#### bsi



# EC Certificate - Full Quality Assurance System

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

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Issued To:

OrbusNeich Medical B.V. 3871 AN Hoevelaken Drs. W.van Royenstraat 5 The Netherlands CE 619995

drug-eluting coronary stents. Design, development, manufacture of sterile intravascular catheters, coronary stents and

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):

3/2

Medical Devices Stewart Brain, Head of Compliance & Risk -

First Issued: 2015-02-03

Date: 2018-04-18

Expiry Date: 2023-04-21

...making excellence a habit. Page 1 of 2

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# EC Certificate - Full Quality Assurance System

Supplementary Information to CE 619995

Issued To:

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

#### Product

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

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

2018-04-18

Issued To:

OrbusNeich Medical B.V.
Drs: W.van Royenstraat 53871 AN Hoevelaken
The Netherlands

Pharmaceutical Co., Ltd. Yuanzai Industrial Area Fujian Province, 350313 Chunghwa Chemical Synthesis & Biotech Co., Ltd Subcontractor: New Taipei City 23850 Fujian Kerui ,Tung-Hsing St. Service(s) supplied Crucial Supplier Crucial Supplier

Laserstrahl-Materialbearbeitungen

Manufacture

NJ 08540

Im Kirchenfelde 12-14

Hannover

D-31157 Sarstedt

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Page 1 of 4

### bsi.

## EC Certificate - Full Quality Assurance System By Royal Charter

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: 2018-04-18 CE 619995

Drs. W.van Royenstraat 5 OrbusNeich Medical B.V.

The Netherlands 3871 AN Hoevelaken Issued To:

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

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Page 2 of 4



# 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 2018-04-18

OrbusNeich Medical B.V. Drs. W.van Royenstraat 5

Issued To:

3871 AN Hoevelaken The Netherlands

E15 2ST United Kingdom Quality First International Suites 317 & 318 Burford Business Centre Subcontractor: 11 Burford Road Pantheon 1 Ssens B.V. London **EU Representative** Service(s) supplied Manufacture

Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit Rechain

**ETO Sterilization** 

The Netherlands 7521 PR Enschede

Avenue Andre Ernst 21

B-4800 Verviers

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Page 3 of 4

### bsi.



# 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: 2018-04-18 CE 619995

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

Issued To:

The Netherlands

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

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Page 4 of 4

### bsi



## EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 619995 2018-04-18

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

Issued To:

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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Validity of this castificate is circulateral on the coully system being resonance to the reduc-y-morphic activities of the restrict body. This approval exception in products disposed now homes on this configuration unless specificate a great of this state.

This certificate was sound deem outside and is noticed by the conditions of the specific caments of the Directive as demonstrated through the isothers for manufactured by a titled purity on bother of the company

redom and Cordan; BSI, Kitspank Cour. Carly Awards, Kriswillell, Addar (Kyrins 1925 art 1st. 4 at 185 (8) (8) Assurance for Libraria, position of in Engl. of incider number 78(882) or 780 (2)(6)(6) in the course Wards Wards Libraria

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## EC Certificate - Full Quality Assurance System Certificate History

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

The Netherlands

Date	Reference	Action
19 May 2017	8604338	Add ScoreFlex Coronary Dilatation Catheter, Sapphire NC Coronary Dilatation Catheter, Sapphire II NC Coronary Dilatation Catheter to 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, Venio.

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Where, if this explaints is conditional on the quarty system by a manched to the regimenrate of the blocking as dismansiated discount for explicit contains an abstract of the human and provided of the property contains in this contribute, unless specifically agreed with SSI.
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# EC Design-Examination Certificate

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

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Issued To:

OrbusNeich Medical B.V. Drs. W.van Royenstraat 5 3871 AN Hoevelaken CE 646780 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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Page 1 of 4

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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	617-104-1	617-154-1	617-204-1	620-104-1	620-154-1	620-204-1	622-104-1	622-154-1	622-204-1	625-104-1	625-154-1	625-204-1	627-104-1	627-154-1	627-204-1	
Balloon Diameter (mm)	1.75	1.75	1.75	2.0	2.0	2.0	2.25	2.25	2.25	2.5	2.5	2.5	2.75	2.75	2.75	30
Balloon Length (mm)	16	15	20	10	15	20	10	15	20	10	15 %	20	10	15	20	10

First Issued: 12 May 2016

Date: 31 January 2017

Expiry Date: 11 May 2021

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Page 2 of 4

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# EC Design-Examination Certificate

By Royal Charter

Supplementary Information to CE 646780

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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Page 3 of 4

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Information of Contain 20. Advisor Charl, Tary Annual Endedd Miller Annual Right for the 44 75 Can 900 US Assistant to the discovered England in the number 2000 to an 200 Greatest lags Cost, Lorent Wester to Amerika as 10 Early Officer 2000.

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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	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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Page 4 of 4

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This particular was bound informatically and is bound by the constitute of the constitute. estoriaes (2004 a.º 1851, Johansel Chart Charle Agente, Monadell, Mona Agente, 14,5 APP, 167 - 446 128, 180 9288 160 - 607 - 123 (1950), response de la reglació una el mandra 1905/201 de 266 (1960-65 legit 36-66), tradicio vel 446, tr 160 - 627 (1951) Agente de Companiente

# Certificate of Registration

By Royal Charter

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

Expiry Date: 2021-06-07 Effective Date: 2018-06-08

Page: 1 of 1



Original Registration Date: 2016-06-01

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This certificate was issued electronically and centuris the property of BSI and is bound by the contribute day in a contract day in a contribute can be authority also online.

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60 LOTERADO, Ators Attended Court Davidos Lo, Knowled, Mittal Court Anna Aca of the 852 Group of Consular is

DCN: 100181 EFF, DATE: 12/07/10 Page 1 of 3

DC-0021 Rev 02

DCN: 160042 EFF, DATE: 03/11/2016 Page 1 of 3

## **EC Declaration of Conformity**

## JADE PTA Balloon Dilatation Catheter

Product Name Classification Conformity Assessment

JADE PTA Balloon Dilatation Catheter Class IIa (MDD Annex IX) MDD 93/42/EEC, Annex II

Manufacturer:

Address:

EU Authorized Representative:

Name: Address:

Quality First International Limited

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

Burford Business Centre

11 Burford Roed Stratford, London E15 2ST United Kingdom

BSI Assurance UK Limited Kitemark Court, Davy Avenue Knowlhill, Milton Keynes, MKS 8PP,

Name: Address:

Notified Body:

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 loberitication Number, 0086. All products on the attached schedule meet the provisions of the abovennentioned 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.

