40B-31	2.0	40
625E-20B-31	2.5	20
625E-40B-31	2.5	40
630E-20B-31	3.0	20
630E-40B-31	3.0	40
635E-20B-31	3.5	20
635E-40B-31	3.5	40
640E-20B-31	4.0	20
640E-40B-31	4.0	40
645E-20B-31	4.5	20
645E-40B-31	4.5	40
650E-20B-31	5.0	20
650E-40B-31	5.0	40
655E-20B-31	5.5	20
655E-40B-31	5.5	40
660E-20B-31	6.0	20
660E-40B-31	6.0	40
620E-15X-31	2.0	15
620E-20X-31	2.0	20
620E-40X-31	2.0	40
625E-15X-31	2.5	15
625E-20X-31	2.5	20
625E-40X-31	2.5	40
630E-15X-31	3.0	15
630E-20X-31	3.0	20
630E-40X-31	3.0	40
635E-15X-31	3.5	15
635E-20X-31	3.5	20
635E-40X-31	3.5	40
640E-15X-31	4.0	15
640E-20X-31	4.0	20

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)
645E-40X-31	4.0	40
645E-15X-31	4.5	15
645E-20X-31	4.5	20
645E-40X-31	4.5	40
650E-15X-31	5.0	15
650E-20X-31	5.0	20
650E-40X-31	5.0	40
655E-15X-31	5.5	15
655E-20X-31	5.5	20
655E-40X-31	5.5	40
660E-15X-31	6.0	15
660E-20X-31	6.0	20
660E-40X-31	6.0	40

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# EC Certificate - Full Quality Assurance System

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

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By Royal Charter

Certificate No: CE 511137

## Certificate Scope:

The design, development and manufacture of ARROWg+ and Blue Plus Central Venous Catheters (CVC); Arrowg+ and Blue CVCs, hemodialysis catheters and Percutaneous Sheath Introducers (PSI); non-coated CVC, PSI, hemodialysis catheters, Peripherally Inserted Central Catheters (PICCs), thermofusion 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), drainage catheters, Pneumothorax/Thoracentesis products, arterial catheterization products, Percutaneous Thrombolytic Device (PTD), central catheters with Chlorag+ and technology, 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 relating to obtaining and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

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: 0086):

Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: 2006-10-18

Date: 2018-01-15

Expiry Date: 2021-10-17

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Page 1 of 2

First Issued: 2006-10-18

Date: 2018-01-15

Expiry Date: 2021-10-17

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated by a the periodic surveillance activities of the notified body. This approval extends to products designed and/or manufactured by a third party on behalf of the certificate holder. This certificate, unless specifically agreed with BSI, may not be used electronically and is bound by the conditions of the contract.  
Information on BSI: BSI, 88, Kingsway, Guildford, Surrey, GU1 9AT, UK. Tel: +44 (0)1256 346000  
Fax: +44 (0)1256 346001  
Email: bsi@bsi.com  
BSI is a registered charity. Registered in England under number 2098721. In Scotland under number 50260682. A member of BSI Group of Companies.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated by the regular surveillance activities of the Notified Body. This approval extends to products designed and/or manufactured by a third party on behalf of the certificate holder. This certificate, unless specifically agreed with BSI, may not be used electronically and is bound by the conditions of the contract.  
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Fax: +44 (0)1256 346001  
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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: **2018-01-15**  
 Issued To: **Arrow International, Inc.**  
 (subsidiary of Teleflex, Incorporated)  
 2400 Bernville Road  
 Reading  
 Pennsylvania  
 19605  
 USA

### Subcontractor: Service(s) supplied

Acme Monaco Corporation  
 75 Winchell Drive  
 New Britain  
 CT 06052  
 USA

Manufacture

Arrow Internacional de Chihuahua  
 S.A. de C.V., Ave Washington 3701,  
 Edificio 2  
 Colonia Panamerica, Chihuahua  
 CP31200  
 Mexico

Manufacture  
Packaging

Arrow Internacional de Chihuahua  
 S.A. de C.V., Ave Washington 3701,  
 Interior Circuito Industrial Alta  
 Tecnologia Edificio 40  
 Colonia Panamerica, Chihuahua,  
 Chihuahua  
 CP31200  
 Mexico

Manufacture  
Packaging

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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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 (subsidiary of Teleflex, Incorporated)  
 2400 Bernville Road  
 Reading  
 Pennsylvania  
 19605  
 USA

### 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  
 CP31114  
 Mexico

Manufacture  
Packaging

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

Manufacture

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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: **2018-01-15**

Issued To:

**Arrow International, Inc.**  
(Subsidiary of Teleflex, Incorporated)  
2400 Berrville Road  
Reading  
Pennsylvania  
19605  
USA

#### Subcontractor:

Arrow International CR, a.s.

Janska 2359/47

Zdar nad Sazavou

59101

Czech Republic

Arrow International CR, a.s.

Prasaka 209

50004 Hradec Králové

Czech Republic

Arrow International, Inc.

16 Elizabeth Drive

Chelmsford

Massachusetts 01824

USA

Arrow International, Inc.

312 Commerce Place

Asheboro

North Carolina 27203

USA

Service(s) supplied

Manufacture

Manufacture

Manufacture

ETO Sterilization  
Manufacture

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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: **2018-01-15**

Issued To:

**Arrow International, Inc.**  
(Subsidiary of Teleflex, Incorporated)  
2400 Berrville Road  
Reading  
Pennsylvania  
19605  
USA

#### Subcontractor:

Bivalent Ltd

Parkmore West Business Park

Galway

Ireland

Celestica Oregon LLC

18870 NE Riverside Parkway

Portland

OR 97230

USA

Custom Wire Technologies, Inc.

1123 Mineral Springs Drive

Port Washington

WI 53074

USA

EpiTex Feinwerktechnik GmbH

Im Schwilbogen 24

72581 Dettingen/Erms

Germany

Service(s) supplied

Manufacture

Manufacture

Manufacture

Manufacture

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**EC Certificate - Full Quality Assurance System**

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



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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: **2018-01-15**

Issued To: **Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)**

**2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA**

**Subcontractor:**

**Sterigenics, Inc.  
10821 Withers Cove Park Drive  
Charlotte  
North Carolina 28278  
USA**

**Service(s) supplied**

**ETO Sterilization**

**ETO Sterilization**

**Sterigenics  
2400 Airport Road  
Santa Teresa  
New Mexico  
88008  
USA**

**ETO Sterilization**

**Sterigenics  
7775 South Quincy  
Willowbrook  
Illinois  
60527  
USA**

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**List of Significant Subcontractors**

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

Certificate No: **CE 511137**

Date: **2018-01-15**

Issued To: **Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)**

**2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA**

**Subcontractor:**

**STERIS AST CZ s.r.o.  
Prumyslova Zona Kosiřov  
Velka Bites Vysocina  
595 01  
Czech Republic**

**Service(s) supplied**

**ETO Sterilization  
Microbiology Service**

**Control of Sterilization  
EU Representative  
Manufacture**

**Teleflex Medical Europe Ltd.  
IDA Business and Technology Park  
Dublin Road, Athlone,  
Co. Westmeath  
Ireland**

**Teleflex Medical  
3015 Carrington Mill Boulevard  
Morrisville  
North Carolina 27560  
USA**

**Design  
Regulatory Compliance**

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 511137**  
Date: **2018-01-15**  
Issued To: **Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
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, Wyoming Pennsylvania from the list of significant subcontractors. Added Teleflex Medical as EU Representative to the list of significant subcontractors.

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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the regular 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 stated with BSI.  
This certificate was issued electronically and is issued by the conditions of the contract.  
Information and Contact: BSI, Customer Care, Davy Avenue, Ipswich, Suffolk IP8 3PP, UK. Tel: +44 (0)300 890000  
BSI, Registration and Certification, 389 Chiswick High Road, Uxbridge, Middlesex UB8 3PH, UK. Tel: +44 (0)1875 910000  
A member of BSI Group of Companies.

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 511137**  
Date: **2018-01-15**  
Issued To: **Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA**

Date	Reference Number	Action
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.
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	EPiFlex Feinwerktechnik, Acme Monaco, Galt Medical, Lake Region Medical (USA and Ireland), Bryvant and Neometrics added to the list of significant subcontractors.

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Page 2 of 4

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BSI, Registration and Certification, 389 Chiswick High Road, Uxbridge, Middlesex UB8 3PH, UK. Tel: +44 (0)1875 910000  
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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 511137  
Date: 2018-01-15  
Issued To: Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA

Date	Reference Number	Action
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 Treatate and Teleflex Medical (North Carolina) added to the list of subcontractors.
12 August 2015	8373794	Update certificate scope to add: central catheters with Chloragrad technology and Change: "mid-line catheters" to "mid-line/peripheral vascular access catheters". Arrow International 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 International de Chihuahua facilities.
26 August 2015	8332115	Scope extension to include the Vascular Positioning System (VPS). Introduction of Sterigents (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.

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Page 3 of 4

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This certificate was issued electronically and is valid for the duration of the certificate.

