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# 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):

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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# 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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# 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<br>& Biotech Co., Ltd<br>1,Tung-Hsing St.<br>Shu-Lin<br>New Taipei City 23850<br>Taiwan | **Crucial Supplier** |
| Fujian Kerui<br>Pharmaceutical Co., Ltd.<br>Yuanzai Industrial Area<br>Fujian Province, 350313<br>China | **Crucial Supplier** |
| MeKo<br>Laserstrahl-Materialbearbeitungen<br>Im Kirchenfelde 12-14<br>Hannover<br>D-31157 Sarstedt<br>Germany | **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 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<br>(Shenzhen) Co., Ltd.<br>No. 1 Jinkui Road<br>Futian Free Trade Zone<br>Shenzhen 518038<br>China | **Design**<br>**Manufacture** |
| OrbusNeich Medical, Inc.<br>5363 NW 35th Avenue<br>Fort Lauderdale<br>FL 33309<br>USA | **Design**<br>**Regulatory Compliance** |
| Patheon, Inc.<br>201 College Rd E<br>Princeton<br>NJ 08540<br>USA | **Crucial Supplier** |

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High 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 |
|---|---|
| Quality First International<br>Suites 317 & 318 Burford Business Centre<br>11 Burford Road<br>London<br>E15 2ST<br>United Kingdom | **EU Representative** |
| Ssens B.V.<br>Pantheon 1<br>7521 PR Enschede<br>The Netherlands | **Manufacture** |
| Sterigenics Belgium (Petit-Rechain) SA<br>Zoning Industriel de Petit Rechain<br>Avenue Andre Ernst 21<br>Verviers<br>B-4800<br>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 |
|---|---|
| SurModics, Inc<br>9924 W. 74th Street<br>Eden Prairie<br>Minnesota 55344-3523<br>USA | **Crucial Supplier** |
| Synergy Health AST, Venlo<br>Faunalaan 38<br>5928 RZ Venlo<br>The Netherlands | **ETO Sterilization** |

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, 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 |
|---|---|---|
| 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, BioInvent International AB, Patheon 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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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 BioInvent International AB. Correction to name of Synergy Health AST, Venlo. |

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# EC Design-Examination Certificate

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

**No.** **CE 646780**

Issued To: **OrbusNeich 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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# EC Design-Examination Certificate

**Supplementary Information to CE 646780**

Issued To: **OrbusNeich 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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# EC Design-Examination Certificate

**Supplementary Information to CE 646780**

Issued To:

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

**Scoreflex NC Coronary Dilatation Catheter**

List of Product Numbers, continued

| Catalog Number | Balloon Diameter (mm) | Balloon Length (mm) |
|---|---|---|
| 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 |

First Issued: **12 May 2016** Date: **31 January 2017** Expiry Date: **11 May 2021**

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EC Design-Examination Certificate

Supplementary Information to CE 646780

Issued To:

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

## Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 12 May 2016 | 10160141 | First issue. |
| 31 January 2017 | 10165754 | Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected. |

First Issued: 12 May 2016 Date: 31 January 2017 Expiry Date: 11 May 2021

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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:

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



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# EC Declaration of Conformity

## JADE PTA Balloon Dilatation Catheter

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

| | | |
|---|---|---|
| Manufacturer: | Name: | OrbusNeich Medical, B.V. |
| | Address: | Drs. W. van Royenstraat 5<br>3871 AN Hoevelaken<br>The Netherlands |
| EU Authorized Representative: | Name: | Quality First International Limited |
| | Address: | Suites 317-318<br>Burford Business Centre<br>11 Burford Road<br>Stratford, London E15 2ST<br>United Kingdom |
| Notified Body: | Name: | BSI Assurance UK Limited |
| | Address: | Kitemark Court, Davy Avenue<br>Knowlhill, Milton Keynes,<br>MK5 8PP,<br>United Kingdom |
| Certificates: | EC Certificate No.: CE 619995 | |
| General Applicable Directives | Medical Device Directive: Council Directive 93/42/EEC of June 14th, 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. C. Hennink

Title: Supplier Quality Assurance Manager RA

Signature:

Place & Date: Hoevelaken, The Netherlands
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 |

| 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: | Name: | OrbusNeich Medical, B.V. |
| | Address: | Drs. W. van Royenstraat 5<br>3871 AN Hoevelaken<br>The Netherlands |
| EU Authorized Representative: | Name: | Quality First International Limited |
| | Address: | Suites 317-318<br>Burford Business Centre<br>11 Burford Road<br>Stratford, London E15 2ST<br>United Kingdom |
| Notified Body: | Name: | BSI Assurance UK Limited |
| | Address: | Kitemark Court, Davy Avenue,<br>Knowlhill, Milton Keynes,<br>MK5 8PP,<br>United Kingdom |
| Certificates: | | EC Certificate No.: CE 619995<br>EC Design Examination Certificate No.: CE 646780 |
| General Applicable Directives | | Medical Device Directive: Council Directive 93/42/EEC of June 14th, 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: E.J. Hennink

Title: Senior Manager QA and RA

Signature:

Place & Date: The Netherlands
September 09, 2016





**Product Schedule:**

| Scoreflex NC Coronary Dilatation Catheter | | |
|---|---|---|
| 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 |
| 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 IIa (MDD Annex IX) |
| Conformity Assessment | : | MDD 93/42/EEC, Annex II |

**Manufacturer:**

Name: OrbusNeich Medical, B.V.
Address: Drs. W. van Royenstraat 5
3871 AN Hoevelaken
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

**General Applicable Directives** Medical Device Directive: Council Directive 93/42/EEC of June 14th, 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. Hermink

Title: Sr Manager QA and VCA

Signature:

Place & Date: Hoevelaken, 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-20A-31 | 4.0 | 20 |
| 640E-40A-31 | 4.0 | 40 |
| 650E-20A-31 | 5.0 | 20 |
| 650E-40A-31 | 5.0 | 40 |
| 660E-20A-31 | 6.0 | 20 |
| 660E-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) |
|---|---|---|
| 640E-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

**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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Certificate No: CE 511137

## Certificate Scope:

**The design, development and manufacture of ARROWg+ard Blue Plus Central Venous Catheters (CVC); Arrowg+ard Blue CVCs, hemodialysis catheters and Percutaneous Sheath Introducers (PSI); non-coated CVC, PSI, hemodialysis catheters, Peripherally Inserted Central Catheters (PICCs), thermodilution catheters, intra-aortic balloon catheters, intra-aortic balloon pumps, angiographic catheters, balloon wedge pressure catheters, guidewires, anesthesia products, mid-line/peripheral vascular access catheters, Multi-Access Catheters (MAC), drainage catheters, Pneumothorax/ Thoracentesis products, arterial catheterization products, Percutaneous Thrombolytic Device (PTD), central catheters with Chlorag+ard 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.**

First Issued: **2006-10-18** Date: **2018-01-15** Expiry Date: **2021-10-17**

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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<br>75 Winchell Drive<br>New Britain<br>CT 06052<br>USA | **Manufacture** |
| Arrow Internacional de Chihuahua<br>S.A. de C.V., Ave Washington 3701,<br>Edificio 2<br>Colonia Panamerica, Chihuahua<br>Chihuahua<br>CP31200<br>Mexico | **Manufacture**<br>**Packaging** |
| Arrow Internacional de Chihuahua<br>S.A. de C.V., Ave Washington 3701,<br>Interior Circuito Industrial Alta<br>Tecnologia Edificio 40<br>Colonia Panamerica, Chihuahua,<br>Chihuahua<br>CP31200<br>Mexico | **Manufacture**<br>**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