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

Authorized Representative:

Signature:

Place & Date:

MARCH 14, 2016 TOTAL AMEN AS SUM BY STANFORD HEMPINE The McMent sons

ONFM-0008 Rev 01
Declaration of Conformity Form Template

DCN: 100181 EFF, DATE: 12/07/10 Page 2 of 3

DC-0021 Rev 02

DCN: 160042 EFF. DATE: 03/11/2016 Page 2 of 3

### Product Schedule:

560-015-41	555-080-41	555-040-41	555-020-41	550-120-41	550-080-41	550-040-41	550-020-41	550-015-41	545-120-41	545-080-41	545-040-41	545-020-41	540-120-41	540-080-41	540-040-41	540-020-41	540-015-41	535-120-41	535-080-41	535-049-41	535-020-41	530-120-41	530-080-41	530-040-41	530-020-41	530-015-41	525-120-41	525-080-41	525-040-41	525-020-41	520-120-41	520-080-41	520-040-41	520-020-41	520-015-41	515-120-41	515-080-41	515-040-41	515-020-41	515-015-41
6.0 mm	5.5 mm	5.5 mm	5.5 mm	5.0 mm	4.5 mm	4.5 mm	4.5 mm	4.5 mm	4.0 mm	3.5 mm	3.5 mm	3.5 mm	3.5 mm	3:0 mm	3.0 mm	3.0 mm	3.0 mm	3.0 mm	2.5 mm	2,5 mm	2.5 mm	25 mm	2,0 mm	2.0 mm	2.0 mm	2.0 mm	2.0 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm								
138101	oo mm		O mm	20 1111	430	4011111	Zollin	20 1011	120 110	The state of the s	40 IIII	10	120 mm	00 1	40 min	20 1181	30 10 10 10 10 10 10 10 10 10 10 10 10 10	1201881	aren oa	40 1181	mm 02	mm 025t	90 mm	40 mm	URB 07	15 mm	120 mm	ac min	anno de	20 mm	MIM OZI	SO INIII	40 mili	Phil 02	3	AS DOLLARS	in the control of the	4O II na	20 11111	mm-cr

ONFM-0006 Rev 01 Declaration of Conformity Form Tempiate

DC-0021 Rev 02

 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

DCN: 100781
EFF, DATE: 12007/10
Page 3 of 3
DCN: 160042
EFF, DATE: 13/11/2016
Page 3 of 3

ONFM-0006 Rev 01

Declaration of Conformity Form Template

DCN: 100181 EFF\_DATE\_1Z/07/10 Page 1 of 2

DC-0028 Rev 02

DCN: 160114 EFF, DATE: 05/26/16 Page 1 of 2

## **EC Declaration of Conformity**

## Scoreflex NC Coronary Dilatation Catheter

Product Name Classification Manufactures: Conformity Assessment

Scoreflex NC Coronary Dilatation Catheter Class III (MDD Annex IX) MDD 93/42/EEC, Annex II

Name: Address:

EU Authorized Representative:

Name: Address:

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

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

United Kingdom

Name: Address:

Notified Body:

Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, BSI Assurance UK Limited

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

Certificates:

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:

Signature:

Place & Date:

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ONFM-0006 Rev 01
Declaration of Conformity Form Template

DCN: 100181 EFF. DATE: 12/07/10 Page 2 of 2

DC-0028 Rev 02

DCN: 160114 EFF, DATE: 05/26/16 Page 2 of 2

Product Schedule:

Sco	Catalog Number	617-104-1	617-154-1	617-204-1	620-104-1	620-154-1	620-204-1	622-104-1	622-154-1	622-204-1	625-104-1	625-154-1	625-204-1	627-104-1	627-154-1	627-204-1	630-104-1	630-154-1	630-204-1	635-104-1	635-154-1	635-204-1	640-104-1		640-154-1
Scoreflex NC Coronary Dilatation Catheter	Balloon Diameter (num)	1.75	1.75	1.75	2.0	2.0	2.0	2.25	2.25	2.25	2.5	2.5	2.5	2.75	2.75	2.75	3.0	3.0	3.0	3.5	<u>ي</u> ن	<b>3.5</b> 1	4.0	4.0	
Catheter	Balloon Length (mm)	10	55	20	10	15	20	10	35	20	10	or or	20	16	i di	20	10	13	20	10	3	20	01	15	

ONFM-0006 Rev 01
Declaration of Conformity Form Template

DCN: 100181 EFF, DATE: 12/07/10 Page 1 of 4

DC-0020 Rev 02

DCN: 160042 EFF, DATE: 03/11/16 Page 1 of 4

EC Declaration of Conformity

Scoreflex PTA Balloon Dilatation Catheter

Product Name Classification Conformity Assessment

Scoreflex PTA Balloon Dilatation Catheter Class IIa (MDD Annéx IX) MDD 93/42/EEC, Annéx II

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

Name

Quality First International Limited

Suites 317-318

EU Authorized Representative:

Name: Address:

United Kingdom 11 Burford Road Stratford, London E15 2ST Burford Business Centre

BSI Assurance UK Limited Kitemark Court, Davy Avenue, Knowlhilf, Milton Keynes, MK5 8PP,

Name: Address:

United Kingdom

EC Certificate No.: CE 619995

General Applicable Directives

Certificates:

Notified Body:

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 61995s and delivered by Notified Body "BSI Assurance III. Imited", Notified Production 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

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

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Authorized Representative:

Signature:

Place & Date:

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ONFM-0008 Rev 01 Declaration of Conformity Form Template

DCN::100181 EFF. DATE: 12/07/10 Page 2 of 4

DCN: 160042 EFF, DATE: 03/11/16 Page 2 of 4

DC-0020 Rev 02

Product Schedule:

550F AOV 31	66UF-75K-31	655F-40X-31	655F-2UX-37	655F-15X-31	650F-40X-31	65UF-2UX-31	650F-75X-31	645F-40X-31	645F-20X-31	645F-15X-31	640F-40X-31	640F-20X-31	640F-15X-31	635F-40X-31	635F-20X-31	635F-15X-31	630F-40X-31	630F-20X-31	630F-15X-31	625F-40X-31	625F-20X-31	625F-15X-31	620F-40X-31	620F-20X-31	620E-15X-31	860F-40B-31	0007-3405-34	855F-2UB-31	000T-400-01	650F-208-31	645F-40B-31	645F-20B-31	640F-40B-31	640F-20B-31	635F-40B-31	635F-20B-31	630F-40B-31	630F-20B-31	625F-40B-31	625F-20B-31	620E-40B-31	620E-20B-31	660F-40A-31	SSOF-20A-31	650F-20A-31	650E-20A-31	640F-20A-31	Caminal Bounds
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ONFM-0006 Rev 01 Declaration of Conformity Form Template

DCN: 180181 EFF, DATE: 12/07/10 Page 3 of 4

DCN: 160042 EFF, DATE: 03/11/16 Page 3 of 4

DC-0020 Rev 02

Catalog Number	Balloon Diameter (mm)	Balloon Langth
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	ea En	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
840F-40N-31	4.0	40