Information and contact: BSI, Knowledge Centre, Dairy Avenue, 3899 Hill Close, Weybridge, Surrey TW20 2EX, UK. Tel: +44 (0) 1344 850001  
BSI, Knowledge Centre, Liberty Square, 3899 Hill Close, Weybridge, Surrey TW20 2EX, UK. Tel: +44 (0) 1344 850001  
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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 511137  
Date: 2018-01-15  
Issued To: Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA

Date	Reference Number	Action
27 April 2017	8718569	Add Packaging services to Edificio 4, 40 and 2 Chihuahua locations per previous review SMO 8405167 & EQ 1015720
11 July 2017	8750813	Removed Arrow Interventional Everett, MA from list of subcontractors and changed subcontractor name from "Edbster s.r.o." to "STERIS AST CZ s.r.o."
Current	8857195	Adding Arrow International de Chihuahua, Edificio 36 as manufacturing subcontractor. Remove information from Arrow International de Chihuahua, Edificio 2 address to match their ISO-13485 certificate.

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Page 4 of 4

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BSI, Knowledge Centre, Liberty Square, 3899 Hill Close, Weybridge, Surrey TW20 2EX, UK. Tel: +44 (0) 1344 850001  
A member of the BSI Group of companies.



DECLARATION OF CONFORMITY  
DC-T-BSI-008

Manufacturer:  
Arrow International, Inc.  
2400 Berwynville Road  
Reading, PA 19605 USA

European Representative:  
Teleflex Medical  
IDA Business and Technology Park  
Duhlin Road  
Athlone, Co. Westmeath, Ireland

Product Name: Sheath Introducers, Multi-Access Catheters (MAC) and Accessories	Technical File #:	T-BSI-008
GMDN Code: 58865 Vascular catheter introduction kit	Classification:	Ia
46505 - Instrument guard, single-use	Classification:	Ia

GMDN Code:	58865 Vascular catheter introduction kit	Classification:	Ia
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
AD-09801	PSI: 8.5 Fr.	9-Mar-98	
AD-09903	PSI: 9 Fr.	9-Mar-98	
AD-09903-S	PSI: 9 Fr.	9-Mar-98	
AH-09801	PSI: 9 Fr.	14-Mar-02	
AH-09601	PSI: 6 Fr.	14-Mar-03	
AK-09701	PSI: 7 Fr.	14-Mar-03	
AK-09801	PSI: 8.5 Fr.	22-Dec-98	
AK-09801-A	PSI: 8.5 Fr.	9-Nov-01	
AT-09875-E	PSI SET: 8.5 FR	21-Dec-15	
BB-09903-C	PSI: 9 Fr.	23-Feb-07	
BR-09903-S	PSI: 9 Fr.	29-Jul-03	
CA-09801-SB	PSI: 8.5 Fr.	23-May-00	
CA-09886	PSI: 8.5 Fr.	23-May-00	
CI-09600	PSI: 6 Fr.	10-Dec-97	
CI-09800	PSI: 8.5 Fr.	28-Jul-03	
CI-09800-SB	PSI: 8.5 Fr.	9-Mar-98	
CI-09803	PSI: 8 Fr.	25-Aug-02	
CI-09830	PSI: 8.5 Fr.	25-Mar-98	
CI-07011	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 11 cm	25-Mar-98	
CI-07024	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 24 cm	25-Mar-98	
CI-07035	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 35 cm	25-Mar-98	
CI-07045	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 45 cm	25-Mar-98	
CI-07065	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 65 cm	25-Mar-98	
CI-07080	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 80 cm	9-Mar-98	
CI-07511	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 11 cm	25-Mar-98	
CI-07524	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 24 cm	25-Mar-98	
CI-07545	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 45 cm	25-Mar-98	
CI-07565	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 65 cm	25-Mar-98	
CI-07590	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 90 cm	25-Mar-98	
CI-07611	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98	
CI-07624	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 24 cm	25-Mar-98	
CI-07635	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 35 cm	25-Mar-98	
CI-07645	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 45 cm	25-Mar-98	
CI-07665	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 65 cm	25-Mar-98	
CI-07690	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 90 cm	25-Mar-98	
CI-07700	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 100 cm	25-Mar-98	
CI-07711	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 11 cm	25-Mar-98	

\*Confidential\*

The footer information below is for reference only.

RAQA-1098 REV. 07 ISSUED: Refer to page

PARENT DOC: RAQA-098 Page 1 of 8



DECLARATION OF CONFORMITY  
DC-T-BSI-008

GMDN Code:	58865 Vascular catheter introduction kit	Classification:	Ia
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
CI-07724	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 24 cm	25-Mar-98	
CI-07735	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 35 cm	25-Mar-98	
CI-07745	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 45 cm	25-Mar-98	
CI-07765	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 65 cm	25-Mar-98	
CI-07780	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 80 cm	25-Mar-98	
CI-07790-R	Super Arrow-Flex® PSI: 7 Fr. x 90 cm	23-Nov-98	
CI-07800	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 100 cm	25-Mar-98	
CI-07811	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 11 cm	25-Mar-98	
CI-07824	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 24 cm	25-Mar-98	
CI-07835	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 35 cm	25-Mar-98	
CI-07845	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 45 cm	25-Mar-98	
CI-07865	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 65 cm	25-Mar-98	
CI-07880	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 80 cm	25-Mar-98	
CI-07900	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 100 cm	25-Mar-98	
CI-07911	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 11 cm	25-Mar-98	
CI-07924	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 24 cm	25-Mar-98	
CI-07965	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 65 cm	25-Mar-98	
CI-07980	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 80 cm	25-Mar-98	
CI-08403	Cath Lab PSI: 4 Fr. x 7.5 cm	25-Mar-98	
CI-08403-A	Cath Lab PSI: 4 Fr. x 11 cm	26-May-98	
CI-08403-AE	Cath Lab PSI: 4 Fr. x 11 cm	17-Feb-06	
CI-08303	Cath Lab PSI: 5 Fr. x 7.5 cm	25-Mar-98	
CI-08303-A	Cath Lab PSI: 5 Fr. x 11 cm	25-Mar-98	
CI-08305	Cath Lab PSI: 5 Fr. x 5 cm	25-Mar-98	
CI-08603	Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98	
CI-08605	Cath Lab PSI: 6 Fr. x 5 cm	25-Mar-98	
CI-08605-HF	High-Flow Cath Lab PSI: 6 Fr. x 5 cm	24-Jan-01	
CI-08703	Cath Lab PSI: 7 Fr. x 11 cm	25-Mar-98	
CI-08705-HF	High-Flow Cath Lab PSI: 7 Fr. x 5 cm	25-Mar-98	
CI-08803	Cath Lab PSI: 8 Fr. x 11 cm	25-Mar-98	
CI-08903	Super Arrow-Flex® Cath Lab PSI: 11 Fr. x 65 cm	25-Mar-98	
CI-71165	Super Arrow-Flex® Cath Lab PSI: 11 Fr. x 80 cm	25-Mar-98	
CI-71180	Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 11 cm	25-Mar-98	
CP-07011	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 11 cm	25-Mar-98	
CP-07511	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 11 cm	25-Mar-98	
CP-07511-P	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 7.5 cm	25-Mar-98	
CP-07611	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98	
CP-07711	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98	
CP-07811	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 11 cm	25-Mar-98	
CP-07911	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 11 cm	25-Mar-98	
CP-08403	Cath Lab PSI: 4 Fr. x 7.5 cm	25-Mar-98	
CP-08503	Cath Lab PSI: 5 Fr. x 7.5 cm	25-Mar-98	
CP-08503-A	Cath Lab PSI: 5 Fr. x 11 cm	25-Mar-98	
CP-08603	Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98	
CP-08603-P	Cath Lab PSI: 6 Fr. x 7.5 cm	25-Mar-98	
CP-08703	Cath Lab PSI: 7 Fr. x 11 cm	25-Mar-98	
CP-08803	Cath Lab PSI: 8 Fr. x 11 cm	25-Mar-98	

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DECLARATION OF CONFORMITY DC-T-BSI-008