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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 |
|---|---|
| Arrow Internacional de Chihuahua<br>S.A. de C.V.<br>Ave. Washington 3701, Edificio 4<br>Colonia Complejo Industrial<br>Las Americas<br>Chihuahua,<br>Chihuahua<br>CP31114<br>Mexico | **Manufacture**<br>**Packaging** |
| Arrow Internacional de Chihuahua<br>S.A. de C.V.<br>Avenida Washington 3701, Edificio 36<br>Col. Complejo Industrial<br>Las Américas<br>Chihuahua<br>Chihuahua<br>CP. 31114<br>Mexico | **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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**2400 Bernville Road**
**Reading**
**Pennsylvania**
**19605**
**USA**

| Subcontractor: | Service(s) supplied |
|---|---|
| Arrow International CR, a.s.<br>Jamska 2359/47<br>Zdar nad Sazavou<br>59101<br>Czech Republic | **Manufacture** |
| Arrow International CR, a.s.<br>Prazska 209<br>50004 Hradec Kralove<br>Czech Republic | **Manufacture** |
| Arrow International, Inc.<br>16 Elizabeth Drive<br>Chelmsford<br>Massachusetts 01824<br>USA | **Manufacture** |
| Arrow International, Inc.<br>312 Commerce Place<br>Asheboro<br>North Carolina 27203<br>USA | **ETO Sterilization**<br>**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

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19605
USA

| Subcontractor: | Service(s) supplied |
|---|---|
| Brivant Ltd<br>Parkmore West Business Park<br>Galway<br>Ireland | **Manufacture** |
| Celestica Oregon LLC<br>18870 NE Riverside Parkway<br>Portland<br>OR 97230<br>USA | **Manufacture** |
| Custom Wire Technologies, Inc.<br>1123 Mineral Springs Drive<br>Port Washington<br>WI 53074<br>USA | **Manufacture** |
| EPflex Feinwerktechnik GmbH<br>Im Schwöllbogen 24<br>72581 Dettingen/Erms<br>Germany | **Manufacture** |

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High 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

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Date: **2018-01-15**

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

| Subcontractor: | Service(s) supplied |
|---|---|
| Galt Medical Corp<br>2220 Merritt Drive<br>Garland<br>TX 75041<br>USA | **Manufacture** |
| Hudson Respiratory Care Tecate S. de R.L<br>de C.V. (A Teleflex Medical Company)<br>Prolongacion Mision Eusebio Kino<br>No. 1316, Rancho El Descanso<br>Tecate, B.C., C.P.,<br>21478<br>Mexico | **Manufacture**<br>**Packaging** |
| Lake Region Medical Ltd.<br>Butlersland<br>New Ross<br>Co. Wexford<br>Ireland | **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

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

| Subcontractor: | Service(s) supplied |
|---|---|
| Lake Region Medical<br>340 Lake Hazeltine Dr.<br>Chaska<br>MN 55318<br>USA | **Manufacture** |
| NeoMetrics Inc.<br>2605 Fernbrook Lane- Suite J<br>Plymouth<br>MN 55447<br>USA | **Manufacture** |
| SaFeMed spol.s.r.o.<br>Trabantska 292<br>19015 Praha 9/Satalice,<br>Czech Republic | **Manufacture**<br>**Packaging** |
| SFM Medical Devices GmbH<br>Suddeutsche Feinmechanik GmbH<br>Brückenstraße 5<br>63607 Wächtersbach<br>Germany | **Manufacture**<br>**Packaging**<br>**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

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**2400 Bernville Road**
**Reading**
**Pennsylvania**
**19605**
**USA**

| Subcontractor: | Service(s) supplied |
|---|---|
| Sterigenics, Inc.<br>10821 Withers Cove Park Drive<br>Charlotte<br>North Carolina 28278<br>USA | **ETO Sterilization** |
| Sterigenics<br>2400 Airport Road<br>Santa Teresa<br>New Mexico<br>88008<br>USA | **ETO Sterilization** |
| Sterigenics<br>7775 South Quincy<br>Willowbrook<br>Illinois<br>60527<br>USA | **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

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**2400 Bernville Road**
**Reading**
**Pennsylvania**
**19605**
**USA**

| Subcontractor: | Service(s) supplied |
|---|---|
| STERIS AST CZ s.r.o.<br>Prumyslova Zona Kosikov<br>Velka Bites Vysocina<br>595 01<br>Czech Republic | **ETO Sterilization**<br>**Microbiology Service** |
| Teleflex Medical Europe Ltd.<br>IDA Business and Technology Park<br>Dublin Road, Athlone,<br>Co. Westmeath<br>Ireland | **Control of Sterilization**<br>**EU Representative**<br>**Manufacture** |
| Teleflex Medical<br>3015 Carrington Mill Boulevard<br>Morrisville<br>North Carolina 27560<br>USA | **Design**<br>**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, Wyomissing Pennsylvania from the list of significant subcontractors. Added Teleflex Medical as EU Representative to the list of significant subcontractors. |





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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.**
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**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 | EpFlex Feinwerktechnik, Acme Monaco, Galt Medical, Lake Region Medical (USA and Ireland), Brivant and NeoMetrics added to the list of significant subcontractors. |

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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 Tecate and Teleflex Medical (North Carolina) added to the list of subcontractors. |
| 12 August 2015 | 8373794 | Update certificate scope to add: central catheters with Chlorag+ard technology, and Change: "mid-line catheters" to "mid-line/peripheral vascular access catheters". Arrow Internacional de Chihuahua (edeficio 4), and Teleflex Medical (Morrisville) added to the list of subcontractors, and Teleflex Medical Durham removed. Corrected Edificio 2 and 40 address typos for these 2 ARROW International de Chihuahua facilities. |
| 26 August 2015 | 8332115 | Scope extension to include the Vascular Positioning System (VPS). Introduction of Sterigenics (Willowbrook) as a significant subcontractor. |
| 29 July 2016 | 8534169 | Addition of Celestica Oregon LLC and Custom Wire Technologies, Inc. as significant subcontractors. |
| 13 October 2016 | 8562443 | Certificate Renewal. Corrected EBSTER s.r.o address. |





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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.
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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 pervious review SMO 8405167 & EQ 1015720 |
| 11 July 2017 | 8750813 | Removed Arrow Interventional Everett, MA from list of subcontractors and changed subcontractor name from "Ebster s.r.o." to STERIS AST CZ s.r.o." |
| Current | 8857195 | Adding Arrow Internacional de Chihuahua, Edificio 36 as manufacturing subcontractor. Remove information from Arrow Internacional de Chihuahua, Edificio 2 address to match their ISO:13485 certificate. |



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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

ARROW INTERNATIONAL

# DECLARATION OF CONFORMITY

DC-T-BSI-008

| Manufacturer: | European Representative: |
|---|---|
| Arrow International, Inc.<br>2400 Bernville Road<br>Reading, PA 19605 USA | Teleflex Medical<br>IDA Business and Technology Park<br>Dublin Road<br>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:** | **IIa** |
| | **46505 – Instrument guard, single-use** | **Classification:** | **I** |

| GMDN Code: | 58865 Vascular catheter introduction kit | Classification | IIa |
|---|---|---|---|
| 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 | |
| AK-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-03 | |
| ❖ 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 | |
| CK-09850 | PSI: 8.5 Fr. | 25-Mar-98 | |
| CL-07011 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 11 cm | 25-Mar-98 | |
| CL-07024 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 24 cm | 25-Mar-98 | |
| CL-07035 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 35 cm | 25-Mar-98 | |
| CL-07045 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 45 cm | 25-Mar-98 | |
| CL-07065 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 65 cm | 25-Mar-98 | |
| CL-07080 | Super Arrow-Flex® Cath Lab PSI: 10 Fr. x 80 cm | 9-Mar-98 | |
| CL-07511 | Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 11cm | 25-Mar-98 | |
| CL-07524 | Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 24 cm | 25-Mar-98 | |
| CL-07545 | Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 45 cm | 25-Mar-98 | |
| CL-07565 | Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 65 cm | 25-Mar-98 | |
| CL-07590 | Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 90 cm | 25-Mar-98 | |
| CL-07611 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 11 cm | 25-Mar-98 | |
| CL-07624 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 24 cm | 25-Mar-98 | |
| CL-07635 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 35 cm | 25-Mar-98 | |
| CL-07645 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 45 cm | 25-Mar-98 | |
| CL-07665 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 65 cm | 25-Mar-98 | |
| CL-07690 | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 90 cm | 25-Mar-98 | |
| CL-07700 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 100 cm | 25-Mar-98 | |
| CL-07711 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 11 cm | 25-Mar-98 | |