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

DC-0020 Rev 02

DCN: 100181 EFF. DATE: 12/07/10 Page 4 of 4

DCN: 160042 EFF. DATE: 03/11/16 Page 4 of 4

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm
640E-40X-31	4.0	40
645E-15X-31	4.5	<b>5</b>
645E-20X-31	4.5	2
645E-40X-31	4.5	4
650E-15X-31	5.0	15
650E-20X-31	5.0	2
650E-40X-31	5.0	4
656E-15X-31	5.5	
665E-20X-31	5.5	250
855E-40X-31	5.5	40
860E-15X-31	6.0	iń.
660E-20X-31	6.0	20
	5	45

#### bsi



# EC Certificate - Full Quality Assurance System

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

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Issued To:

2400 Bernville Road (subsidiary of Teleflex, Incorporated) 19605 Pennsylvania Reading Arrow International, Inc. CE 511137

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):

3/2

Stewart Brain, Head of Compliance & Risk -Medical Devices

First Issued: 2006-10-18

Date: 2018-01-15

Expiry Date: 2021-10-17

\_making excellence a habit. Page 1 of 2

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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 aortic balloon pumps, angiographic catheters, balloon wedge pressure catheters, guidewires, Central Catheters (PICCs), thermodilution catheters, intra-aortic balloon catheters, intraabove product lines; and procedure packs incorporating the above product lines. sterile Vascular Positioning System (VPS) consoles, plus components and accessories for the technology, sterile single-use Vascular Positioning System (VPS) convenience kits and nonproducts, Percutaneous Thrombolytic Device (PTD), central catheters with Chlorag+ard (MAC), drainage catheters, Pneumothorax/ Thoracentesis products, arterial catheterization anesthesia products, mid-line/peripheral vascular access catheters, Multi-Access Catheters Introducers (PSI); non-coated CVC, PSI, hemodialysis catheters, Peripherally Inserted

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:

Date: Issued To: Certificate No: CE 511137 2018-01-15

2400 Bernville Road Arrow International, Inc. (subsidiary of Teleflex, Incorporated)

19605 Pennsylvania Reading

Subcontractor:

Service(s) supplied

Manufacture

Acme Monaco Corporation 75 Winchell Drive New Britain CT 06052

S.A. de C.V., Ave Washington 3701 Arrow Internacional de Chihuahua

Manufacture Packaging

Colonia Panamerica, Chihuahua Edificio 2

Chihuahua CP31200

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

Manufacture Packaging

Chihuahua

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Page 1 of 8

### bsi



# 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:

Issued To:

CE 511137 2018-01-15

(subsidiary of Teleflex, Incorporated)
2400 Bernville Road Arrow International, Inc.

Reading

Pennsylvania

**NSA** 19605

Subcontractor:

Service(s) supplied

Manufacture Packaging

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

Chihuahua CP31114 Chihuahua,

Arrow Internacional de Chihuahua S.A. de C.V. Mexico

Col. Complejo Industrial Avenida Washington 3701, Edificio 36 Las Américas

Chihuahua Chihuahua CP. 31114

Manufacture

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Page 2 of 8

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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:

Issued To: Certificate No: CE 511137 2018-01-15

Arrow International, Inc.

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

Subcontractor:

Manufacture Service(s) supplied

Arrow International CR, a.s. Jamska 2359/47 Czech Republic Zdar nad Sazavou

50004 Hradec Kralove Prazska 209 Arrow International CR, a.s.

Manufacture

Czech Republic

16 Elizabeth Drive Arrow International, Inc.

Manufacture

Massachusetts 01824

Arrow International, Inc. 312 Commerce Place

North Carolina 27203

ETO Sterilization Manufacture

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Page 3 of 8

### bsi



# 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:

Issued To:

CE 511137 2018-01-15

(subsidiary of Teleflex, Incorporated) Arrow International, Inc.

Reading 2400 Bernville Road

**NSA** 19605 Pennsylvania

Subcontractor:

Service(s) supplied

Ireland Parkmore West Business Park Galway Brivant Ltd Manufacture

Celestica Oregon LLC 18870 NE Riverside Parkway

Manufacture

Manufacture

EPflex Feinwerktechnik GmbH Im Schwöllbogen 24 72581 Dettingen/Erms

WI 53074 Port Washington

Custom Wire Technologies, Inc. 1123 Mineral Springs Drive

OR 97230 Portland

Manufacture

Germany

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Page 4 of 8



# 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 2018-01-15

Issued To:

(subsidiary of Teleflex, Incorporated) 2400 Bernville Road Arrow International, Inc.

Pennsylvania 19605 USA Reading

Subcontractor:

2220 Merritt Drive Galt Medical Corp

Manufacture

Service(s) supplied

TX 75041 USA Garland

Hudson Respiratory Care Tecate S. de R.L de C.V. (A Teleflex Medical Company) Prolongacion Mision Eusebio Kino No. 1316, Rancho El Descanso

Manufacture Packaging

21478 Tecate, B.C., C.P.,

\_ake Region Medical Ltd.

Manufacture

New Ross Co. Wexford Butlersland

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Page 5 of 8

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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

(subsidiary of Teleflex, Incorporated) Arrow International, Inc. 2018-01-15

2400 Bernville Road

Issued To:

Pennsylvania 19605 **USA** Reading

Subcontractor: Service(s) supplied

MN 55318 340 Lake Hazeltine Dr. Chaska Lake Region Medical MN 55447 Plymouth 2605 Fernbrook Lane- Suite J NeoMetrics Inc. Manufacture Manufacture

SFM Medical Devices GmbH Suddeutsche Feinmechanik GmbH Czech Republic Trabantska 292 SaFeMed spol.s.r.o. 19015 Praha 9/Satalice, Manufacture
Packaging
Sterilization Manufacture Packaging

Brückenstraße 5

63607 Wächtersbach

ASV

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Page 6 of 8



# 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:

Issued To: Certificate No: CE 511137 2018-01-15

Arrow International, Inc. (subsidiary of Teleflex, Incorporated) 2400 Bernville Road

19605 Reading Pennsylvania

Subcontractor:

Service(s) supplied

**ETO Sterilization** 

Sterigenics, Inc. 10821 Withers Cove Park Drive Charlotte

North Carolina 28278

**ETO Sterilization** 

Sterigenics 7775 South Quincy

ETO Sterilization

New Mexico 88008

Santa Teresa 2400 Airport Road Sterigenics

Illinois 60527 USA Willowbrook

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Page 7 of 8

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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:

Issued To:

CE 511137 2018-01-15

(subsidiary of Teleflex, Incorporated) Arrow International, Inc.

Pennsylvania Reading 2400 Bernville Road

**USA** 

19605

Subcontractor:

Service(s) supplied

Velka Bites Vysocina Prumyslova Zona Kosikov STERUS AST CZ s.r.o.