GMDN Code:	5865 Vascular catheter introduction kit	Classification	IIa
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
CR-08903	Cath Lab PSI: 9 Ft. x 11 cm	25-Mar-98	
CR-07645	Super Arrow Flex® PSI: 6 Ft. x 45 cm	19-Feb-99	
CR-07745	Super Arrow Flex® PSI: 7 Ft. x 45 cm	30-Jun-98	
CR-0745-NT	Super Arrow Flex® PSI: 7 Ft. x 45 cm	21-Jul-99	
CT-07860	Super Arrow Flex® PSI: 8 Ft. x 60 cm	25-Mar-98	
CW-08403	Cath Lab PSI: 4 Ft. x 7.5 cm	25-Mar-98	
CW-08503	Cath Lab PSI: 5 Ft. x 7.5 cm	3-Feb-99	
CW-08503-A	Cath Lab PSI: 5 Ft. x 11 cm	25-Mar-98	
CW-08603	Cath Lab PSI: 6 Ft. x 11 cm	25-Mar-98	
CW-08803	Cath Lab PSI: 8 Ft. x 11 cm	25-Mar-98	
CW-08903	Cath Lab PSI: 9 Ft. x 11 cm	25-Mar-98	
❖ DE-09600-UNH	PSI: 6 Ft.	13-Sep-17	
❖ DE-09875-HZO	PSI Kit: 8.5 Ft.	11-Jun-12	
❖ DE-09875-HZO	PSI Kit: 8.5 Ft.	14-Sep-17	
❖ DM-09875-HZO	PSI: 9 Ft.	30-Mar-98	
❖ GR-08403	Cath Lab PSI: 4Ft. x 11 cm	17-Feb-12	
❖ GR-08503-A	Cath Lab PSI: 5 Ft. x 11 cm	21-Oct-10	
❖ GR-08603	Cath Lab PSI: 6 Ft. x 11 cm	21-Oct-10	
❖ GR-08703	Cath Lab PSI: 7 Ft. x 11 cm	21-Oct-10	
❖ GR-09903-S	PSI: 9 Ft.	6-Jan-03 or 14-May-99	
❖ HR-09903-S	PSI: 9 Ft.	23-Sep-98	
HP-09903	PSI: 9 Ft.	14-Jul-02 or 08-April-98	
❖ HZ-09801	PSI: 8.5 Ft.	5-Aug-05	
❖ IK-09600	PSI: 6 Ft.	27-Jun-05	
❖ LU-09903	PSI: 9 Ft.	14-Jul-00	
❖ MS-07803	PSI: 9 Ft.	19-Sep-01	
❖ MS-09600	PSI: 6 Ft.	17-Jan-13	
❖ NL-09801-MUMC	PSI Kit 9 Ft.	10-Dec-97 or 14-May-99	
❖ SG-09903	PSI: 9 Ft.	16-Jun-08	
❖ SI-09600-LJ	PSI: 6 Ft.	25-Mar-98	
SI-09700	PSI: 7 Ft.	19-Dec-97	
SI-09700-LJ	PSI: 7 Ft.	12-Mar-08	
SI-09803-CV	PSI: 8.5 Ft.	21-Aug-98	
SI-09806	PSI: 8.5 Ft.	9-Mar-98	
SI-09808	PSI: 8 Ft.	10-Dec-97	
❖ SI-09808-LJ	PSI: 8 Ft.	14-Mar-08	
SI-09870-E	PSI: 8.5 Ft.	10-Dec-97	
❖ SI-09875-E	PSI: 8.5 Ft.	11-Apr-05	
❖ SI-09875-EAAG	PSI: 8.5 Ft.	17-Jun-02	
SI-09875-E5B	PSI: 8.5 Ft.	10-Dec-97	
SI-09880	PSI: 8.5 Ft.	14-Jan-00	
SI-09880-LF	PSI: 8.5 Ft.	13-Dec-03	
❖ SI-09880-OB	PSI: 8.5 Ft.	17-Jun-02	
SI-09880-SB	PSI: 8.5 Ft.	9-Mar-98	
SI-09880-SE	PSI: 8.5 Ft.	10-Dec-97	
SI-09903-E	PSI: 9 Ft.	10-Dec-97	

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DECLARATION OF CONFORMITY DC-T-BSI-008

GMDN Code:	5865 Vascular catheter introduction kit	Classification	IIa
PSI Finished Goods #	Device Description	Date CE Mark First Affixed	
SS-09903-S	PSI: 9 Ft.	17-Oct-07	
❖ SU-09903-C	PSI: 9 Ft.	3-Apr-07	
❖ UB-09903-C	PSI: 9 Ft.	30-Oct-01	
❖ UE-09800	PSI: 8.5 Ft.	13-Feb-01	
❖ UR-09903	PSI: 9 Ft.	24-Oct-08	
❖ UR-09880-LF	PSI: 8.5 Ft.	4-Dec-02	
WH-09880-T	PSI: 8.5 Ft.	19-Dec-97	
PSI Part #	Device Description	Czech Part #	(if applicable)
(if applicable)			
K-09601-014	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
K-09701-004	Sheath Ext: 7 Ft x 4-1/8"	N/A	
K-09701-005	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
K-09800-008	Sheath Ext Assy w/Dilator: 8.5 Ft	N/A	
K-09808-005	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
K-09880-012	Sheath Ext Assy w/Dilator: 8.5 Ft	N/A	
K-09880-015	Sheath Ext Assy w/DI Comm: 8.5ft Hydrop	N/A	
L-07011-001B	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07024-001B	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07035-001C	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07045-001E	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07065-001C	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07080-001A	Sheath Ext Assy w/Dilator: 10 Ft	N/A	
L-07511-001B	Sheath Ext Assy w/Dilator: 5 Ft	N/A	
L-07524-001B	Sheath Ext Assy w/Dilator: 5 Ft	N/A	
L-07545-001D	Sheath Ext Assy w/Dilator: 5 Ft	N/A	
L-07565-001B	Sheath Ext Assy w/Dilator: 5 Ft	N/A	
L-07590-001B	Sheath Ext Assy w/Dilator: 5 Ft	N/A	
L-07611-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07624-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07635-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07645-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07665-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07690-001C	Sheath Ext Assy w/Dilator: 6 Ft	N/A	
L-07700-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07711-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07724-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07735-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07745-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07765-001	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07780-001C	Sheath Ext Assy w/Dilator: 7 Ft	N/A	
L-07800-001D	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07811-001B	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07824-001C	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07835-004	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07845-001D	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07865-001D	Sheath Ext Assy w/Dilator: 8 Ft	N/A	
L-07900-001B	Sheath Ext Assy w/Dilator: 9 Ft	N/A	

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PSI Part # (if applicable)	Device Description	Czech Part # (if applicable)
L-07911-001B	Sheath Ext Assy w/Dilator: 9 Ft	N/A
L-07924-001B	Sheath Ext Assy w/Dilator: 9 Ft	N/A
L-07965-001C	Sheath Ext Assy w/Dilator: 9 Ft	N/A
L-07980-001B	Sheath Ext Assy w/Dilator: 9 Ft	N/A
L-08705-003A	Sheath Ext Assy w/Dilator: 7 Ft	N/A
L-09807-002	Sheath Ext Assy w/Dilator: 8.5 Ft	LZ-09807-002
L-71180-001	Sheath Ext Assy w/Dilator: 11 Ft	N/A
LP-09803-006	Sheath Ext Assy w/Dil Comm: 8.5 Ft Hydrop	N/A
LP-09803-009	Sheath Ext Assy w/Dil Comm: 8.5 Ft Hydrop	N/A
LP-09804-007	Sheath Ext Assy w/Dilator: 9 Ft	N/A
LP-09873-001	Sheath Ext Assy w/Slope-Dil Comm: 9 Ft	N/A
LP-09903-008	Sheath Ext Assy w/Dil Comm: 9 Ft Hydrophi	N/A
LP-09903-009	Sheath Ext Assy w/Slope-Dil Comm: 9 Ft	N/A
LP-09903-017	Sheath Ext Assy w/Dil Comm: 9 Ft Hydrophi	N/A
P-07511-001	Sheath Ext Assy w/Dilator: 5 Ft	N/A
R-07645-001A	Sheath Ext Assy w/Dilator: 6 Ft	N/A
R-07745-007	Sheath Ext Assy w/Dilator: 7 Ft	N/A
R-07790-001	Sheath Ext Assy w/Dilator: 7 Ft	N/A
T-01000-033A	Sheath Ext Assy w/Dilator: 6 Ft	N/A
T-07860-001	Sheath Ext Assy w/Dilator: 8 Ft	N/A
T-45509-010A	Sheath Ext Assy w/Dilator: 6 Ft	N/A
T-45509-013A	Sheath Ext Assy w/Dilator: 5 Ft	N/A
W-08403-012D	Sheath Ext Assy w/Dilator: 4 Ft	N/A
W-08403-014	Sheath Ext Assy w/Dilator: 4 Ft	N/A
W-08413-014	Sheath Ext Assy w/Dilator: 5 Ft	N/A
W-08503-004B	Sheath Ext Assy w/Dilator: 5 Ft	N/A
W-08503-005C	Sheath Ext Assy w/Dilator: 5 Ft	N/A
W-08613-004C	Sheath Ext Assy w/Dilator: 6 Ft	N/A
W-08613-006C	Sheath Ext Assy w/Dilator: 7 Ft	N/A
W-08803-014C	Sheath Ext Assy w/Dilator: 8 Ft	N/A
W-08903-005C	Sheath Ext Assy w/Dilator: 9 Ft	N/A
Z-09800-008	Sheath Ext Assy w/Dil Comm: 8.5 Ft Hydrop	N/A
<b>GMDN Code:</b> Cath-Gard Finished Good	<b>45S05 - Instrument guard, single-use</b>	<b>Classification:</b> I
<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
A1-08803	Cath-Gard Catheter Contamination Shield for use with Interventional Products - Percutaneous Sheath Introducers	22-May-1998
SA-09847	Sheath Adapter w/Cath-Gard	17-Oct-02
ST-09807	Cath-Gard Catheter Contamination Shield with Tuohy-Borst Adapter on Proximal End for use with 7 and 7.5 Ft. Catheters and Arrow Percutaneous Sheath Introducer Systems	22-May-1998
ST-09870	Twistlock(TM) Cath-Gard Catheter Contamination Shield for use with 7 Ft. Catheters	22-May-1998
ST-09875	Twistlock(TM) Cath-Gard Catheter Contamination Shield for use with 7.5 and 8 Ft. Catheters	22-May-1998