ARROW INTERNATIONAL

DECLARATION OF CONFORMITY

DC-T-BSI-008

| GMDN Code: | 58865 Vascular catheter introduction kit | Classification | IIa |
|---|---|---|---|
| PSI Finished Goods # | Device Description | Date CE Mark First Affixed | |
| CL-07724 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 24 cm | 25-Mar-98 | |
| CL-07735 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 35 cm | 25-Mar-98 | |
| CL-07745 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 45 cm | 25-Mar-98 | |
| CL-07765 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 65 cm | 25-Mar-98 | |
| CL-07780 | Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 80 cm | 25-Mar-98 | |
| CL-07790-R | Super Arrow Flex® PSI: 7 Fr. x 90 cm | 23-Nov-98 | |
| CL-07800 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 100 cm | 23-Nov-98 | |
| CL-07811 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 11 cm | 25-Mar-98 | |
| CL-07824 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 24 cm | 25-Mar-98 | |
| CL-07835 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 35 cm | 25-Mar-98 | |
| CL-07845 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 45 cm | 25-Mar-98 | |
| CL-07865 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 65 cm | 25-Mar-98 | |
| CL-07880 | Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 80 cm | 25-Mar-98 | |
| CL-07900 | Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 100 cm | 25-Mar-98 | |
| CL-07911 | Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 11 cm | 25-Mar-98 | |
| CL-07924 | Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 24 cm | 25-Mar-98 | |
| CL-07965 | Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 65 cm | 25-Mar-98 | |
| CL-07980 | Super Arrow-Flex® Cath LabPSI: 9 Fr. x 80 cm | 25-Mar-98 | |
| CL-08403 | Cath Lab PSI: 4 Fr. x 7.5 cm | 26-May-98 | |
| CL-08403-A | Cath Lab PSI: 4 Fr. x 11 cm | 17-Feb-06 | |
| ❖ CL-08403-AE | Cath Lab PSI: 4 Fr. x 11 cm | 25-Mar-98 | |
| CL-08503 | Cath Lab PSI: 5 Fr. x 7.5 cm | 25-Mar-98 | |
| CL-08503-A | Cath Lab PSI: 5 Fr. x 11 cm | 25-Mar-98 | |
| CL-08505 | Cath Lab PSI: 5 Fr. x 5 cm | 25-Mar-98 | |
| CL-08603 | Cath Lab PSI: 6 Fr. x 11 cm | 25-Mar-98 | |
| CL-08605 | Cath Lab PSI: 6 Fr. x 5 cm | 24-Jan-01 | |
| CL-08605-HF | High-Flow Cath Lab PSI: 6 Fr. x 5 cm | 25-Mar-98 | |
| CL-08703 | Cath Lab PSI: 7 Fr. x 11 cm | 25-Mar-98 | |
| CL-08705-HF | High-Flow Cath Lab PSI: 7 Fr. x 5 cm | 25-Mar-98 | |
| CL-08803 | Cath Lab PSI: 8 Fr. x 11 cm | 25-Mar-98 | |
| CL-08903 | Cath Lab PSI: 9 Fr. x 11 cm | 25-Mar-98 | |
| CL-71165 | Super Arrow-Flex® Cath Lab PSI: 11 Fr. x 65 cm | 25-Mar-98 | |
| CL-71180 | Super Arrow-Flex® Cath Lab PSI: 11 Fr. x 80 cm | 25-Mar-98 | |
| CP-07011 | Super Arrow-Flex® Cath Lab PSI: 10 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-07611-P | Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 7.5 cm | 25-Mar-98 | |
| CP-07711 | Super Arrow-Flex® Cath Lab PSI: 7 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., 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 | |

| GMDN Code: | 58865 Vascular catheter introduction kit | Classification | IIa |
|---|---|---|---|
| PSI Finished Goods # | Device Description | Date CE Mark First Affixed | |
| CP-08903 | Cath Lab PSI: 9 Fr. x 11 cm | 25-Mar-98 | |
| CR-07645 | Super Arrow Flex® PSI: 6 Fr. x 45 cm | 19-Feb-99 | |
| CR-07745 | Super Arrow Flex® PSI: 7 Fr. x 45 cm | 30-Jun-98 | |
| CR-07745-NT | Super Arrow Flex® PSI: 7 Fr. x 45 cm | 21-Jul-99 | |
| CT-07860 | Super Arrow Flex® PSI: 8 Fr. x 60 cm | 25-Mar-98 | |
| CW-08403 | Cath Lab PSI: 4 Fr. x 7.5 cm | 25-Mar-98 | |
| CW-08503 | Cath Lab PSI: 5 Fr. x 7.5 cm | 25-Mar-98 | |
| CW-08503-A | Cath Lab PSI: 5 Fr. x 11 cm | 3-Feb-99 | |
| CW-08603 | Cath Lab PSI: 6 Fr. x 11 cm | 25-Mar-98 | |
| CW-08703 | Cath Lab PSI: 7 Fr. x 11 cm | 25-Mar-98 | |
| CW-08803 | Cath Lab PSI: 8 Fr. x 11 cm | 25-Mar-98 | |
| CW-08903 | Cath Lab PSI: 9 Fr. x 11 cm | 25-Mar-98 | |
| ❖ DE-09600-UNH | PSI: 6 Fr. | 13-Sep-17 | |
| ❖ DE-09875-HZO | PSI Kit: 8.5 Fr. | 11-Jun-12 | |
| ❖ DE-09875-HZO1 | PSI Kit: 8.5 Fr. | 14-Sep-17 | |
| ❖ DM-09875 | PSI: 9 Fr. | 30-Mar-98 | |
| ❖ GR-08403 | Cath Lab PSI: 4Fr. x 11 cm | 17-Feb-12 | |
| ❖ GR-08503-A | Cath Lab PSI: 5 Fr. x 11 cm | 21-Oct-10 | |
| ❖ GR-08603 | Cath Lab PSI: 6 Fr., 11 cm | 21-Oct-10 | |
| ❖ GR-08703 | Cath Lab PSI: 7 Fr. x 11 cm | 21-Oct-10 | |
| ❖ HK-09903-S | PSI: 9 Fr. | 6-Jan-03 or 14-May-99 | |
| HP-09903 | PSI: 9 Fr. | 14-Sep-98 | |
| ❖ HZ-09801 | PSI: 8.5 Fr. | 23-Jul-02 or 08-April-98 | |
| ❖ IK-09600 | PSI: 6 Fr. | 5-Aug-05 | |
| ❖ LU-09903 | PSI: 9 Fr. | 27-Jun-05 | |
| ❖ MS-07803 | PSI: 9 Fr. | 14-Jul-00 | |
| ❖ MS-09600 | PSI: 6 Fr. | 19-Sep-01 | |
| ❖ NL-09801-MUMC | PSI Kit 9 Fr. | 17-Jan-13 | |
| ❖ SG-09903 | PSI: 9 Fr. | 10-Dec-97 or 14-May-99 | |
| SI-09600 | PSI: 6 Fr. | 16-Jun-08 | |
| ❖ SI-09600-LJ | PSI: 6 Fr. | 25-Mar-98 | |
| SI-09700 | PSI: 7 Fr. | 19-Dec-97 | |
| SI-09700-LJ | PSI: 7 Fr. | 12-Mar-08 | |
| SI-09803-CV | PSI: 8.5 Fr. | 21-Aug-98 | |
| SI-09806 | PSI: 8.5 Fr. | 9-Mar-98 | |
| SI-09808 | PSI: 8 Fr. | 10-Dec-97 | |
| ❖ SI-09808-LJ | PSI: 8 Fr. | 14-Mar-08 | |
| SI-09870-E | PSI: 8.5 Fr. | 10-Dec-97 | |
| SI-09875-E | PSI: 8.5 Fr. | 10-Dec-97 | |
| ❖ SI-09875-EANG | PSI: 8.5 Fr. | 11-Apr-05 | |
| SI-09875-ESB | PSI: 8.5 Fr. | 17-Jun-02 | |
| SI-09880 | PSI: 8.5 Fr. | 10-Dec-97 | |
| SI-09880-LF | PSI: 8.5 Fr. | 14-Jan-00 | |
| ❖ SI-09880-QE | PSI: 8.5 Fr. | 15-Dec-03 | |
| SI-09880-SB | PSI: 8.5 Fr. | 17-Jun-02 | |
| SI-09880-SE | PSI: 8.5 Fr. | 9-Mar-98 | |
| SI-09903-E | PSI: 9 Fr. | 10-Dec-97 | |