Czech Republic

**ETO Sterilization** Microbiology Service

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

Control of Sterilization
EU Representative
Manufacture

Regulatory Compliance

3015 Carrington Mill Boulevard

North Carolina 27560

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 511137 2018-01-15

Issued To:

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

ASU	19605
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Date	Reference Number	Action
18 October 2006		First Issue.
28 March 2007		Re-issue due to extension to scope, addition of manufacturing locations and an alternative subcontractor for sterilization.
18 May 2010	7522899	Re-issue due to clarify previously supplied information to the company's name at three locations and extend the scope to cover
		"Intra-Aortic Balloon Pumps."  Added Arrow at Jamska as a subcontractor.
		Removed Arrow International, Inc, Wyomissing Pennsylvania from
		the list of significant subcontractors.  Added Teleflex Medical as EU Representative to the list of
		significant subcontractors.

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## EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 511137 2018-01-15

Arrow International, Inc. (subsidiary of Teleflex, Incorporated)

2400 Bernville Road

Issued To:

Pennsylvania 19605 Reading

Date 29 September 2010	Reference Number 7572925	Action  Action  Action  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 Intern

(subsidiary)

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

19605 USA

Pennsylvania

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 Ortober 2016	8562443	Certificate Renewal. Corrected EBSTER s.r.o address.

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Page 3 of 4

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

Issued To:

CE 511137 2018-01-15

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

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.

...making excellence a habit." Page 4 of 4

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DC-T-BSI-008

hand Sheeth Introducers, Multi-Access Catheters (MAC) and Accessories	Manufacturer:  Arrow International, Inc. 2400 Benryille Road Reading, PA 19605 USA A
ters (MAC) and Accessories Trehnical He#:	European Representative: Taleflex Medical IDA Business and Technology Park Dublin Road Athlone, Co. Westmeath, Ireland

GMDN Code:	58865 Vascular catheter introduction kit	Classification Date CE Mark
PSI Finished Goods#	Device Description	First Affixed
♦ AD-09801	PSI: 8.5 Fr.	9-Mar-98
AD-09903	PSI: 9 Fr.	9-Mar-98
❖ AD-09903-S	PSI: 9 Ft.	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-0903-C	PSU 9 Fr.	23-Feb-07
S-20000 da	PSI: 9 Fr.	29-Jul-03
* CV 00501 SB	PSI: 8.5 Fr	23-May-00
CA-00886	PSI: 8.5 Fr.	23-May-03
* C1-09600	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	A-Mar-Ao
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
CI_07545	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 45 cm	25-Mar-98
CI07565	Super Arrow-Flex@ Cath Lab PSI: 5 Fr. x 65 cm	25-Mar-98
CI_07590	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 90 cm	25-Mar-98
CI-07611	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 11 cm	25-Mar-98
CI -07624	Super Arrow-Flex® Cath Lab PSI: 6 Ft. x 24 cm	25-Mar-98
CI .07635	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 35 cm	25-Mar-98
CI 107645	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 45 cm	25-Mar-98
CL-07045	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 65 cm	25-Mar-98
C1-07690	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
	Simer Arrow-Flex® Cath Lab PSE 7 Fr. x 11 cm	25-Mar-98

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REV. 07 The footer information below is for reference only

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Refer to Agile Page 1 of 8

RAGA-TOSS



## DECLARATION OF CONFORMITY

DC-T-BSI-008

	Cath Lab rate of the Villiam	CP-08603-P
25-Mar-98	Cash Lab PSI: 6 Fr., 11 cm	CP-08603
25-Mar-98	Cath Lab PSI: 5 Fr. x 11 cm	CP-08503-A
25-Mar-98	Cath Lab PSI: 5 Ff. x 7.5 cm	CP-08503
25-Mar-98	Cath Lab PSI: 4 Fr. x 7.5 cm	CP-08403
25-Mar-98	Super Arrow-Flex® Cath Lab PSI: 9 Fr. x 11 cm	CP-07911
25-Mar-98	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 11 cm	CP-07711
25-Mar-98	Singer Arrow-Flex® Cath Lab PSI: 7 Fr. x 11 cm	CP-07011-F
25-Mar-98	Super Arrow-Flex® Cath Lab PSI: 6 Fr. x 7.5 cm	CP-07611
25-Mar-98	Super Amour Flowin Coth Lab PSI: 6 Fr. x 11 cm	CP-0/511-P
25-Mar-98	Super Arrow-Flex® Cath Lab PSI: 5 Fr. x 7.5 cm	CP-07511
25-Mar-98	Super Arrow-Flow® Cath Lab PSI: 5 Fr. x 11 cm	CP-07011
25-Mar-98	Super Action Flavo Cath I sh PSI: 10 Fr x 11 cm	CL-71180
25-Mar-98	Super Arrow-Flexos Cath Lab PST-11 Fr x 80 cm	CL-71165
25-Mar-98	Cam cau Flex® Cat I at PSI: 11 Fr x 65 cm	CL-08903
25-Mar-98	Cath Lab Deli o Er w l l em	CL-08803
25-Mar-98	Cast tab DOI: 8 Fr v 1   rm	CL-08/05-HI
25-Mar-98	Ulich Flow Cath I ah PSI: 7 Fr. x 5 cm	CL-08703
25-Mar-98	Digitation Cam Law 1 cm	CL-08603-HJ
24-Jan-01	Cam Lag For or to x 5 cm	CL-08605
25-Mar-98	Cash Lab PSI: 6 Ft x 5 cm	CL-08603
25-Mar-98	Cam Lab Por 6 for a 11 cm	CL-08505
25-Mar-98	Call Lab Poli & Fr & Som	CL-08503-A
25-Mar-98	Carl Lab Col. S Fr v   1 mm	CL-08503
25-Mar-98	Cath Lab Pott 4 Fr. x 11 cm	◆ CL-08403-AE
17-Feb-06	Cath Lab PSI, 4 Fr. x 11 cm	CL-08403-A
26-May-98	Call Lab PSE 4 FE x 11 cm	CL-08403
25-Mar-98	Super Allow-Flexas Cattle Catt	CL-07980
25-Mar-98	Super Arrow-riexe Carl Lao x 51. 5 Fr x 80 cm	CL-07965
25-Mar-98	Super Allowations Community Delico Fr v 65 cm	CL-0/924
25-Mar-98	Super Arrow-Flex® Catt Lab PSI: 9 Fr. x 24 cm	CL-07911
25-Mar-98	Super Arrow-Piexe Cam Lao 191. 9 Fr y     cm	CL-07900
25-Mar-98	Super Alrow-Flexes Caut Late to Co of Fr v 100 cm	CL-07880
25-Mar-98	Super AlTow-Flexie Cau Lab Lab Lab Cat. A Co. Cau	CL-07865
25-Mar-98	Super Arrow-Fiex® Cath Lab PSE 8 Fr. x 65 cm	CL-07845
25-Mar-98	Super Arrow-Fiex® Cam Lab rol. o rl. a o viii.	CL-07835
25-Mar-98	Super Arrow-Flex® Cath Lab PSE of E. X 24 cm	CL-07824
25-Mar-98	Super Arrow-Flex® Cath Lab PSI: 8 Ff. x 11 cm	CL-07811
25 Mar-02	Super Arrow-Flex® Cath Lab PSI: 8 Fr. x 100 cm	CL-07800
22-Nov-20	Super Arrow Flex® PSI: 7 Fr. x 90 cm	CL-07790-R
22-MT-76	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 80 cm	CL-07780
06-TRIAI-C7	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 65 cm	CL-07765
25-Mar-90	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 45 cm	CL-07745
30 -refy >0	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 35 cm	CL-07735
06 -TRIMI-C7	Super Arrow-Flex® Cath Lab PSI: 7 Fr. x 24 cm	CL-07724
First Affixed	Device Description	PSI Finished Goods #