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GMDN Code: Cath-Gard Finished Good	Device Description	Classification: I
ST-09880	Cath-Gard(R) Catheter Contamination Shield for use with 7 and 7.5 Ft. Catheters and Arrow Percutaneous Sheath Introducer Systems	22-May-1998
ST-09885	Twistlock(TM) Cath-Gard(R) Catheter Contamination Shield for use with 8.0 - 8.5 Ft. Catheters	01-Feb-2000
EU-00001-ST	Cath-Gard@ Catheter Contamination Shield for use with 4 and 5 Ft. Catheters and Arrow Percutaneous Sheath Introducer Systems	1-Mar-14
<b>GMDN Code:</b> Cath-Gard Part # (if applicable)	<b>Device Description</b>	<b>Czech Part # (if applicable)</b>
A-09880-001	CATH-GARD: 7.5 FR X80CM W/T-B ADAPTER	N/A
A1-08803-002	CATH-GARD: 5.6 FR X30CM	N/A
B001-0010-001	CATH-GARD: 34CM	N/A
L-09800-004A	CATH-GARD: 7.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER	N/A
L-09880-001A	CATH-GARD: 7.0 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER	N/A
L-09885-001	CATH-GARD: 8.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER	N/A
P-00001-002	CATH-GARD: 5.6 FR X80CM W/T-B ADAPTER	N/A
P-09800-003	Cath-Gard Catheter Contamination Shield: 80 cm with Tuohy-Borst Adapter	N/A
P-09806-014	CATH-GARD: 7.5 FR X80CM W/T-B ADAPTER - Packaged	N/A
PZ-00001-003	CATH-GARD: 5.6 FR X80CM W/T-B ADAPTER	N/A
ST-09600-003	CATH-GARD: 5.6 FR X30.5CM	N/A
ST-09600-004	CATH-GARD: 5.6 FR X30.5CM - Packaged	N/A
ST-09680-002	CATH-GARD: 5.6 FR X80CM	N/A
ST-09680-001	CATH-GARD: 7.0 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER - Packaged	N/A
ST-09875-001	CATH-GARD: 7.5 FR X112CM	N/A
ST-09880-004	CATH-GARD: 7.5 FR X80CM	N/A
ST-09880-005	CATH-GARD: 7.5 FR X80CM - Packaged	N/A
ST-09885-001	CATH-GARD: 8.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER - Packaged	N/A
T-09800-009A	CATH-GARD: 7.5 FR X112CM	TZ-05050-005
T-09880-012A	CATH-GARD: 7.0 FR X112CM	N/A
T-14703-002	CATH-GARD: 7.0 FR X 33 CM WITH TWISTLOCK(TM) ADAPTER	N/A
<b>GMDN Code:</b> Trauma Finished Goods Product #	<b>58865 Vascular catheter introduction kit</b>	<b>Classification:</b> IIa
<b>Device Description</b>	<b>Date CE Mark First Affixed</b>	
E1-04060	Peripheral Emergency Infusion Device - EID™	17-June-1998
E1-04080	Emergency Infusion Device - EID™	17-June-1998
RC-05801	Trauma Kit	24-June-2002
RC-09700	RICO® Rapid Infusion Catheter Exchange Set	16-June-1998

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GMDN Code:	58865 Vascular catheter introduction kit	Classification: IIa
Trauma Finished Goods Product #	Device Description	Date CE Mark First Affixed
RC-09859	RIC@ Rapid Infusion Catheter Exchange Set	16-June-1998

Trauma Part # (if applicable)	Device Description	Czech Part # (if applicable)
IC-04060-001	Sheath: 6 Fr. x 1-1/2" (3.81 cm) Radiopaque with Dilator over 20 Ga. IV Needle	N/A
IC-04080-017B	8.5 Fr. x 3-1/2" (8.9 cm) Arrow/Flex(R) Radiopaque FEP Sheath/Dilator over 17 Ga. x 5-1/2" (14 cm) IV Needle, .035" (89 mm) dia. x 13-3/16" (33.5 cm) Spring Wire Guide, 5 mL. Luer-Lock Syringe and Stribby Tubing	N/A
S-09850-001A	Sheath: 8.5 Fr. x 3-1/2" (8.89 cm) Arrow-Flex(R) Radiopaque FEP with Tissue Dilator	N/A
C-09700-001	Sheath: 7 Fr. x 2" (5.08 cm) Arrow-Flex(R) Radiopaque Polyurethane with Tissue Dilator	N/A
C-09850-001A	Sheath: 8.5 Fr. x 2-1/2" (6.4 cm) Arrow-Flex(R) Radiopaque FEP with Tissue Dilator	N/A

GMDN Code:	Device Description	Classification	Date CE Mark First Affixed
MAC	58865 Vascular catheter introduction kit	IIa	
CA-11142	MAC™ Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	22-June-2001	
CH-11242-1SB	MAC™ Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 7.5 Fr. Catheters	30-May-2017	
DM-11142-TS	MAC™ Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve for use with 8 - 8.5 Fr. Catheters	12-December-2006	
NL-11142-AMP	MAC™ Two-Lumen Central Venous Access Set With Integral Hemostasis Valve/Side Port for use with 7 - 8 Fr. Catheters	29-Aug-2013	
NL-11142-MDMC	MAC™ Two-Lumen Central Venous Access Set With Integral Hemostasis Valve/Side Port for use with 8 - 8.5 Fr. Catheters	02-DEC-2015	
SI-11142	MAC™ Two-Lumen Central Venous Access Set With Integral Hemostasis Valve/Side Port for use with 7 - 8 Fr. Catheters	06-July-2000	
SI-11142-S	MAC™ Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	21-May-2003	
SI-11242	MAC™ Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	19-February-2002	

MAC Part # (if applicable)	Device Description	Czech Part # (if applicable)
K-11142-004C	Sheath Extension Assembly: 2-L 9 Fr. x 10 cm	K-11142-011
K-11242-001A	Sheath Extension Assembly: 2-L 9 Fr. x 4-1/2"	K-11242-008

\* Finished goods identified with this mark are intended for use exclusively in areas where MDD requirements are applicable. Not to be sold in the US or Japan.

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DECLARATION OF CONFORMITY

DC-T-BSI-008

Arrow International, Inc. hereby declares that the above documented product(s) meets the provisions of the Medical Device Directive, EC COUNCIL DIRECTIVE 93/42/EEC. This declaration is made on the basis of the following Annex II certificates (BC Design Examination and Quality System), issued by The British Standards Institute, with Notified Body number 0086. This declaration authorizes Arrow International, Inc. to affix the CE-Marking to the products listed herein.

<input checked="" type="checkbox"/>	Medical Device Directive: CONCL. DIRECTIVE 93/42/EEC.
<input type="checkbox"/>	Other:
CERTIFICATE NUMBERS:	
Annex IIa Certificate(s)	CE 511157
Annex IIb Certificate(s)	N/A
Annex V Certificate (Class I Sterile/Measuring Function products only)	N/A

ARROW INTERNATIONAL, INC., Reading, PA USA  
 Krista Hughes *etc* *Krista Hughes* 25 OCT 2017  
 Christine Ford  
 Regulatory Affairs Representative (Print and Sign) Date  
 Kathleen Whangar *Kathleen Whangar* 25 OCT 2017  
 Quality Assurance Representative (Print and Sign) Date

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 DC. Added GR-08503-A, GR-08603 and GR-08703 per BCR-011057, BCR-011058, and BCR-011056 respectively. Removed the following obsolete Finished Goods: BB-09903-NA, KK-09903-C, SL-09903-E.
1	21-Dec-2011	Added DE-09803-HZO to Declaration per ECR-014307.
2	17-Feb-2012	Added GR-08403 per ECR-014319.
3	11-Jun-2012	Added DE-09873-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-MDMC per ECR 018256. Removed DE-09803-HZO per ECR-016026. Per BCR-019142 removed KZ-09601, KZ-09701-001, KZ-09701-005, KZ-09800-001, KZ-09808-004, KZ-09880-002, KZ-09880-004, IEFZ-09803-001, IEFZ-09803-002, IEFZ-09875-00, IEFZ-09903-004, IEFZ-09903-005, IEFZ-09903-006, WZ-08403-001, WZ-08513-001, WZ-08603-001, and WZ-08703-001.
5	18-Mar-2015	Added BB-09903-AG per ECR-024121. Added K-11242-008, K-11142-011 per ECR-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 the consultation.
6	18-Dec-2015	Added NL-11142-MDMC per ECR-020233/BCO-036641.
7	21-Dec-2015	Added AT-09875-E per ECR-026737/BCO-037472.
8	23-Jan-2016	Updated GMDN codes.
9	28-Feb-2017	Administrative change: BB-09903-AG is appropriately included on DC-L-BSI-016 and is not covered by DC-T-BSI-018; removed BB-09903-AG.
10	1-Jun-2017	Added CH-11242-1SB per ECR-030828.
11	21-Sep-2017	Added DE-09800-1NH per ECR-031362.
12	25-Oct-2017	Added DE-09875-HZ01 per ECR-032009. Updated product description for code BU-00001-ST per ECR-032020.

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DECLARATION OF CONFORMITY DC-T-BSI-015

Manufacturer: Arrow International, Inc. 2400 Bensville Road Reading, PA 19603 USA

European Representative: Teleflex Medical IDA Business and Technology Park Dublin Rd. Athlone, Co. Westmeath, Ireland

Product Name: Arterial Catheterization Devices
TECHNICAL FILE OR DESIGN DOSSIER #: T-BSI-015
GMDN Code: 10689 Arterial blood pressure catheter

Table with columns: GMDN Code, Arterial Finished Good Number, Device Description, Classification, Date CE Mark First Affixed. Lists various arterial catheter models and their specifications.



DECLARATION OF CONFORMITY DC-T-BSI-015

Table with columns: Arterial Part #, Device Description, Date CE Mark First Affixed. Lists various arterial catheter models and their specifications.

\*Finished goods identified with this mark are intended for use exclusively in areas where MDD requirements are applicable. Not to be sold in the US or Japan.

Table with columns: Arterial Part #, Device Description, Date CE Mark First Affixed. Lists various arterial catheter models and their specifications.