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| GMDN Code: | 58865 Vascular catheter introduction kit | Classification | IIa |
|---|---|---|---|
| PSI Finished Goods # | Device Description | Date CE Mark First Affixed | |
| SS-09903-S | PSI: 9 Fr. | 17-Oct-07 | |
| ❖ SU-09903-C | PSI: 9 Fr. | 3-Apr-07 | |
| ❖ UB-09903-C | PSI: 9 Fr. | 30-Oct-01 | |
| ❖ UE-09800 | PSI: 8.5 Fr. | 13-Feb-01 | |
| ❖ UK-09903 | PSI: 9 Fr. | 24-Oct-08 | |
| ❖ UR-09880-LF | PSI: 8.5 Fr. | 4-Dec-02 | |
| WH-09800-T | PSI: 8.5 Fr. | 19-Dec-97 | |

| PSI Part # (if applicable) | Device Description | Czech Part # (if applicable) |
|---|---|---|
| K-09601-014 | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| K-09701-004 | Sheath Ext: 7 Fr x 4-1/8" | N/A |
| K-09701-005 | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| K-09800-008 | Sheath Ext Assy w/Dilator: 8.5 Fr | N/A |
| K-09808-005 | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| K-09880-012 | Sheath Ext Assy w/Dilator: 8.5 Fr | N/A |
| K-09880-015 | Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop | N/A |
| L-07011-001B | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07024-001B | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07035-001C | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07045-001E | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07065-001C | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07080-001C | Sheath Ext Assy w/Dilator: 10 Fr | N/A |
| L-07511-001B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| L-07524-001B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| L-07545-001D | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| L-07565-001B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| L-07590-001B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| L-07611-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07624-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07635-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07645-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07665-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07690-001C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| L-07700-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07711-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07724-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07735-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07745-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07765-001 | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07780-001C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-07800-001D | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07811-001B | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07824-001C | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07835-004 | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07845-001D | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07865-001D | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| L-07900-001B | Sheath Ext Assy w/Dilator: 9 Fr | N/A |

| PSI Part # (if applicable) | Device Description | Czech Part # (if applicable) |
|---|---|---|
| L-07911-001B | Sheath Ext Assy w/Dilator: 9 Fr | N/A |
| L-07924-001B | Sheath Ext Assy w/Dilator: 9 Fr | N/A |
| L-07965-001C | Sheath Ext Assy w/Dilator: 9 Fr | N/A |
| L-07980-001B | Sheath Ext Assy w/Dilator: 9 Fr | N/A |
| L-08705-003A | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| L-09807-002 | Sheath Ext Assy w/Dilator: 8.5 Fr | LZ-09807-002 |
| L-71180-001 | Sheath Ext Assy w/Dilator: 11 Fr | N/A |
| LF-09803-006 | Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop | N/A |
| LF-09803-009 | Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop | N/A |
| LF-09804-007 | Sheath Ext Assy W/Dilator: 9 Fr | N/A |
| LF-09875-001 | Sheath Ext Assy w/Stope-Dil Comm:9 Fr | N/A |
| LF-09903-008 | Sheath Ext Assy w/Dil Comm: 9fr Hydrophi | N/A |
| LF-09903-009 | Sheath Ext Assy W/Stope-Dil Comm:9 Fr | N/A |
| LF-09903-017 | Sheath Ext Assy w/Dil Comm: 9fr Hydrophi | N/A |
| P-07511-001 | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| R-07645-001 | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| R-07745-001A | Sheath Ext Assy w/Dilator: 7 F | N/A |
| R-07745-007 | Sheath Ext Assy w/Dilator: 7 F | N/A |
| R-07790-001 | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| T-01000-033A | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| T-07860-001 | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| T-45509-010A | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| T-45509-013A | Sheath Ext Assy w/Dilator: 5 F | N/A |
| W-08403-012D | Sheath Ext Assy w/Dilator: 4 Fr | N/A |
| W-08403-014 | Sheath Ext Assy w/Stope-Dil Comm:4 Fr | N/A |
| W-08413-014 | Sheath Ext Assy w/Dilator: 4 Fr | N/A |
| W-08503-004B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| W-08503-005C | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| W-08513-004B | Sheath Ext Assy w/Dilator: 5 Fr | N/A |
| W-08603-005D | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| W-08613-004C | Sheath Ext Assy w/Dilator: 6 Fr | N/A |
| W-08703-006C | Sheath Ext Assy w/Dilator: 7 Fr | N/A |
| W-08803-014C | Sheath Ext Assy w/Dilator: 8 Fr | N/A |
| W-08903-005C | Sheath Ext Assy w/Dilator: 9 Fr | N/A |
| Z-09800-008 | Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop | N/A |

| GMDN Code: | 46505 – Instrument guard, single-use | Classification: I |
|---|---|---|
| Cath-Gard Finished Good # | Device Description | Date CE Mark First Affixed |
| AI-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 Fr. Catheters and Arrow Percutaneous Sheath Introducer Systems | 22-May-1998 |
| ST-09870 | TwistLock(TM) Cath-Gard Catheter Contamination Shield for use with 7 Fr. Catheters | 22-May-1998 |
| ST-09875 | TwistLock(TM) Cath-Gard Catheter Contamination Shield for use with 7.5 and 8 Fr. Catheters | 22-May-1998 |



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| GMDN Code: | 46505 – Instrument guard, single-use | Classification: I |
|---|---|---|
| Cath-Gard Finished Good # | Device Description | Date CE Mark First Affixed |
| ST-09880 | Cath-Gard(R) Catheter Contamination Shield for use with 7 and 7.5 Fr. 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 Fr. Catheters | 01-Feb-2000 |
| EU-00001-ST | Cath-Gard® Catheter Contamination Shield for use with 4 and 5 Fr Catheters and Arrow Percutaneous Sheath Introducer Systems | 21-Mar-14 |

| Cath-Gard Part # (if applicable) | Device Description | Czech Part # (if applicable) |
|---|---|---|
| A-09880-001 | CATH-GARD: 7-7.5 FR X80CM W/T-B ADAPTER | N/A |
| AI-08803-002 | CATH-GARD: 5-6 FR X30CM | N/A |
| B001-0010-001 | CATH-GARD: 34CM | N/A |
| I-09800-004A | CATH-GARD: 7.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER | N/A |
| I-09880-001A | CATH-GARD: 7.0 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER | N/A |
| I-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-09806-003 | Cath-Gard Catheter Contamination Shield: 80 cm with Tuohy-Borst Adapter | N/A |
| P-09806-014 | CATH-GARD: 7-7.5 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-09870-001 | CATH-GARD: 7.0 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER - Packaged | N/A |
| ST-09875-001 | CATH-GARD: 7.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER - Packaged | N/A |
| ST-09880-004 | CATH-GARD: 7-7.5 FR X80CM | N/A |
| ST-09880-005 | CATH-GARD: 7-7.5 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 |