DC-T-BSI-008

GMDN Code:	58865 Vascular catheter introduction kit	Classification IIa
PSI Finished Goods #	Device Description	First Affixed
CP-08903	Cath Lab PSL: 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 Ft.	23-Jui-02 or 08-April-98
❖ IK-09600	PSI: 6 Fr.	3-Aug-03
♦ LU-09903	PSI: 9 Ft.	27-100 C0-mu-72
◆ 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	PSL 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-OE	PSU 8.5 Fr.	15-Dec-03
SI-09880-SB	PSI: 8.5 Fr.	17-Jun-02
S1-09880-SE	PSI: 8.5 Fr.	9-Mar-98
1	DCI- 0 Fr	10-Dec-97

RAGA-T065

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The toates information balow is for reference only

REV. 07 ISSUED: Refer to Agite PARENT DOC: RAQA-086

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ARROW INTERNATIONAL

PSI Finished Goods #

58865 Vascular catheter introduction kit

SS-09903-S SU-09903-C UB-09903-C UE-09800 UE-09800 UR-09800-LF WH-09800-T

Perie Description
PSI: 9 Fr.
PSI: 9 Fr.
PSI: 9 Fr.
PSI: 9 Fr.
PSI: 8.5 Fr.
PSI: 8.5 Fr.
PSI: 8.5 Fr.

Classification IIa
Date CE Mark
Einst Affixed
17-Oct-07
3-Apr-07
30-Oct-01
13-Feb-01
13-Feb-02
19-Dec-97