A-04016-015	16ga X 7" Cath/19ga NDI	N/A
A-04018-001	18ga X 1-3/4" Cath/20ga NDI	N/A
A-04018-009	18ga X 4-1/4" Cath/20ga NDI	N/A
A-04020-011A	20ga X 4-1/4" Cath/22ga NDI	N/A
A-04022-001	22ga X 1-3/4" Cath/25ga NDI	AZ-04022-001
A-04120-015	20ga X 1-1/2" Cath/22ga NDI w/Coating	N/A
A-04122-003b	22ga X 1-3/8" Cath/23ga NDI w/Coating	N/A
A-04122-010	Catheter S.L.: 22 Ga X 1-3/8"	N/A
A-04220-009b	22GA X 1-3/8" CATH/23GA NDI W/COATING	N/A
A-04016-015	16ga X 7" Cath/19ga NDI	N/A
A-04122-010	Catheter S.L.: 22 Ga X 1-3/8"	N/A
A-04220-009b	Catheterization Dev: 20 Ga Radial Artery	N/A
H-04120-003B	Catheter/Insert Tube: 20 Ga X 2-1/2"	N/A
H-04120-005	Catheter S.L.: 20 Ga X 3-1/16"	N/A
H-04125-001	Catheter S.L.: 20 Ga X 3-1/16"	HZ-04125-001
H-04130-004	Catheter/Insert Tube: 20 Ga X 8"	N/A
K-04018-001B	Catheter S.L. Comm: 18 Ga X 12.7 Cm	N/A
K-04124-001	Catheter S.L. Comm: 24 Ga X 4 Cm	N/A
K-04220-003A	Catheterization Dev: 20 Ga Radial Artery	N/A
K-14402-003	22 Ga X 4.45 Cm Cath/ 7.5 Ga NDI Comm	N/A
K-15111-001	Sheath Ext Assy W/Dilator: 5 Fr	N/A
N/A	Catheter S.L.: 18 Ga X 8 Cm Hydrophilic	PZ-00818-002
N/A	Catheter S.L.: 20 Ga X 8 Cm Hydrophilic	PZ-00820-002
N/A	Catheter S.L.: 18 Ga X 12 Cm Hydrophilic	PZ-01218-002
N/A	Catheter S.L.: 18 Ga X 12 Cm Hydrophilic	PZ-01218-003
N/A	CATHETER S.L.: 20 GA X 5 CM HYDROPHILIC	PCZ-00520-001
N/A	CATHETER S.L.: 22 GA X 5 CM HYDROPHILIC	PCZ-00522-001
N/A	CATHETER S.L.: 18 GA X 8 CM HYDROPHILIC	PCZ-00818-001
N/A	CATHETER S.L.: 22 GA X 8 CM HYDROPHILIC	PCZ-00822-001
N/A	Catheter S.L.: 24 Ga X 2.5 Cm Hydrophilic	PCZ-00524-001
N/A	Catheter S.L.: 24 Ga X 5 Cm Hydrophilic	PCZ-00524-001
N/A	Catheter S.L.: 20 Ga X 8 Cm Hydrophilic	PCZ-00820-001
N/A	CATHETER S.L.: 18 GA X 12 CM HYDROPHILIC	PCZ-01218-001
N/A	CATHETER S.L.: 20 GA X 12 CM HYDROPHILIC	PCZ-01220-001
N/A	CATHETER S.L.: 22 GA X 12 CM HYDROPHILIC	PCZ-01222-001
N/A	Catheter S.L.: 18 Ga X 16 Cm Hydrophilic	PCZ-01681-001
N/A	CATHETER S.L.: 20 GA X 16 CM HYDROPHILIC	PCZ-01620-001
N/A	CATHETER S.L.: 18 GA X 23 CM HYDROPHILIC	PCZ-02318-001
P-04020-005A	20ga X 1-3/4" Cath/22ga NDI w/Coating	N/A
P-04020-007	Catheterization Dev: 20 Ga Radial Artery	N/A
PC-00520-001	Catheter S.L.: 20 Ga X 2" (5 Cm) Hydrophilic	N/A
PC-00522-001	Catheter S.L.: 22 Ga X 2" (5 Cm) Hydrophilic	N/A
PC-00818-001	Catheter S.L.: 18 Ga X 3-1/4" (8 Cm) Hydrophilic	N/A
PC-00820-001	Catheter S.L.: 20 Ga X 3-1/4" (8 Cm) Hydrophilic	N/A
PC-00822-001	Catheter S.L.: 22 Ga X 3-1/4" (8 Cm) Hydrophilic	N/A
PC-01218-001	Catheter S.L.: 18 Ga X 5" (12 Cm) Hydrophilic	N/A
PC-01220-001	Catheter S.L.: 20 Ga X 5" (12 Cm) Hydrophilic	N/A
PC-01618-001	Catheter S.L.: 18 Ga X 6-1/2" (16 Cm) Hydrophilic	N/A

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PC-01620-001	Catheter S.L.: 20 Ga X 6-1/2" (16 Cm) Hydrophilic	N/A
PC-02318-001	Catheter S.L.: 18 Ga X 9-1/4" (23 Cm) Hydrophilic	N/A
N/A	CATHETER S.L.: 24 GA X 2.5 CM HYDROPHILIC	PCZ-00524-002
N/A	CATHETER S.L.: 20 GA X 5 CM HYDROPHILIC	PCZ-00520-002
N/A	CATHETER S.L.: 22 GA X 5 CM HYDROPHILIC	PCZ-00522-002
N/A	CATHETER S.L.: 24 GA X 5 CM HYDROPHILIC	PCZ-00524-002
N/A	CATHETER S.L.: 18 GA X 8 CM HYDROPHILIC	PCZ-00818-002
N/A	CATHETER S.L.: 20 GA X 8 CM HYDROPHILIC	PCZ-00820-002
N/A	CATHETER S.L.: 22 GA X 8 CM HYDROPHILIC	PCZ-00822-002
N/A	CATHETER S.L.: 18 GA X 12 CM HYDROPHILIC	PCZ-01218-002
N/A	CATHETER S.L.: 20 GA X 12 CM HYDROPHILIC	PCZ-01220-002
N/A	CATHETER S.L.: 22 GA X 12 CM HYDROPHILIC	PCZ-01222-002
N/A	CATHETER S.L.: 18 GA X 16 CM HYDROPHILIC	PCZ-01618-002
N/A	CATHETER S.L.: 20 GA X 16 CM HYDROPHILIC	PCZ-01620-002
N/A	CATHETER S.L.: 18 GA X 23 CM HYDROPHILIC	PCZ-02318-002

Arrow International, Inc. hereby declares that the above documented product(s) meets the provisions of the Medical Device Directive, EC COUNCIL DIRECTIVE. This declaration is made on the basis of the following Annex II certificate (QC Design Examination and Quality System), issued by The British Standards Institute, with Notified Body number 0086. This declaration authorizes Arrow International, Inc. to affix the CE-Marking to the products listed herein.

- DIRECTIVES AND STANDARDS:**
- Medical Device Directive: COUNCIL DIRECTIVE 90/269/EEC.
  - Other:
- CERTIFICATE NUMBERS:**
- Annex II: Certificate(s) OE 614137, ISO 13485: FM 512674
  - Annex V: Certificate (Class I Sterile/Measuring Function products only) N/A

ARROW INTERNATIONAL, INC., Reading, PA USA  
 Kristin Hughes  
 Regulatory Management or Designee (Print and Sign)  
 Date: 13 Dec 2017

Matt Whinton  
 Senior Manager Quality Assurance or Designee (Print and Sign)  
 Date: 14 Dec 2017

**REVISION HISTORY:**

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-016).
1	07 Jan-2010	Addition of DE-01618-ZB.
2	7 Mar-2011	Addition of new SAC Ext. 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-04120-1, 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.

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DECLARATION OF CONFORMITY  
DC-T-BSI-015

Rev Level	Date	Description
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-ID.
7	4-Sep-2012	Added new finished goods AA-10411-1, AA-10524-1, AA-11511-3, AA-115611-3, 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-ID, UN-00820, UW-04120-C, and ZB-01618. Added DE-00820-EKBI per ECR-017838.
9	10-Mar-2014	Added TT-00820-R 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-005720-001, PCZ-005722-001, 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-WKCIH per ECR-021128.
11	19-Oct-2015	Updated components to include A-04122-012 used in KA-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-MDNC per ECR-027174/BCO-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-00572-002, PCZ-00574-002, 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-00572-PBX, SAC-00822-PBX, SAC-01222-PBX, SAC-00324-PBX, and SAC-00524-PBX per ECR-029490. Added DE-00820-NKHS, 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.

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The footer information below is for reference only

# bsi.



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

Carlos Pflanga, SVP, System Certification and Compliance

Original Registration Date: 2006-12-19

Latest Revision Date: 2018-01-08

Effective Date: 2016-10-31

Expiry Date: 2019-02-28

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, thrombolysis, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolotherapy, vascular positioning system (VPS) styles, 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.

Devices include: percutaneous thrombolytic device and rotor, vascular access, intravascular administration sets, intra-aortic balloon pumps, ultrasonic cardiac blood flow monitors, spring wire guides and percutaneous sheath introducers. Processing and packaging of sutures (absorbable and non absorbable), light panels, and the manufacturing of ligating clips, breathing circuits and feeding tubes.

This certificate is traceable to this company's original registration certificate #951 001269 dated March 30, 2006 and issued by TUV.