| GMDN Code: | 58865 Vascular catheter introduction kit | Classification IIa |
|---|---|---|
| Trauma Finished Goods Product # | Device Description | Date CE Mark First Affixed |
| EI-04060 | Peripheral Emergency Infusion Device – EID™ | 17-June-1998 |
| EI-04080 | Emergency Infusion Device - EID™ | 17-June-1998 |
| RC-05801 | Trauma Kit | 24-June-2002 |
| RC-09700 | RJC® 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-09850 | RIC® Rapid Infusion Catheter Exchange Set | 16-June-1998 | |

| Trauma Part # (if applicable) | Device Description | Czech Part # (if applicable) |
|---|---|---|
| I-04060-001 | Sheath: 6 Fr. x 1-1/2" (3.81 cm) Radiopaque with Dilator over 20 Ga. TW Needle | N/A |
| I-04080-017B | 8.5 Fr. x 3-1/2" (8.9 cm) ArrowFlex(R) Radiopaque FEP Sheath/Dilator over 17 Ga. x 5-1/2" (14 cm) TW Needle, .035" (.89 mm) dia. x 13-3/16" (33.5 cm) Spring-Wire Guide, 5 mL Luer-Lock Syringe and Sterility 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: | 58865 Vascular catheter introduction kit | Classification | IIa |
|---|---|---|---|
| MAC Finished Good # | Device Description | Date CE Mark First Affixed | |
| 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-ISB | 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-Dcember-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-MUMC | 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.



ARROW INTERNATIONAL

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 (EC 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 93/42/EEC.

☐ Other: ____

**CERTIFICATE NUMBERS:**

| | |
|---|---|
| Annex II.3 Certificate(s) | CE 511137 |
| Annex II.4 Certificate (Class III products only) | N/A |
| Annex V Certificate (Class I Sterile/Measuring Function products only) | N/A |

ARROW INTERNATIONAL, INC., Reading, PA USA

Krista Hughes obo Christine Ford — 25Oct2017

Regulatory Affairs Representative (Print and Sign) — Date

Kathleen Whanger — 25OCT2017

Quality Assurance Representative (Print and Sign) — Date

**REVISION HISTORY:**

| Rev Level | Date | Description |
|---|---|---|
| 0 | 04-Nov-2010 | Original issue of DC-T-BSI-008 in new DC format – Replaces DC-BSI-018. Refer to DC-BSI-018 for revision history of previous DOC. AddedGR-08503-A, GR-08603, and GR-08703 per ECR-011057, ECR-011058, and ECR-011056 respectively. Removed the following obsolete Finished Goods: BB-09903-NA, KK-09903-C, SI-09908-E. |
| 1 | 21-Dec-2011 | Added DE-09803-HZO to Declaration per ECR-014307. |
| 2 | 17-Feb-2012 | Added GR-08403 per ECR-014519. |
| 3 | 11-Jun-2012 | Added DE-09875-HZO to Declaration per ECR-015641.Update DOC with GMDN. |
| 4 | 28-Feb-2014 | Added component part numbers to support the Procedure Pack initiative. Added GMDN code. Added NL-09801-MUMC per ECR 018256, Removed DE-09803-HZO per ECR-ECR-016026. Per ECR-019142 removed KZ-09601, KZ-09701-001, KZ-09701-005, KZ-09800-001, KZ-09808-004, KZ-09880-002, KZ-09880-004, LFZ-09803-001, LFZ-09803-002, LFZ-09875-00, LFZ-09903-004, LFZ-09903-005, LFZ-09903-006, WZ-08403-001, WZ-08513-001, WZ-08603-001, and WZ-08703-001. |
| 5 | 18-Mar-2015 | Added BB-09903-AG per ECO-024121. Added K-11242-008, K-11142-011 per ECO-029601. Update format to indicate market specific codes. Merged DOC's DC-T-BSI-020 MAC, DC-T-BSI-026 Cath-Gard Products and T-BSI-029 Trauma to file consolidation |
| 6 | 18-Dec-2015 | Added NL-11142-MUMC per ECR-026233/ECO-036641. |
| 7 | 21-Dec-2015 | Added AT-09875-E per ECR-026737/ECO-037472 |
| 8 | 25-Jan-2016 | Updated GMDN codes |
| 9 | 28-Feb-2017 | Administrative change: BB-09903-AG is appropriately included on DC-D-BSI-016 and is not covered by DC-T-BSI-018: removed BB-09903-AG . |
| 10 | 1-Jun-2017 | Added CH-11242-ISB per ECR-030828. |
| 11 | 21-Sep-2017 | Added DE-09600-UNH per ECR-031362 |
| 12 | 25-Oct-2017 | Added DE-09875-HZO1 per ECR-032009. Updated product description for code EU-00001-ST per ECR-032020. |

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# DECLARATION OF CONFORMITY

DC-T-BSI-015

| Manufacturer: | European Representative: |
|---|---|
| Arrow International, Inc.<br>2400 Bernville Road<br>Reading, PA 19605 USA | Teleflex Medical<br>IDA Business and Technology Park<br>Dublin Rd.<br>Athlone, Co. Westmeath, Ireland |

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

| GMDN Code: | 10689 Arterial blood pressure catheter | Classification: |
|---|---|---|
| Arterial Finished Good Number | Device Description | Date CE Mark First Affixed |
| AA-15511-S | ACCESS TRAY | 11/19/03 |
| ❖ AD-04018 | ARTERIAL LINE SET | 04/12/07 |
| ❖ AE-04018 | ARTERIAL LINE SET | 11/03/09 |
| AG-04120 | RA CATH SET: 20 GA X 2-1/2 | 12/21/03 |
| AV-04020 | ART./VENOUS CATH SET:20GA CATH/22GA NDL | 11/12/98 |
| ❖ BB-01218 | ARTERIAL CATH. KIT: GA x CM | 06/21/06 |
| ❖ BB-04018 | ARTERIAL CATH KIT: 18 GA X | 01/06/00 |
| ❖ BB-04018-C | ARTERIAL CATH. SET: 18GA x 12.7CM | 04/12/07 |
| ❖ BB-04018-GH | ARTERIAL CATH KIT: 18GA X 12.7CM | 01/16/01 |
| CK-04018 | ARTERIAL CATH SET: 18 GA X 5 | 04/12/07 |
| ❖ DE-00820-BAB | ARTERIAL SET: 20 GA X 8 CM | 05/30/17 |
| ❖ DE-00820-OLD | ARTERIAL CATH. SET: 20 GA x 8CM | 10/28/09 |
| ❖ DE-00820-RB | ARTERIAL CATH. KIT: 20 GA x 8CM | 02/21/11 |
| ❖ DE-00820-EKBI | Arterial Cath. Set: 20 Ga X 8cm | 08/29/13 |
| ❖ DE-00820-MKHS | Arterial Cath. Set: 20 Ga X 8cm | 01/04/17 |
| ❖ DE-00820-UB | Arterial Cath. Set: 20 Ga X 8cm | 01/04/17 |
| ❖ DE-00820-VB | ARTERIAL CATH. KIT : 20 GA X 8 CM | 04/06/17 |
| ❖ DE-00820-WKKH | ARTERIAL CATH. SET: 20 GA X 8CM | 3/27/14 |
| ❖ DE-00820-WO | Arterial Cath. Set: 20 Ga X 8cm | 01/04/17 |
| ❖ DE-00820-WO1 | Arterial Cath. Set: 20 Ga X 8cm | 05/12/17 |
| ❖ DE-01618-HZO | ARTERIAL CATH. KIT: 18 GA x 16CM | 02/11/11 |
| ❖ DE-01618-OLD | ARTERIAL CATH. KIT: 18 GA x 16CM | 09/13/2017 |
| ❖ DE-01618-VB | ARTERIAL CATH. KIT : 18 GA X 16 CM | 04/06/17 |
| ❖ DE-01618-ZB | ARTERIAL CATH. SET: 18GA x 16CM | 01/06/10 |
| FA-04014 | ART./VENOUS CATH SET:14 GA CATH/18 GA NDL | 11/02/98 |
| FA-04016 | ART./VENOUS CATH SET:16 GA CATH/19 GA NDL | 11/02/98 |
| FA-04018 | ARTERIAL CATH SET:18 GA CATH/20 GA NDL | 04/12/07 |
| FA-04020 | ARTERIAL CATH SET:20 GA CATH/22 GA NDL | 11/02/98 |
| GH-04120 | RA CATH SET: 20 GA X 2-1/2 | 02/04/98 |
| GH-04120-E | RA CATH SET: 20 GA X 3-1/16 | 03/03/98 |
| GH-04122 | RA CATH SET: 22 GA X 1-3/8 | 02/04/98 |
| ❖ GH-04124 | RA CATH SET: 24 GA X 4 CM | 12/09/99 |
| GH-04125 | ARTERIAL CATH. SET: 20GA x 3-1/16 | 03/03/98 |
| GH-04150 | FEMORAL ARTERY CATH SET: 20 GA X 8 | 03/02/98 |
| ❖ MONZINO-00818 | ARTERIAL CATH. SET: 18GA x 8CM | 04/11/07 |