## **DECLARATION OF CONFORMITY**

DC-T-BSI-008

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



DC-T-BSI-008

Device Description.   10	NA	Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop	Z-09800-008
Sheath Ext Assy w/Dilator: 9 Fr 11B Sheath Ext Assy w/Dilator: 9 Fr 11B Sheath Ext Assy w/Dilator: 9 Fr 12B Sheath Ext Assy w/Dilator: 9 Fr 13C Sheath Ext Assy w/Dilator: 7 Fr 13C Sheath Ext Assy w/Dilator: 7 Fr 13C Sheath Ext Assy w/Dilator: 8.5 Fr 13C Sheath Ext Assy w/Dilator: 8.5 Fr 13C Sheath Ext Assy w/Dilator: 9 Fr 13C Sheath Ext Assy w/Dilator: 5 Fr 13C Sheath Ext Assy w/Dilator: 7 Fr 13C Sheath Ext Assy w/Dilator: 6 Fr 13C Sheath Ext Assy w/Dilator: 6 Fr 13C Sheath Ext Assy w/Dilator: 5 Fr	NA	Sheath Ext Assy w/Dilator: 9 Fr	W-08903-005C
Sheath Ext Assy w/Dilator: 9 Fr 11B Sheath Ext Assy w/Dilator: 9 Fr 11B Sheath Ext Assy w/Dilator: 9 Fr 11C Sheath Ext Assy w/Dilator: 7 Fr 13A Sheath Ext Assy w/Dilator: 7 Fr 13B Sheath Ext Assy w/Dilator: 8.5 Fr 13B Sheath Ext Assy w/Dilator: 8.5 Fr 13B Sheath Ext Assy w/Dilator: 8.5 Fr 13C Sheath Ext Assy w/Dilator: 1 Fr 13D Sheath Ext Assy w/Dilator: 9 Fr 13D Sheath Ext Assy w/Dilator: 7 Fr 13D Sheath Ext Assy w/Dilator: 7 Fr 13D Sheath Ext Assy w/Dilator: 7 Fr 13D Sheath Ext Assy w/Dilator: 8 Fr 13D Sheath Ext Assy w/Dilator: 5 Fr	N/A	Sheath Ext Assy w/Dilator: 8 Fr	W-08803-014C
Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 8.5fr Hydrop Sheath Ext Assy w/Dilator: 8.5fr Hydrop Sheath Ext Assy w/Dilator: 10 Fr Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop Off Sheath Ext Assy w/Dil Comm: 9 Fr Off Sheath Ext Assy w/Dilator: 5 Fr Off Sheath Ext Assy w/Dilator: 7 Fr Off Sheath Ext Assy w/Dilator: 7 Fr Off Sheath Ext Assy w/Dilator: 7 Fr Off Sheath Ext Assy w/Dilator: 5 Fr	NIA	Sheath Ext Assy w/Dilator: / Fr	W-08703-006C
Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 8.5 Fr Sheath Ext Assy w/Dilator: 8.5 Fr Sheath Ext Assy w/Dilator: 8.5 Fr Sheath Ext Assy w/Dilator: 9 Fr O07 Sheath Ext Assy w/Dilator: 9 Fr O01 Sheath Ext Assy w/Dil Comm: 9 Fr O01 Sheath Ext Assy w/Dil Comm: 9 Fr O01 Sheath Ext Assy w/Dilator: 5 Fr O01 Sheath Ext Assy w/Dilator: 7 Fr O01 Sheath Ext Assy w/Dilator: 7 Fr O01 Sheath Ext Assy w/Dilator: 7 Fr O01 Sheath Ext Assy w/Dilator: 5 Fr O02 Sheath Ext Assy w/Dilator: 5 Fr O04 Sheath Ext Assy w/Dilator: 5 Fr O05 Sheath Ext Assy w/Dilator: 5 Fr	N/A	Sheath Ext Assy w/Dilator: 6 Fr	W-08613-004C
Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 11 Fr Sheath Ext Assy w/Dilator: 11 Fr Sheath Ext Assy w/Dilator: 9 Fr Old Sheath Ext Assy w/Dilator: 7 Fr Old Sheath Ext Assy w/Dilator: 5 Fr Sheath Ext Assy w/Dilator: 5 Fr Sheath Ext Assy w/Dilator: 5 Fr Old Sheath Ext Assy w/Dilator: 5 Fr Old Sheath Ext Assy w/Dilator: 5 Fr	WA NA	Sheath Ext Assy w/Dilator: 6 Fr	W-08603-005D
Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 8.5 Fr Sheath Ext Assy w/Dilator: 8.5 Fr Sheath Ext Assy w/Dilator: 11 Fr Sheath Ext Assy w/Dilator: 11 Fr Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 9 Fr Off Sheath Ext Assy w/Dilator: 7 Fr Off Sheath Ext Assy w/Dilator: 6 Fr Off Sheath Ext Assy w/Dilator: 6 Fr Off Sheath Ext Assy w/Dilator: 6 Fr Off Sheath Ext Assy w/Dilator: 5 Fr	NA	Sheath Ext Assy w/Dilator; 5 Fr	W-08513-004B
Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dil Comm: 8.5 ft Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  O1  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O1  Sheath Ext Assy w/Dilator: 5 Fr  O1  Sheath Ext Assy w/Dilator: 5 Fr  O1  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O12  Sheath Ext Assy w/Dilator: 5 Fr  O12  Sheath Ext Assy w/Dilator: 5 Fr  O12  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  O14  Sheath Ext Assy w/Dilator: 5 Fr  O15  Sheath Ext Assy w/Dilator: 5 Fr  O16  Sheath Ext Assy w/Dilator: 5 Fr  O17  Sheath Ext Assy w/Dilator: 5 Fr  O18  Sheath Ext Assy w/Dilator: 5 Fr  O19  O19  Sheath Ext Assy w/Dilator: 5 Fr  O10  Sheath Ext Assy w/Dilator: 5 Fr	NA	Sheath Ext Assy w/Dilator: 5 Fr	W-08503-005C
Sheath Ext Assy w/Dilator: 9 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 7 Fr Sheath Ext Assy w/Dilator: 8.5 fr Hydrop Sheath Ext Assy w/Dilator: 8.5 fr Hydrop Sheath Ext Assy w/Dilator: 10 Fr Sheath Ext Assy w/Dilator: 9 Fr Off Sheath Ext Assy w/Dilator: 5 Fr Off Sheath Ext Assy w/Dilator: 7 Fr Off Sheath Ext Assy w/Dilator: 5 Fr Off Sheath Ext Assy w/Dilator: 4 Fr Off Sheath Ext Assy w/Dilator: 4 Fr	NA	Sheath Ext Assy w/Dilator: 5 Ft	W-08503-004B
July  Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  On  Sheath Ext Assy w/Dilator: 9 Fr  On  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 6 Fr  Sheath Ext Assy w/Dilator: 5 Fr	NA	Sheath Ext Assy w/Dilator: 4 Fr	W-08413-014
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 11 Fr  Sheath Ext Assy w/Dilator: 11 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Old Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Old Sheath Ext Assy w/Dilator: 7 Fr  Old Sheath Ext Assy w/Dilator: 8 Fr  Old Sheath Ext Assy w/Dilator: 6 Fr  Sheath Ext Assy w/Dilator: 6 Fr  Sheath Ext Assy w/Dilator: 5 Fr	N/A	Sheath Ext Assy w/Stopc-Dil Comm:4 Fr	W-08403-014
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  On  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8 Fr  Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 4 Fr	W-08403-012D
July  Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5fr Hydrop  Sheath Ext Assy w/Dilator: 8.5fr Hydrop  Sheath Ext Assy w/Dilator: 11 Fr  Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Old  Sheath Ext Assy w/Dilator: 7 Fr  Old  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8 Fr  Sheath Ext Assy w/Dilator: 8 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 5 F	T-45509-013A
July  Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  One  Sheath Ext Assy w/Dilator: 9 Fr  One  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  On  Sheath Ext Assy w/Dilator: 5 Fr  On  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  On  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 6 Fr	N/A	Sheath Ext Assy w/Dilator: 6 Fr	T-45509-010A
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 1 Fr  Sheath Ext Assy w/Dilator: 1 Fr  Sheath Ext Assy w/Dilator: 1 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr  Sheath Ext Assy w/Dilator: 7 Fr	N/A	Sheath Ext Assy w/Dilator: 8 Fr	T-07860-001
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dil Comm: 8.5 ff Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Stope-Dil Comm: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr	N/A	Sheath Ext Assy w/Dilator: 6 Fr	T-01000-033A
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dil Comm: 8.5 ft Hydrop  Sheath Ext Assy w/Dil Comm: 8.5 ft Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 ft Hydrophi  Sheath Ext Assy w/Dil Comm: 9 ft Hydrophi  Sheath Ext Assy w/Dil Comm: 9 ft Hydrophi  Sheath Ext Assy w/Dilator: 5 Fr  Old Sheath Ext Assy w/Dilator: 5 Fr	N/A	Sheath Ext Assy w/Dilator: 7 Fr	R-07790-001
Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  One Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 5 Fr	NA	Sheath Ext Assy w/Dilator: 7 F	R-07745-007
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 17 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.1 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dil Comm: 8.5ft Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Stope-Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 7 F	R-07745-001A
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dil Comm: 8.5ft Hydrop  Sheath Ext Assy w/Dilator: 9 Fr  Old Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Stope-Dil Comm: 9 Fr  Sheath Ext Assy w/Stope-Dil Comm: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 6 Fr	R-07645-001
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dil Comm: 8.5 ft Hydrop  Sheath Ext Assy w/Dil Comm: 8.5 ft Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Stope-Dil Comm: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 5 Fr	P-07511-001
July  Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 fr Hydrop  Sheath Ext Assy w/Dil Comm: 8.5 fr Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  O01  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dilotor: 9 Fr	N/A	Sheath Ext Assy w/Dil Comm: 9fr Hydrophi	LF-09903-017
ik) Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 11 Fr  Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop  Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr  Sheath Ext Assy w/Dil Comm: 9 Fr	N/A	Sheath Ext Assy W/Stope-Dil Comm:9 Fr	LF-09903-009
Jik)         Device Description           11B         Sheath Ext Assy w/Dilator: 9 Fr           11B         Sheath Ext Assy w/Dilator: 9 Fr           11C         Sheath Ext Assy w/Dilator: 9 Fr           11B         Sheath Ext Assy w/Dilator: 7 Fr           13A         Sheath Ext Assy w/Dilator: 7 Fr           13A         Sheath Ext Assy w/Dilator: 8.5 Fr           12         Sheath Ext Assy w/Dilator: 11 Fr           13         Sheath Ext Assy w/Dilator: 9 Fr           12         Sheath Ext Assy w/Dilator: 9 Fr           13         Sheath Ext Assy w/Dilator: 9 Fr           14         Sheath Ext Assy w/Dilator: 9 Fr           15         Sheath Ext Assy w/Dilator: 9 Fr           1007         Sheath Ext Assy w/Dilator: 9 Fr           101         Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dil Comm: 9fr Hydrophi	LF-09903-008
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr	NA	Sheath Ext Assy w/Stopc-Dil Comm:9 Fr	LF-09875-001
Device Description	N/A	Sheath Ext Assy W/Dilator: 9 Fr	LF-09804-007
is)  Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr  IIB Sheath Ext Assy w/Dilator: 9 Fr  IIC Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 11 Fr  Sheath Ext Assy w/Dilator: 8.5 fr Hydrop  Sheath Ext Assy w/Dilator: 8.5 fr Hydrop	N/A	Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop	LF-09803-009
ik) Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.1 Fr  Sheath Ext Assy w/Dilator: 11 Fr	N/A	Sheath Ext Assy w/Dil Comm: 8.5fr Hydrop	LF-09803-006
July Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr  Sheath Ext Assy w/Dilator: 8.5 Fr	NA	Sheath Ext Assy w/Dilator: 11 Fr	L-71180-001
Device Description  Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 7 Fr	LZ-09807-002	Sheath Ext Assy w/Dilator: 8.5 Fr	109807-002
Ile)  Device Description  IlB Sheath Ext Assy w/Dilator: 9 Fr  IlB Sheath Ext Assy w/Dilator: 9 Fr  ICC Sheath Ext Assy w/Dilator: 9 Fr  ICC Sheath Ext Assy w/Dilator: 9 Fr  Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 7 Fr	L-08705-003A
le)  Device Description  B Sheath Ext Assy w/Dilator: 9 Fr  B Sheath Ext Assy w/Dilator: 9 Fr  C Sheath Ext Assy w/Dilator: 9 Fr	N/A	Sheath Ext Assy w/Dilator: 9 Fr	L-07980-001B
Device Description    Device Description	N/A	Sheath Ext Assy w/Dilator: 9 Fr	1-07965-001C
Device Description  Sheath Ext Assy w/Dilator: 9 Fr	NA	Sheath Ext Assy w/Dilator: 9 Fr	L-07924-001B
Device Description	N/A	Sheath Ext Assy w/Dilator: 9 Fr	L-07911-001B
	(if applicable)	Device Description	PSI Part#