Original Registration Date: 2006-12-19  
Latest Revision Date: 2018-01-08

Effective Date: 2016-10-31  
Expiry Date: 2019-02-28

Page: 2 of 5

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be viewed on the BSI website at [www.bsigroup.com/bsi/our-services](http://www.bsigroup.com/bsi/our-services). For more information visit [www.bsi.com](http://www.bsi.com) or the attached appendix. A reference of the BSI Group is provided.

BSI Group Headquarters, BSI, 389 Chiswick Avenue, Uxbridge, Middlesex, UK. 1890 Stratford Drive, Suite 800, Hampton, VA 20746-4302 USA

A reference of the BSI Group is provided.

Certificate No: **FM 512674**

Location

Registered Activities

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

Design, development, manufacture, servicing and distribution of the following catheters: intravascular, anesthesia, hemodialysis, abdominal, thoracic and pleural drainage, atherectomy, electrophysiology/pacing, thermoliftation, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolotomy, vascular positioning system (VPS) styles, 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.

Devices include: percutaneous thrombolytic device and rotor, vascular access, intravascular administration sets, intra-aortic balloon pumps, ultrasonic cardiac blood flow monitors, spring wire guides and percutaneous sheath introducers. Processing and packaging of sutures (absorbable and non absorbable), light panels, and the manufacturing of ligating clips, breathing circuits and feeding tubes.

Arrow International, Inc.  
312 Commerce Place  
Asheboro  
North Carolina  
27203  
USA

Manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, abdominal, thoracic and pleural drainage catheters, feeding tubes, embolotomy catheters, spring wire guides, and percutaneous sheath introducers. Processing and packaging of sutures (absorbable and non absorbable) and light panels. Labeling requirement and QM/R regulatory clearance at distribution sites (traceability). Contract manufacturing operations of ligating clips, plus components and accessories for the above product lines.

Arrow International CR, a.s.  
Praszka 209  
Hradec Kralove  
50004  
Czech Republic

Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermoliftation catheters, intrathecal catheterization catheters, intra-aortic balloon catheters, percutaneous sheath introducers, spring wire guides and related components and accessories for the above products. Contract manufacturing operations for breathing circuits, balloon dilatation catheters and the Cardio Dynamic catheters.

Original Registration Date: 2006-12-19  
Latest Revision Date: 2018-01-08

Effective Date: 2016-10-31  
Expiry Date: 2019-02-28

Page: 3 of 5

Certificate No: **FM 512674**

Location

Registered Activities

Arrow Internacional de Chihuahua de S.A. de C.V.  
Ave. Washington 3701  
Interior: Circuito Industrial  
Alta Tecnologia, Edificio 40  
Col. Panamericana  
Chihuahua  
CP 31200  
Mexico

Manufacture and distribution of intravascular catheters, abdominal, thoracic and pleural drainage catheters, percutaneous sheath introducers, spring wire guides, and packaging and distribution of anesthesia catheters, and hemodialysis catheters. Manufacturing and distribution of related components and accessories for the above product lines and packaging and distribution of anesthesia catheters, hemodialysis catheters.

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, percutaneous sheath introducers, spring wire guides, and related components and accessories for the above product lines and packaging and distribution of anesthesia catheters, hemodialysis catheters.

Arrow International CR, a.s.  
Janska 2359/47  
Zdar Nad Sazavou  
59101  
Czech Republic

Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermoliftation catheters, intra-aortic balloon 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. Manufacturing material warehouse and distribution process activities.

Arrow International, Inc.  
Berks Corporate Center  
760 Corporate Building #7  
Reading  
Pennsylvania  
19605  
USA

Design, development, manufacture and distribution of electrophysiology / pacing, thermoliftation, 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-aortic balloon pumps.

Original Registration Date: 2006-12-19  
Latest Revision Date: 2018-01-08

Effective Date: 2016-10-31  
Expiry Date: 2019-02-28

Page: 4 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/bsi/certificate](http://www.bsigroup.com/bsi/certificate). To be used in conjunction with the scope above as the method of approval.

Approved: Head of Product Registration, BSI Group Limited, 1990, Watlington Drive, Suite 800, West Nyack, NY 10994-2133, USA. A Member of the BSI Group of Companies.

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/bsi/certificate](http://www.bsigroup.com/bsi/certificate). To be used in conjunction with the scope above as the method of approval.

Approved: Head of Product Registration, BSI Group Limited, 1990, Watlington Drive, Suite 800, West Nyack, NY 10994-2133, USA. A Member of the BSI Group of Companies.

Certificate No: **FM 512674**

**Location**

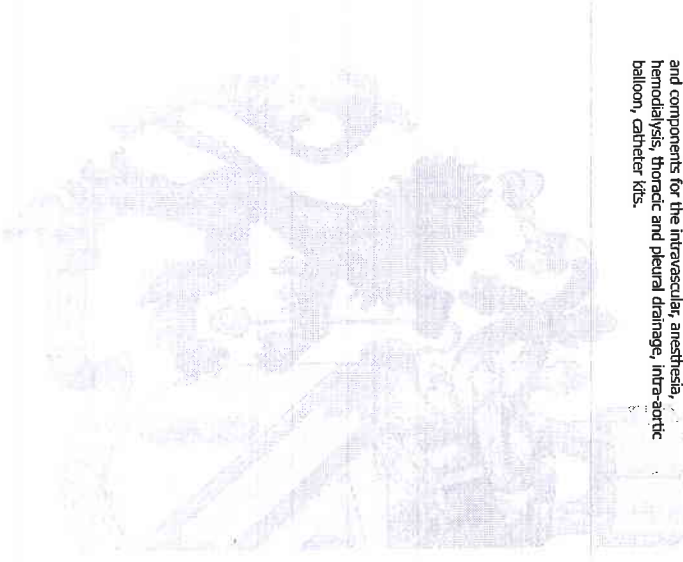
Arrow Internacional de Chihuahua  
S.A. de C.V.  
Ave. Washington 3701, Edificio 4  
Colonia Complejo Industrial Las Americas  
Chihuahua  
CP 31114  
Mexico

**Registered Activities**

Manufacture and distribution of Intravascular catheters, anesthesia catheters, hemodialysis catheters, abdominal, thoracic and pleural drainage catheters, feeding tubes, endoscopy catheters, spring wire guides, and percutaneous sheath introducers. Labeling requirement and CDR regulatory clearance at distribution sites. Plus components and accessories for the above product lines.

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

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



Original Registration Date: 2006-12-19  
Latest Revision Date: 2018-01-08

Effective Date: 2016-10-31  
Expiry Date: 2019-02-28

Page: 5 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/Certification](http://www.bsigroup.com/Certification). To be read in conjunction with the copy above or the attached appendix.  
Address: Headquarters: BSI Group America Inc, 13750 Wallingford Drive, Suite 201, Herndon, VA 20170-6007 USA  
A member of the BSI Group of companies



By Royal Charter

# EC Certificate - Full Quality Assurance System

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

No. CE 647900

Issued To: Vascular Solutions LLC

6464 Sycamore Court North

Minneapolis

Minnesota

55369

USA

In respect of:

**Design, Development, and Manufacturing of Guidewires, Hemostatic and Embolic Agents for Peripheral Use, Fluid Delivery Kits, Surgical Laser Procedure Kits, Intravascular Catheters Used for Diagnostic, Angiographic, Embolic Delivery and/or Embolectomy, Support and Exchange Applications, Vascular Access Devices Including ultrasound guided devices, and Accessories for use in Catheterization Procedures, and Retrieval Devices**

**Those aspects of Annex II related to maintaining the sterility of accessory Torque Devices, SmartNeedle Monitor Covers, and Auto-Fill Syringe Kits. Those aspects of Annex II related to maintaining the sterility and metrology function of inflation devices**

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: 2016-06-10

Date: 2018-07-06

Expiry Date: 2022-07-01

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Page 1 of 1

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. The applicant, BSI, and the certificate holder, Vascular Solutions LLC, are responsible for ensuring that the quality system remains in compliance with the requirements of the Directive. The certificate holder shall ensure that the certificate holder is notified by the Notified Body of any changes to the quality system. Information for Certificate Holders: Contact BSI, Kitemark Court, Davy Avenue, Loughborough, Leicestershire, LE11 1AA, UK. Tel: +44 (0)145 393 3920. BSI Assurance is a service of the BSI Group. For more information, visit [www.bsi.com](http://www.bsi.com). BSI is a registered charity in the UK, registered number 2522234. It is also a member of the European Conformity Assessment Bodies (UK) Ltd. A number of BSI Group companies are registered with the Charity Commission.



By Royal Charter

# 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 647900

Date: 2018-07-06

Issued To:

Vascular Solutions LLC

6464 Sycamore Court North

Minneapolis

Minnesota

55369

USA

### Subcontractor:

Service(s) supplied

#### Biomerics LLC

12560 Fletcher Lane, Suite 300

Rogers

MIN 55374

USA

#### Manufacture

#### Caritka Medical, Inc.

6550 Wedgwood Road North

Suite 300

Maple Grove

Minnesota

55311

USA

#### Manufacture

#### E-Beam Services, Inc.

2775 Henkle Drive

Lebanon

Ohio

45036

USA

#### E Beam Sterilization

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Page 1 of 7

Information for Certificate Holders: Contact BSI, Kitemark Court, Davy Avenue, Loughborough, Leicestershire, LE11 1AA, UK. Tel: +44 (0)145 393 3920. BSI Assurance is a service of the BSI Group. For more information, visit [www.bsi.com](http://www.bsi.com). BSI is a registered charity in the UK, registered number 2522234. It is also a member of the European Conformity Assessment Bodies (UK) Ltd. A number of BSI Group companies are registered with the Charity Commission.