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| | | |
|---|---|---|
| NL-00520-CZE | ARTERIAL CATH. SET: 20 GA X 5 CM | 10/10/2016 |
| ❖ NL-00520-MUMC | ARTERIAL CATH. KIT: 20 GA X 5CM | 02/29/16 |
| ❖ NL-00820-ZUY | ARTERIAL CATH. KIT: 20 GA X 8 CM | 05/27/16 |
| NL-01618-CZE | ARTERIAL CATH. SET: 18 GA X 16 CM | 10/10/2016 |
| ❖ NL-01618-ZUY | ARTERIAL CATH. KIT: 18 GA X 16 CM | 05/27/16 |
| ❖ OY-04022 | RA CATH SET: 22 GA x 4.45 CM | 03/14/02 |
| RA-04018 | RA CATH SET: 18 GA X 1-3/4 | 06/16/05 |
| RA-04020 | RA CATH SET: 20 GA X 1-3/4 | 10/12/04 |
| RA-04022 | RA CATH SET: 22 GA X 1-3/4" (4.45 CM) | 07/31/06 |
| RA-04120 | RA CATH SET: 20 GA X 1-1/2 | 11/11/04 |
| RA-04122 | RA CATH SET: 22 GA X 1-3/8 | 10/12/04 |
| RA-04220 | RA CATH SET: 20 GA X 1-1/2 | 11/11/04 |
| RA-04220-W | RA CATH SET: 20 GA X 1-1/2 | 04/01/04 |
| ❖ TI-00820-IR | Arterial Catheterization Kit | 11/21/2013 |
| ❖ ZB-00820 | ARTERIAL CATH. KIT: GA x CM | 06/06/06 |
| ❖ SAC-00324 | ARTERIAL CATH SET: 24GA X 3CM | 11/11/08 |
| SAC-00520 | ARTERIAL CATH SET: 20GA X 5CM | 01/08/04 |
| ❖ SAC-00522 | ARTERIAL CATH SET: 22GA X 5CM | 07/03/04 |
| ❖ SAC-00524 | ARTERIAL CATH SET: 24GA X 5CM | 11/20/08 |
| SAC-00818 | ARTERIAL CATH SET: 18 GA X 8CM | 01/08/04 |
| SAC-00820 | ARTERIAL CATH SET: 20GA X 8CM | 11/20/08 |
| ❖ SAC-00822 | ARTERIAL CATH SET: 22GA X 8CM | 03/15/05 |
| SAC-01218 | ARTERIAL CATH SET: 18GA X 12CM | 12/20/04 |
| SAC-01220 | ARTERIAL CATH SET: 20GA X 12CM | 03/16/05 |
| SAC-01222 | ARTERIAL CATH SET: 22GA X 12CM | 03/16/05 |
| SAC-01618 | ARTERIAL CATH SET: 18GA X 16CM | 03/16/05 |
| SAC-01620 | ARTERIAL CATH SET: 20GA X 16CM | 03/16/05 |
| SAC-02318 | ARTERIAL CATH SET: 18GA X 23CM | 01/08/04 |
| SAC-00324-PBX | ARTERIAL CATH. SET: 24 GA X 2.5CM | 12/01/2016 |
| SAC-00520-PBX | ARTERIAL CATH SET: 20GA X 5CM | 12/01/2016 |
| SAC-00522-PBX | ARTERIAL CATH. SET: 22 GA X 5CM | 12/01/2016 |
| SAC-00524-PBX | ARTERIAL CATH. SET: 24 GA X 5CM | 12/01/2016 |
| SAC-00818-PBX | ARTERIAL CATH SET: 18 GA X 8CM | 12/01/2016 |
| SAC-00820-PBX | ARTERIAL CATH. SET: 20 GA X 8CM | 12/01/2016 |
| SAC-00822-PBX | ARTERIAL CATH SET: 22GA X 8CM | 12/01/2016 |
| SAC-01218-PBX | ARTERIAL CATH SET: 18GA X 12CM | 12/01/2016 |
| SAC-01220-PBX | ARTERIAL CATH SET: 20GA X 12CM | 12/01/2016 |
| SAC-01222-PBX | ARTERIAL CATH SET: 22GA X 12CM | 12/01/2016 |
| SAC-01618-PBX | ARTERIAL CATH. SET: 18 GA X 16CM | 12/01/2016 |
| SAC-01620-PBX | ARTERIAL CATH SET: 20GA X 16CM | 12/01/2016 |
| SAC-02318-PBX | ARTERIAL CATH SET: 18GA X 23CM | 12/01/2016 |
| ❖ UK-00820-ART | ARTERIAL CATH KIT: 20GA X 8CM | 03/05/14 |

❖ 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.

| Arterial Part # (if applicable) | Device Description | Czech Part # (if applicable) |
|---|---|---|
| A-04014-015 | 14 Ga X 6" (16 Cm) Cath/18 Ga Xtw Needle | N/A |

| | | |
|---|---|---|
| A-04016-015 | 16ga X 7" Cath/19ga Ndl | N/A |
| A-04018-001 | 18ga X 1-3/4" Cath/20ga Ndl | N/A |
| A-04018-009 | 18ga X 4-1/4" Cath/20ga Ndl | N/A |
| A-04020-011A | 20ga X 4-1/4" Cath/22ga Ndl | N/A |
| A-04022-001 | 22ga X 1-3/4" Cath/25ga Ndl | AZ-04022-001 |
| A-04120-015 | 20ga X 1-1/2" Cath/22ga Ndl W/Coating | N/A |
| A-04122-003b | 22ga X 1-3/8" Cath/23ga Ndl W/Coating | N/A |
| A-04122-010 | Catheter S-L: 22 Ga X 1-3/8" | N/A |
| A-04122-012 | 22GA X 1-3/8" CATH/23GA NDL W/COATING | N/A |
| A-04220-009b | Catheterization Dev: 20 Ga Radial Artery | N/A |
| A-04016-015 | 16ga X 7" Cath/19ga Ndl | 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-04150-004 | 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 /25 Ga Ndl Comm | N/A |
| K-15511-001 | 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-00324-001 |
| NA | 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 Ndl 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-00324-002 |
| 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 certificates (EC 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 93/42/EEC. | |
| ☐ Other: | |
| CERTIFICATE NUMBERS: | |
| Annex II.3 Certificate(s) | CE 611137, ISO 13485: FM 512674 |
| Annex II.4 Certificate (Class III products only) | N/A |
| Annex V Certificate (Class I Sterile/Measuring Function products only) | N/A |

ARROW INTERNATIONAL, INC., Reading, PA USA

Kristie Hughes for Christine Ford — 13 Dec 2017

Regulatory Management or Designee (Print and Sign) — Date

Matt Winton — 14 Dec 2017

Senior Manager Quality Assurance or Designee (Print and Sign) — Date

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-046). |
| 1 | 07 Jan- 2010 | Addition of DE-01618-ZB. |
| 2 | 7- Mar- 2011 | Addition of new SAC kit: 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 Acess kits AA-10407-1, AA-10507-1 and AA-10511-1. Added GMDN Codes. Added GH-04120, GH-04120-B, 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. |

ARROW INTERNATIONAL

# 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-10607-1D. |
| 7 | 4-Sep-2012 | Added new finished goods AA-10411-1, AA-10524-1, AA-15511-3, AA-15611-3, 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-10607-1D, UN-00820, UW-04120-C, and ZB-01618. Added DE-00820-EKBI per ECR-017888. |
| 9 | 10-Mar-2014 | Added TI-00820-IR 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-00520-001, PCZ-00522-001, 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-WKKH per ECR-021128. |
| 11 | 19-Oct-2015 | Updated components to include A-04122-012 used in RA-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-MUMC per ECR-027174/ECO-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-00522-002, PCZ-00524-002, 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-00522-PBX, SAC-00822-PBX, SAC-01222-PBX, SAC-00324-PBX, and SAC-00524-PBX per ERC-028490. Added DE-00820-MKHS, 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. |

bsi.