THE REAL PROPERTY.	MASOS - Instrument quard, single-use	Classification: I
Cath-Gard Finished Good		Date CE Mark First
AJ-08803	Cath-Gard Catheter Contamination Shield for use with Interventional Products - Percuraneous Sheath Introducers	22-May-1998
SA-09847	Sheath Adapter w/Cath-Gard	17-Oct-02
	Cath-Gard Catheter Contamination Shield with Tuohy-Borst Adapter on Proximal End for use with 7 and 7.5 Fr. Catheters and 22-May-1998 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 22-May-1998 with 7.5 and 8 fr. Catheters	22-May-1998

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## DECLARATION OF CONFORMITY

DC-T-BSI-008

CMIN Code	16505 - Instrument guard, single-use	Classification:
nished Good		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	22-May-1998
	Systems	
ST-09885	rwistLock(TM) Cath-Gard(R) Catheter Contamination Shield for use with 8.0 - 8.5 Fr, Catheters	01-Feb-2000
	Cath-Gard® Catheter Contamination Shield for use with 4 and 5 Fr 1-Mar-14	21-Mar-14
FD-00001-S1	Catheters and Arrow Percutaneous Sheath Introducer Systems	

Cath-Gard Part #	Device Description	(if applicable)
A-09880-001	CATH-GARD: 7-7.5 FR X80CM W/T-B ADAPTER	N/A
A1_08803-002		N/A
B001-0010-001		N/A
I-09800-004A	X X 80 CM WITH TWISTLOCK(TM)	N/A
I-09880-001A		N/A
1-09885-001	RD: 8.5 FR X 80 CM WITH TWISTLOCK(IM)	NA
P-00001-002	CATH-GARD: 5-6 FR X80CM W/T-B ADAPTER	NA
P-09806-003	Cath-Gard Catheter Contamination Shield: 80 cm with Tuony- Borst Adapter	N/A
P-09806-014	CATH-GARD: 7-7.5 FR X80CM W/T-B ADAPTER - Packaged	NA
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(1M) ADAPTER - Packaged	N/A
ST-09875-001	CATH-GARD: 7.5 FR X 80 CM WITH TWISTLOCK(1M) ADAPTER - Packaged	N/A
ST-09880-004	CATH-GARD: 7-7.5 FR X80CM	NA
ST-09880-005	CATH-GARD: 7-7.5 FR X80CM - Packaged	NA
ST-09885-001	CATH-GARD: 8.5 FR X 80 CM WITH TWISTLOCK(TM) ADAPTER - Packaged	N/A
V600-00800-T	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(1M) ADAPTER	N/A

GMDN Code:	58865 Vascular catheter introduction kit	Classification   11a
Trauma Finished	Device Description	Affixed Affixed
Goods Product #	No. of the last of	17_lines 1998
E1-04060	Peripheral Emergency Infusion Device - EID' "	1/-Julic-1770
10000	Emergency Inflision Device - EIDEM	17-June-1998
E1-04050	Lilling School assessment of the second	200C man 1 PC
RC-05801	Trauma Kit	74-JIIIC-2002
RC-09700	RIC® Rapid Infusion Catheter Exchange Set	10-June-1990

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DC-T-BSI-008

16-June-1998	RJC® Rapid Infusion Catheter Exchange Set	RC-09850
Affixed Mark First	Device Description	Trauma Finished Goods Product #
Classification   IIa	58865 Vascular catheter introduction kit	GMDN Code:

Trauma Part# (if applicable)	Czech Device Description (frapp	Czech Part# (if applicable)
1-04060-001	Sheath: 6 Fr. x 1-1/2" (3.81 cm) Radiopaque with Dilator over 20 N/A	
	Ga TW Needle	
I-04080-017B	8.5 Fr. x 3-1/2" (8.9 cm) ArrowFlex(R) Radiopaque FEP N/A	
	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	
S-09850-001A	Sheath: 8.5 Fr. x 3-1/2" (8.89 cm) Arrow-Flex(R) Radiopaque FEPIN/A	
	with Tissue Dilator	
C-09700-001	Sheath: 7 Fr. x 2" (5.08 cm) Arrow-Flex(R) Radiopaque N/A	
	Polyurethane with Tissue Dilator	
C-09850-001A	Sheath: 8.5 Fr. x 2-1/2" (6.4 cm) Arrow-Flex(R) Radiopaque FEP N/A	
	with Tissue Dilator	

GMDN Code:	58865 Vascular catheter introduction kit	Classification — • IIIa
d Good#		Date CE Mark First
CA-11142	MACTM Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	22-June-2001
❖ CH-11242-ISB	MACTM Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 7.5 Fr Catheters	30-May-2017
❖ DM-11142-TS	MACTM Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve for use with 8 – 8.5 Fr. Catheters	12-Dcember-2006
* NL-11142-AMP	MACTM 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	gral [arg	02-DEC-2015
SI-11142	MACTM 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 <sup>TM</sup> Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	21-May-2003
ST-11242	MACTM Two-Lumen Central Venous Access Set with Integral Hemostasis Valve for use with 7 - 8 Fr. Catheters	19-February-2002