By Royal Charter

## 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 647900**  
Date: **2018-07-06**  
Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

Subcontractor:	Service(s) supplied
E-Beam Services, Inc. 3400 Union Street Lafayette Indiana 47905 USA	<b>E Beam Sterilization</b>
Galt Medical Corp 2220 Merritt Drive Garland, TX 75041 USA	<b>Manufacture</b>
Harland Medical Systems 7418 Washington Ave S Eden Prairie MN 55344 USA	<b>Manufacture</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 647900**  
Date: **2018-07-06**  
Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

Subcontractor:	Service(s) supplied
Hammac Medical Products IDA Business Park Castleroa Roscommon Ireland	<b>Manufacture</b>
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	<b>ETO Sterilization</b>
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	<b>Manufacture</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 647900**  
 Date: **2018-07-06**  
 Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

Subcontractor:	Service(s) supplied
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	<b>Gamma Sterilization</b>
Teleflex Medical IDA Business and Technology Park Dulinn Road Athlone Co. Westmeath Ireland	<b>EU Representative</b>
Vascular Solutions LLC 14005 13th Avenue Plymouth Minnesota 55441 USA	<b>Manufacture</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 647900**  
 Date: **2018-07-06**  
 Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

Subcontractor:	Service(s) supplied
Vascular Solutions LLC 6401 Sycamore Court North Maple Grove Minnesota 55369 USA	<b>Regulatory Compliance</b>
Vascular Solutions LLC 6420 Sycamore Lane North Minneapolis Minnesota 55369 USA	<b>Manufacture</b>

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# bsi.



By Royal Charter

## EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 647900  
Date: 2018-07-06  
Issued To: Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

Date	Reference Number	Action
10 June 2016	8466178	First Issue – Transfer from another Notified Body
15 December 2016	8649395	Addition of Sterigenics Willowbrook, IL as a significant subcontractor for EO sterilization.
27 January 2017	8588049	Amend the scope to include guidewires. Addition of Precision Wire Components to the certificate as significant subcontractors for manufacturing.
30 June 2017	8760886	Certificate renewal. Subcontractor name change from Stens Isomedix Services to Isomedix Operations, Inc.
Current	8940684	Change of legal manufacturer name from "Vascular Solutions, Inc." to "Vascular Solutions LLC." Change of multiple subcontractor names from "Vascular Solutions, Inc." to "Vascular Solutions LLC." Change EU Representative to Teleflex Medical (Ireland). Removal of Vascular Solutions Zentusa Limited. Clarifications to sterilization services supplied for several subcontractors, and corrections to several subcontractor addresses.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the regular surveillance audits of the notified body. This approval certificate will be cancelled if the products designed and/or manufactured by a third party on behalf of the company do not conform to the requirements of the certificate. This certificate was issued electronically and is bound by the conditions of the contract.

Approved by our Registrar, BSI, Kenneth Coyle, Essex Avenue, 1, London, Middlesex, UK. Tel: +44 (0)1293 690969  
BSI also operates an Internet presence at: [www.bsi.com](http://www.bsi.com) or [www.bsi.com.uk](http://www.bsi.com.uk)  
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## EC Design-Examination Certificate

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

No. **CE 678707**  
 Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

In respect of:  
**Twin-Pass Dual Access Catheters**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

*Stewart Brain*  
 Stewart Brain, Head of Compliance & Risk -  
 Medical Devices

First Issued: **2018-09-26**

Date: **2018-09-26**

Expiry Date: **2023-09-25**

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Page 1 of 3

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 certificate was issued electronically and is bound by the conditions of the contract.  
 Information and Contact: BSI, Customer Court, Davy Avenue, Ipswich, Suffolk, IP11 1AA, UK. Tel: +44 (0)1473 209100  
 BSI Assurance UK Limited, registered in England under number 2049221 at 389 Chiswick High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.

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## EC Design-Examination Certificate

Supplementary Information to CE 678707

Issued To: **Vascular Solutions LLC**  
**6464 Sycamore Court North**  
**Minneapolis**  
**Minnesota**  
**55369**  
**USA**

### Twin-Pass Dual Access Catheters

Catalog Number	Device Name	Model Type	Intended purpose per IFU	Classification
5200	Twin-Pass Dual Access Catheter Twin-Pass Torque	Twin-Pass	The Twin-Pass catheters are intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, and for use during two guidewire procedures.  The Twin-Pass is also used to sub selectively infuse/deliver diagnostic or therapeutic agents.	Class III
5201		Twin-Pass Torque	The Twin-Pass catheter is intended to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.	Class III

First Issued: **2018-09-26**

Date: **2018-09-26**

Expiry Date: **2023-09-25**

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Page 2 of 3

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 certificate was issued electronically and is bound by the conditions of the contract.  
 Information and Contact: BSI, Customer Court, Davy Avenue, Ipswich, Suffolk, IP11 1AA, UK. Tel: +44 (0)1473 209100  
 BSI Assurance UK Limited, registered in England under number 2049221 at 389 Chiswick High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.

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By Royal Charter

## EC Design-Examination Certificate

Supplementary Information to CE 678707

Issued To:

Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

### Certificate History

Date	Reference Number	Action
Current	8780393	First issue.

First Issued: **2018-09-26**

Date: **2018-09-26**

Expiry Date: **2023-09-25**

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Page 3 of 3

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 certificate was issued electronically and is held by the certificate of the contract.

Information on BSI: Copyright © BSI, Khayatskiy Lane, 25/12, Moscow, 125080, Russia. Tel: +44 (0) 300 550099  
BSI Assurance, 389, Market Street, London, EC1M 6QU. Tel: +44 (0) 20 8996 9001. Fax: +44 (0) 20 8996 7001  
A member of the BSI Group of Companies.

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# EC Design-Examination Certificate

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

bsi.



# EC Design-Examination Certificate

Supplementary Information to CE 678708

No. CE 678708

Issued To: Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

Issued To: Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

In respect of:  
**SuperCross Microcatheters**

### SuperCross Microcatheters

Model Number	Device Name	Distal Tip	Working Length	Intended purpose per IFU	Classification
5300	SuperCross	Straight	130cm	The SuperCross microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.	III
5301	SuperCross	Straight	150cm		
5340	SuperCross FT	flexible	130cm		
5341	SuperCross FT	flexible	150cm		
5302		45°	130cm		
5303		5302	150cm		
5304		90°	130cm		
5305		90°	150cm		
5306	SuperCross AT	120°	130cm		
5307	SuperCross AT	120°	150cm		
5308			130cm		
5309		90° XT	150cm		

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

*Stewart Brain, Head of Compliance & Risk - Medical Devices*

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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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 certificate was issued electronically and is bound by the conditions of the contract. Information on our (corporation) BSI, Kirtlington Road, Epsom, Surrey, Middlesex TW20 9HQ, UK. Tel: +44 (0)181 609 9000. BSI Assurance (UK Limited) registered in England under number 2868231 in the Companies High Road, London W1A 4AL, UK. A member of BSI Group of Companies.

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 certificate was issued electronically and is bound by the conditions of the contract. Information on our (corporation) BSI, Kirtlington Road, Epsom, Surrey, Middlesex TW20 9HQ, UK. Tel: +44 (0)181 609 9000. BSI Assurance (UK Limited) registered in England under number 2868231 in the Companies High Road, London W1A 4AL, UK. A member of BSI Group of Companies.

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By Royal Charter

## EC Design-Examination Certificate

Supplementary Information to CE 678708

Issued To:  
Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

### Certificate History

Date	Reference Number	Action
Current	8780397	First Issue.

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

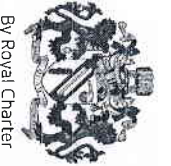
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Page 3 of 3

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

For further information contact BSI, Knowledge Centre, Delta Avenue, Watlington, Oxford, OX4 4AL, UK. Tel: +44 (0)1865 853333. Fax: +44 (0)1865 853344. Email: [bsi.enquiries@bsi.org.uk](mailto:bsi.enquiries@bsi.org.uk). Website: [www.bsi.org.uk](http://www.bsi.org.uk). BSI Assurance UK Limited, registered in England, number 2803234. In 389, Chiswick Uxbridge, Middlesex, UK. A registered company in England, number 02037931.

# bsi.



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

Holds Certificate Number:

**MD 648016**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, Development, Manufacturing, and Distribution of Guidewires, Vascular and Topical Hemostasis Devices, Embolectomy Catheters, Surgical Lasers, Intravascular Catheters, Vascular Access Devices, Vascular Introducer Kits, Fluid Delivery Kits, Embolization Devices and Retrieval Devices.

For and on behalf of BSI:

*Stewart Brain*

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-08

Effective Date: 2017-07-16

Latest Revision Date: 2018-08-23

Expiry Date: 2019-02-28

Page: 1 of 2



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Certificate No: **MD 648016**

Location

Vascular Solutions LLC  
6464 Sycamore Court North  
Minneapolis  
Minnesota  
55369  
USA

Registered Activities

Design, Development, and Manufacturing of Guidewires, Vascular and Topical Hemostasis Devices, Embolectomy Catheters, Intravascular Catheters, Vascular Access Devices, Vascular Introducer Kits, Fluid Delivery Kits, Embolization Devices and Retrieval Devices.