By Royal Charter

# 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 Pitanga, 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



...making excellence a habit.



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, thermodilution, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolectomy, vascular positioning system (VPS) stylets, consoles and accessories, plus components and accessories for the above product lines. Contract manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal.

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

Certificate No: **FM 512674**

| Location | Registered Activities |
|---|---|
| Arrow International, Inc.<br>(subsidiary of Teleflex, Incorporated)<br>2400 Bernville Road<br>Reading<br>Pennsylvania<br>19605<br>USA | Design, development, manufacture, servicing and distribution of the following catheters: intravascular, anesthesia, hemodialysis, abdominal, thoracic and pleural drainage, atherectomy, electrophysiology/pacing, thermodilution, wedge pressure, intra-aortic balloon, angiography, cholangiography, embolectomy, vascular positioning system (VPS) stylets, consoles and accessories, plus components and accessories for the above product lines. Contract manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal.<br><br>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.<br>312 Commerce Place<br>Asheboro<br>North Carolina<br>27203<br>USA | Manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, abdominal, thoracic and pleural drainage catheters, feeding tubes, embolectomy catheters, spring wire guides, and percutaneous sheath introducers. Processing and Packaging of sutures (absorbable and non absorbable) and light panels. Labeling requirement and CMDR 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.<br>Prazska 209<br>Hradec Kralove<br>50004<br>Czech Republic | Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermodilution catheters, intrautine 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





Certificate No: **FM 512674**

| Location | Registered Activities |
|---|---|
| Arrow Internacional de Chihuahua de S.A. de C.V.<br>Ave. Washington 3701<br>Interior Circuito Industrial<br>Alta Tecnología, Edificio 40<br>Col. Panamericana<br>Chihuahua<br>CP 31200<br>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 packing and distribution of anesthesia catheters, hemodialysis catheters. |
| Arrow Internacional de Chihuahua<br>S.A. de C.V.<br>Ave. Washington 3701<br>Edificio 2<br>Col. Panamericana<br>Chihuahua<br>CP 31200<br>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 packing and distribution of anesthesia catheters, hemodialysis catheters. |
| Arrow International CR, a.s.<br>Jamska 2359/47<br>Zdar Nad Sazavou<br>59101<br>Czech Republic | Design, development, manufacture and distribution of intravascular catheters, anesthesia catheters, hemodialysis catheters, thermodilution 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. |
| Arrow International, Inc.<br>Berks Corporate Center<br>760 Corporate<br>Building #7<br>Reading<br>Pennsylvania<br>19605<br>USA | Manufacturing material warehouse and distribution process activities. |
| Arrow International, Inc.<br>(subsidiary of Teleflex, Incorporated)<br>16 Elizabeth Drive<br>Chelmsford<br>Massachusetts<br>01824<br>USA | Design, development, manufacture and distribution of electrophysiology / pacing, thermodilution, angiography and wedge pressure catheters; intra-aortic balloons and pumps; and components and accessories for these product lines. Manufacture of cholangiography devices. Servicing of intra-aorticballoon pumps. |

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

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

Certificate No: **FM 512674**

| Location | Registered Activities |
|---|---|
| Arrow Internacional de Chihuahua<br>S.A. de C.V.<br>Ave. Washington 3701, Edificio 4<br>Colonia Complejo Industrial Las Americas<br>Chihuahua<br>CP 31114<br>Mexico | Manufacture and distribution of Intravascular catheters, anhestesia catheters, hemodialysis catheters, abdominal, thoracic and pleural drainage catheters, feeding tubes, embolectomy catheters, spring wire guides, and percutaneous sheath introducers. Labeling requirement and CMDR regulatory clearance at distribution sites. Plus components and accessories for the above product lines. |
| Arrow Internacional de Chihuahua<br>S.A. de C.V.<br>Avenida Washington # 3701<br>Edificio 36<br>Colonia Complejo Industrial Las Americas<br>Chihuahua<br>CP 31114<br>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

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# 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 Emboiic 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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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<br>12560 Fletcher Lane, Suite 300<br>Rogers<br>MN 55374<br>USA | **Manufacture** |
| Cartika Medical, Inc.<br>6550 Wedgwood Road North<br>Suite 300<br>Maple Grove<br>Minnesota<br>55311<br>USA | **Manufacture** |
| E-Beam Services, Inc.<br>2775 Henkle Drive<br>Lebanon<br>Ohio<br>45036<br>USA | **E Beam 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 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.<br>3400 Union Street<br>Lafayette<br>Indiana<br>47905<br>USA | **E Beam Sterilization** |
| Galt Medical Corp<br>2220 Merritt Drive<br>Garland, TX 75041<br>USA | **Manufacture** |
| Harland Medical Systems<br>7418 Washington Ave S<br>Eden Prairie<br>MN 55344<br>USA | **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 647900

Date: 2018-07-06

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

| Subcontractor: | Service(s) supplied |
|---|---|
| Harmac Medical Products<br>IDA Business Park<br>Castlerea<br>Roscommon<br>Ireland | **Manufacture** |
| Isomedix Operations, Inc.<br>380 90th Avenue NW<br>Minneapolis<br>MN 55433<br>USA | **ETO Sterilization** |
| Lake Region Medical<br>340 Lake Hazeltine Drive<br>Chaska<br>Minnesota 55318<br>USA | **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 647900**

Date: **2018-07-06**

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

| Subcontractor: | Service(s) supplied |
|---|---|
| Merit Medical Systems, Inc.<br>1600 West Merit Parkway<br>South Jordan<br>UT 84095<br>USA | **Manufacture** |
| Merit Medical Systems, Inc.<br>14646 Kirby Drive<br>Houston<br>Texas 77047<br>USA | **Manufacture** |
| Phillips-Medisize Ireland<br>High Road<br>Letterkenny<br>Co. Donegal<br>Ireland | **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 647900**

Date: **2018-07-06**

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

| Subcontractor: | Service(s) supplied |
|---|---|
| Polymicro Technologies<br>a Subsidiary of Molex<br>18019 N. 25th Ave.<br>Phoenix<br>AZ 85023<br>USA | **Manufacture** |
| Precision Wire Components<br>10230 SW Spokane Court<br>Tualatin<br>Oregon 97062<br>USA | **Manufacture** |
| Sterigenics US, LLC<br>7775 South Quincy Street<br>Willowbrook<br>Illinois 60527<br>USA | **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 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<br>Lodge Road<br>Westport<br>County Mayo<br>Ireland | **Gamma Sterilization** |
| Teleflex Medical<br>IDA Business and Technology Park<br>Dublin Road<br>Athlone<br>Co. Westmeath<br>Ireland | **EU Representative** |
| Vascular Solutions LLC<br>14005 13th Avenue<br>Plymouth<br>Minnesota<br>55441<br>USA | **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 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<br>6401 Sycamore Court North<br>Maple Grove<br>Minnesota<br>55369<br>USA | **Regulatory Compliance** |
| Vascular Solutions LLC<br>6420 Sycamore Lane North<br>Minneapolis<br>Minnesota<br>55369<br>USA | **Manufacture** |

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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A member of BSI Group of Companies.

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# 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 Steris Isomedix Services to Isomedix Operations, Inc. |
| Current | 8940684 | Change of legal manufacturer name from "Vascular Solutions, Inc." to "Vascular Solutions LLC."<br>Change of multiple subcontractor names from "Vascular Solutions, Inc." to "Vascular Solutions LLC."<br>Change EU Representative to Teleflex Medical (Ireland).<br>Removal of Vascular Solutions Zerusa Limited. Clarifications to sterilization services supplied for several subcontractors, and corrections to several subcontractor addresses. |

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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, Head of Compliance & Risk - Medical Devices

First Issued: **2018-09-26** Date: **2018-09-26** Expiry Date: **2023-09-25**

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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.<br><br>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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# 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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# EC Design-Examination Certificate

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

**No.** **CE 678708**

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

In respect of:

**SuperCross Microcatheters**

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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# EC Design-Examination Certificate

**Supplementary Information to CE 678708**

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

**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 | | | 150cm | | |
| 5340 | SuperCross FT | flexible | 130cm | | |
| 5341 | | | 150cm | | |
| 5302 | SuperCross AT | 45° | 130cm | | |
| 5303 | | | 150cm | | |
| 5304 | | 90° | 130cm | | |
| 5305 | | | 150cm | | |
| 5306 | | 120° | 130cm | | |
| 5307 | | | 150cm | | |
| 5308 | | 90° XT | 130cm | | |
| 5309 | | | 150cm | | |

First Issued: **2018-09-26** Date: **2018-09-26** Expiry Date: **2023-09-25**

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# 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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# 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, Head of Compliance & Risk - Medical Devices

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

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



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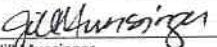
Certificate No: **MD 648016**

| Location | Registered Activities |
|---|---|
| Vascular Solutions LLC<br>6464 Sycamore Court North<br>Minneapolis<br>Minnesota<br>55369<br>USA | 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<br>14005 13th Avenue<br>Plymouth<br>Minnesota<br>55441<br>USA | Receiving, Kit Manufacturing (Vari-Lase), Final Inspection and Release, Warehousing/Distribution |
| Vascular Solutions LLC<br>6401 Sycamore Court North<br>Maple Grove<br>Minnesota<br>55369<br>USA | Sales, HR, Marketing, Finance |
| Vascular Solutions LLC<br>6420 Sycamore Lane North<br>Minneapolis<br>Minnesota<br>55369<br>USA | Catheter Component Manufacturing including extrusion, coils, snare loops, braiding, and laser processing |

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

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

## Declaration of Conformity

| | |
|---|---|
| **Manufacturer:** | Vascular Solutions LLC<br>6464 Sycamore Court North<br>Minneapolis, MN 55369 USA |
| **European Representative:** | Teleflex Medical<br>IDA Business and Technology Park<br>Dublin Road, Athlone<br>Co. Westmeath, Ireland |
| **Product Name:** | Twin-Pass V2 dual access catheter<br>Twin-Pass Torque dual access catheter |
| **Reference/Catalog Number:** | 5200, 5201 |
| **Generic Indication(s):** | 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.<br>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. |
| **Classification:** | Class III<br>Rule 6 |
| **GMDN Code** | 32151 – Peripheral/Coronary Vascular Infusion Catheter |
| **Conformity Assessment Route:** | Annex II of the EC-Directive (Council Directive 93/42/EEC of 14 June 1993) |
| **Declaration of Conformity:** | 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. |
| **Standards Applied:** | (see attached) |
| **Notified Body:** | BSI<br>Kitemark Court, Davey Avenue,<br>Knowlhill<br>Milton Keynes, MK5 8PP, UK<br>Notified Body Number: 0086 |
| **EC Certificate(s)** | ISO 13485:2003 and ISO 13485:2012 # 648016<br>EC Certificate #647900 |
| **Date CE Mark Affixed:** | June 13, 2013<br>Twin-Pass Torque: December 8, 2016 |
| **Place of Issuance:** | Vascular Solutions LLC<br>6464 Sycamore Court North<br>Minneapolis, MN 55369<br>USA |
| **Signature of Authorized Individual:** |  **Date of Issue:** November 26, 2018 |
| **Name (printed)** | Jill Munsinger |



RG2093
Rev. A

Standards Applied:

| Area | Standard |
|---|---|
| **Quality System** | **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. |
| **Biocompatibility** | **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 |
| | **EN ISO 10993-12:2012:** Biological evaluation of medical devices Part 12, Sample preparation and reference materials. |
| **Controlled Environments** | **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) |
| **Freedom from manufacturing residues** | **EN ISO 109937:2008/AC:2009:** Biological evaluation of medical devices -Part 7, Ethylene oxide sterilization residuals |
| **Sterilization and Pyrogenicity** | **EN ISO 11138-1:2017:** Sterilization of Health Care Products – Biological Indicators – Part 1, General requirements |
| | **EN ISO 11138-2:2017:** 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: 2002:** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" –Part 1, Requirements for terminally sterilized medical devices |
| **Packaging** | **EN ISO 116071:2009+A1:2014:** Packaging for terminally sterilized medical devices -Part 1, Requirements for materials, sterile barrier systems and packaging systems |
| **Labeling** | **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, labeling, and information to be supplied – Part 1, General Requirements |
| **Clinical** | **EN ISO 14155:2011:** Clinical investigation of medical devices for human subjects |
| **Product Specific** | **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 |
| | **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 |

REVISION HISTORY

| Rev | Reason |
|---|---|
| A | New release of design dossier |

# Declaration of Conformity

| | | | |
|---|---|---|---|
| **Manufacturer:** | Vascular Solutions, LLC.<br>6464 Sycamore Court North<br>Minneapolis, MN 55369<br>USA | | |
| **European Representative:** | Teleflex Medical<br>IDA Business and Technology Park<br>Dublin Road, Athlone | | |
| **Product Name:** | SuperCross microcatheter<br>SuperCross Flexible Tip microcatheter<br>SuperCross Angled Tip microcatheter | | |
| **Reference/Catalog Number:** | 5300, 5301<br>5340, 5341<br>5302, 5303, 5304, 5305, 5306, 5307, 5308, 5309 | | |
| **Generic Indication(s):** | 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. | | |
| **Classification:** | Class III, Rule 6 | | |
| **GMDN Code** | 17846 - Vascular guide-catheter, single-use | | |
| **Conformity Assessment Route:** | Annex II of the EC-Directive (Council Directive 93/42/EEC of 14 June 1993) | | |
| **Declaration of Conformity:** | 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. | | |
| **Standards Applied:** | (see attached) | | |
| **Notified Body:** | BSI<br>Kitemark Court, Davey Avenue,<br>Knowlhill<br>Milton Keynes, MK5 8PP, UK<br>Notified Body Number: 0086 | | |
| **EC Certificate(s)** | ISO 13485:2003 and ISO 13485:2012 # MD 648016<br>EC Certificate #CE 647900<br>DE Certificate # CE 678708 | | |
| **Date CE Mark Affixed:** | SuperCross microcatheter: September 14, 2010<br>SuperCross Flexible Tip microcatheter: July 30, 2012<br>SuperCross Angled Tip microcatheter: September 22, 2014 | | |
| **Place of Issuance:** | Vascular Solutions, Inc.<br>6464 Sycamore Court North<br>Minneapolis, MN 55369<br>USA | | |
| **Signature of Authorized Individual:** | Jill Munsinger | **Date of Issue:** 11/29/18 | November 29, 2018 |
| **Name/Title:** | Jill Munsinger, Sr. Director, Regulatory Affairs | | |



RG2098
Rev. A

**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: *in vitro* 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 |

REVISION HISTORY

| Rev | Reason |
|---|---|
| A | Initial Release of Class III DoC |
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