Vascular Solutions LLC  
14005 13th Avenue  
Plymouth  
Minnesota  
55441  
USA

Sales, HR, Marketing, Finance

Vascular Solutions LLC  
6401 Sycamore Court North  
Maple Grove  
Minnesota  
55369  
USA

Catheter Component Manufacturing including extrusion, coils, snare loops, braiding, and laser processing

Vascular Solutions LLC  
6420 Sycamore Lane North  
Minneapolis  
Minnesota  
55369  
USA

Original Registration Date: 2016-06-08  
Latest Revision Date: 2018-08-23


Effective Date: 2017-07-16  
Expiry Date: 2019-02-28

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be accessed [online](http://www.bsigroup.com/bsi/Products). Printed copies can be obtained at [www.bsigroup.com/bsi/Products](http://www.bsigroup.com/bsi/Products). Information and Contact: BSI, Customer Care, Bay Avenue, Kingston, Surrey, Surrey, UK. Tel: +44 (0)20 999 9000. BSI American UK Limited, registered in England under number 7605321 at 389 Chiswick High Road, London W6 4AL, UK. A member of the BSI Group of Companies.

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be accessed [online](http://www.bsigroup.com/bsi/Products). Printed copies can be obtained at [www.bsigroup.com/bsi/Products](http://www.bsigroup.com/bsi/Products). Information and Contact: BSI, Customer Care, Bay Avenue, Kingston, Surrey, Surrey, UK. Tel: +44 (0)20 999 9000. BSI American UK Limited, registered in England under number 7605321 at 389 Chiswick High Road, London W6 4AL, UK. A member of the BSI Group of Companies.

**Declaration of Conformity**

<b>Manufacturer:</b>	Vascular Solutions LLC 6464 Sycamore Court North Minneapolis, MN 55369 USA
<b>European Representative:</b>	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone Co. Westmeath, Ireland
<b>Product Name:</b>	Twin-Pass V2 dual access catheter Twin-Pass Torque dual access catheter
<b>Reference/Catalog Number:</b>	5200, 5201
<b>Generic Indication(s):</b>	The Twin-Pass catheters are intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, and for use during two guidewire procedures. The Twin-Pass catheter is also used to subselectively infuse/deliver diagnostic or therapeutic agents. The Twin-Pass Torque catheter is intended to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.
<b>Classification:</b>	Class III Rule 6
<b>GMDN Code</b>	32151 – Peripheral/Coronary Vascular Infusion Catheter
<b>Conformity Assessment Route:</b>	Annex II of the EC-Directive (Council Directive 93/42/EEC of 14 June 1993)
<b>Declaration of Conformity:</b>	We hereby declare that the distributed CE marked products, specified on this Declaration of Conformity, conform to the required documentation in accordance with Annex II of the EC-Directive, the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.
<b>Standards Applied:</b>	(see attached)
<b>Notified Body:</b>	BSI Kitemark Court, Davy Avenue, Knowlhill Milton Keynes, MK5 8PP, UK Notified Body Number: 0086
<b>EC Certificate(s)</b>	ISO 13485:2003 and ISO 13485:2012 # 648016 EC Certificate #647900
<b>Date CE Mark Affixed:</b>	June 13, 2013
<b>Place of Issuance:</b>	Twin-Pass Torque: December 8, 2016 Vascular Solutions LLC 6464 Sycamore Court North Minneapolis, MN 55369 USA
<b>Signature of Authorized Individual:</b>	
<b>Name (printed)</b>	Jill Munsinger
<b>Date of Issue:</b>	November 26, 2018

Area	Standards Applied:
<b>Quality System</b>	Standard EN ISO 13485:2012/AC:2012: Medical Devices -Quality management systems- Requirements for regulatory purposes EN ISO 14971:2012: Medical Devices – Application of risk management to medical devices EN ISO 109931:2009/AC:2010: Biological evaluation of medical devices— Part 1, Guidance on selection of tests EN ISO 10993-4:2009: Biological evaluation of medical devices – Part 4, Selection of tests for interaction with blood EN ISO 10993-5:2009: Biological evaluation of medical devices— Part 5, Tests for cytotoxicity, in vitro methods EN ISO 10993-10:2010: Biological evaluation of medical devices – Part 10, Tests for irritation and skin sensitization EN ISO 10993-11:2009: Biological evaluation of medical devices— Part 11, Tests for systemic toxicity
<b>Controlled Environments</b>	EN ISO 10993-12:2012: Biological evaluation of medical devices Part 12, Sample preparation and reference materials EN ISO 14644-1: 2015: Cleanrooms and associated controlled environments – Part 1, Classification of air cleanliness by particle concentration EN ISO 14644-2: 2015: Cleanrooms and associated controlled environments – Part 2, Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
<b>Freedom from manufacturing residues</b>	EN ISO 109937:2008/AC:2009: Biological evaluation of medical devices -Part 7, Ethylene oxide sterilization residues EN ISO 11338-1:2017: Sterilization of Health Care Products – Biological Indicators – Part 1, General requirements EN ISO 11338-2:2017: Sterilization of health care products – Biological Indicators – Part 2, Biological indicators for ethylene oxide sterilization processes EN ISO 11335:2014: Sterilization of health care products – Ethylene oxide –Requirements for development, validation and routine control of a sterilization process for medical devices EN ISO 11737-1:2006: Sterilization of Medical Devices – Microbiological methods – Part 1: Determination of a population of microorganisms on assembly EN ISO 11737-2:2009: Sterilization of Medical Devices –Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process. EN 556-1: 2002: Sterilization of medical devices: Requirements for medical devices to be designated "STERILE" –Part 1, Requirements for terminally sterilized medical devices
<b>Sterilization and Pyrogenicity</b>	EN ISO 116071:2009+A1:2014: Packaging for terminally sterilized medical devices -Part 1, Requirements for materials, sterile barrier systems and packaging systems EN 1041: 2013: Specification for information supplied by the manufacturer of medical devices EN ISO 15223-1:2016: Medical devices—Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1, General Requirements EN ISO 10555-1:2013: Sterile, single-use intravascular catheters – Part 1, General requirements EN ISO 62366: 2009: Medical devices-Application of usability engineering to medical devices EN ISO 594-1:1986: Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 1, General requirements ISO 594-2:1998: Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 2, Lock fittings
<b>Packaging</b>	
<b>Labeling</b>	
<b>Clinical</b>	
<b>Product Specific</b>	



RG2093  
Rev. A

REVISION HISTORY

Rev	Reason
A	New release of design dossier

**Declaration of Conformity**

<b>Manufacturer:</b>	Vascular Solutions, LLC. 6464 Sycamore Court North Minneapolis, MN 55369 USA
<b>European Representative:</b>	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone
<b>Product Name:</b>	SuperCross microcatheter SuperCross Flexible Tip microcatheter SuperCross Angled Tip microcatheter
<b>Reference/Catalog Number:</b>	5300, 5301 5340, 5341 5302, 5303, 5304, 5305, 5307, 5308, 5309
<b>Generic Indication(s):</b>	The SuperCross microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.
<b>Classification:</b>	Class III, Rule 6
<b>GMDN Code</b>	17846 - Vascular guide-catheter, single-use
<b>Conformity</b>	Annex II of the EC-Directive (Council Directive 93/42/EEC of 14 June 1993)
<b>Assessment Route:</b>	
<b>Declaration of Conformity:</b>	We hereby declare that the distributed CE marked products, specified on this Declaration of Conformity, conform to the required documentation in accordance with Annex II of the EC - Directive, the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.
<b>Standards Applied:</b>	(see attached)
<b>Notified Body:</b>	BSI Kitemark Court, Davey Avenue, Knowlhill Milton Keynes, MK5 8PP, UK Notified Body Number: 0086
<b>EC Certificate(s)</b>	ISO 13485:2003 and ISO 13485:2012 # MD 648016 EC Certificate #CE 647900 DE Certificate # CE 628708
<b>Date CE Mark Affixed:</b>	SuperCross microcatheter: September 14, 2010 SuperCross Flexible Tip microcatheter: July 30, 2012 SuperCross Angled Tip microcatheter: September 22, 2014
<b>Place of Issuance:</b>	Vascular Solutions, Inc. 6464 Sycamore Court North Minneapolis, MN 55369 USA
<b>Signature of Authorized Individual:</b>	<i>Jim Munstinger</i>
<b>Name/Title:</b>	Jim Munstinger, Sr. Director, Regulatory Affairs
<b>Date of Issue:</b>	11/29/18
	November 29, 2018

**Standards Applied:**

Number	Title
EN ISO 13485:2012	Medical Devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices - Application of risk management to medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices; Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for cytotoxicity: <i>in vitro</i> methods
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample Preparation and Reference Materials
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11138-2:2009	Sterilization of Health Care Products- Biological Indicators - Part 2, Biological Indicators for Ethylene Oxide Sterilization Processes
EN ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2006	Sterilization of Medical Devices - Microbiological methods - Part 1: Determination of a population of microorganisms on assembly
EN ISO 11737-2:2009	Sterilization of Medical Devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 11607-1:2009 A1 2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 1041: 2008	Specification for information supplied by the manufacturer of medical devices
ANSI/AAMI/ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1, General Requirements
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects-Good clinical practice
EN ISO 10555-1:2013	Sterile Single-use Intravascular Catheters - Part 1: General Requirements
EN ISO 62366: 2009	Medical devices - Application of usability engineering to medical devices

PC2098  
Rev. A

REVISION HISTORY

Rev	Reason
A	Initial Release of Class III DoC