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

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

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## DECLARATION OF CONFORMITY

DC-T-BSI-008

Arrow International, Inc. hereby declares that the above documented product(s) meets the provisions of the Medical Device Directive, EC COUNCIL DIRECTIVE 93/42/EEC. This declaration is made on the basis of the following Annex II certificates (EC Design Examination and Quality System), issued by The British Standards Institute, with Notfied Body number 6086. 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/IEEC. CERTIFICATE NUMBERS:

Amex II.3 Certificate(s)

Amex II.4 Certificate (Class III products only)

NIA

Amex V Certificate (Class I Sterile/Measuring Function products only) Other NA

Quality Assurance Representative (Print and Sign)	Kathleen Whanger Kitheleen (Lihonge	Regulatory Affairs Representative (Francand Sign)	ARROW INTERNATIONAL, INC., Reading, PA USA Krista Hugh & Obc High Mush
O Date	tiorizoge was	Date	250ct2017

### REVISION HISTORY:

12 2	11 2	10	9 2	8 2	7 2	6 18	5	4.	3 11	2 17	1 21	0 .	Rev Level
25-Oct-2017	21-Sep-2017	1-Jun-2017	28-Feb-2017	25-Jan-2016	21-Dec-2015	18-Dec-2015	18-Mar-2015	28-Feb-2014	11-Jun-2012	17-Feb-2012	21-Dec-2011	04-Nov-2010	Date
Added DR-09875-HZO1 per ECR-032009. Updated product description for code BU-	Added DE-09600-UNH per ECR-031362	Added CH-11242-ISB per ECR-030828.	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.	Updated GMDN codes	Added AT-09875-E per ECR-026737/ECO-037472	Added NL-11142-MUMC per ECR-026233/ECO-036641.	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	Added component part numbers to support the Procedure Fast Initiative, Acade (VML)-N code, Added NL-09801-MCIMC per ECR 018256, Removed DE-09803-HZO per ECR-ECR-161026, Per ECR-019142 removed KZ-09601, KZ-09701-001, KZ-09701-005, KZ-09800-001, KZ-09808-004, KZ-09880-003, KZ-09880-004, LFZ-09803-001, LFZ-09803-004, LFZ-09803-005, LFZ-09803-006, WZ-08403-001, WZ-08513-001, WZ-08603-001, and WZ-08703-001.	Added DE-09875-HZO to Declaration per ECR-015641. Update DUC with GMDIN.	Added GR-08403 per ECR-014519.	Added DE-09803-HZO to Declaration per ECR-014307.	Original issue of DCT-BSI-008 in new DC format – Replaces DC-BSI-018 for revision history of previous DOC. AddedGR-08503-A, GR-08503, and GR-08703 per ECR-011057, ECR-011058, and ECR-011016 respectively. Removed the following obsolete Finished Goods: BB-09903-NA, KK-09903-C, SI-09908-E.	Description

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DC-T-BSI-015

Ç	ing. PA	2400 Bernville Road	Arrow International Inc.	Manufacturer:
Athlone, Co. Westmeath, Ireland	Dublin Rd.	IDA Business and Technology Park	Teleflex Medical	European Representative:

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

:Classification: lla

GMDN Code:	10689 Arterial blood pressure catheter	Classification:
Arterial Finished Good	Device Description	Date CE Mark First Affixed
A A 16611-6	ACCESS TRAY	11/19/03
AD-04018	ARTERIAL LINE SET	04/12/07
1	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
- 1	ARTERIAL CATH KIT: 18 GA X	01/06/00
ml.	ARTERIAL CATH, SET: 18GA x 12.7CM	04/12/07
_	ARTERIAL CATH KIT: 18GA X 12.7CM	01/16/01
- 15	ARTERIAL CATH SET: 18 GA X 5	04/12/07
◆ DE-00820-BAB	ARTERIAL SET: 20 GA X 8 CM	05/30/17
	ARTERIAL CATH, SET: 20 GA x 8CM	10/28/09
•	ARTERIAL CATH, KIT: 20 GA x 8CM	02/21/11
ы.	Arterial Cath, Set: 20 Ga X 8cm	08/29/13
	Arterial Cath. Set: 20 Ga X 8cm	01/04/17
	Arterial Cath. Set: 20 Ga X 8cm	01/04/17
125	ARTERIAL CATH, KIT: 20 GA X 8 CM	04/06/17
	ARTERIAL CATH, SET: 20 GA X 8CM	3/27/14
*	Arterial Cath, Set: 20 Ga X 8cm	01/04/17
	Arterial Cath. Set: 20 Ga X 8cm	05/12/17
	ARTERIAL CATH, KIT: 18 GA x 16CM	02/11/11
37	ARTERIAL CATH, KIT: 18 GA x 16CM	7107/21/60
×	ARTERIAL CATH. KIT: 18 GA X 16 CM	04/06/17
	ARTERIAL CATH, SET: 18GA x 16CM	01/00/10
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
* NONZNO-00818	ARTERIAL CATH SET: 18GA x 8CM	04/11/07

## DECLARATION OF CONFORMITY

DC-T-BSI-015

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ARTERIAL CATH KIT: 20GA X 8CM	ARTERIAL CATH SET: 18GA X 23CM	ARTERIAL CATH SET: 20GA X 16CM	ARTERIAL CATH. SET: 18 GA X 16CM	ARTERIAL CATH SET: 22GA X 12CM	ARTERIAL CATH SET: 20GA X 12CM	ARTERIAL CATH SET: 18GA X 12CM	ARTERIAL CATH SET: 22GA X 8CM	ARTERIAL CATH. SET: 20 GA X 8CM	ARTERIAL CATH SET: 18 GA X 8CM	ARTERIAL CATH. SET: 24 GA X 5CM	ARTERIAL CATH. SET: 22 GA X 5CM	ARTERIAL CATH SET: 20GA X 5CM	ARTERIAL CATH, SET: 24 GA X 2.5CM	ARTERIAL CATH SET: 18GA X 23CM	ARTERIAL CATH SET: 20GA X 16CM	ARTERIAL CATH SET: 18GA X 16CM	ARTERIAL CATH SET: 22GA X 12CM	ARTERIAL CATH SET: 20GA X 12CM	ARTERIAL CATH SET: 18GA X 12CM	ARTERIAL CATH SET: 22GA X 8CM	ARTERIAL CATH SET: 20GA X 8CM	ARTERIAL CATH SET: 18 GA X 8CM	ARTERIAL CATH SET: 24GA X 5CM	ARTERIAL CATH SET: 22GA X 5CM	ARTERIAL CATH SET: 20GA X 5CM	ARTERIAL CATH SET: 24GA X 3CM	ARTERIAL CATH. KIT: GA x CM	Arterial Catheterization Kit	RA CATH SET: 20 GA X 1-1/2	RA CATH SET: 20 GA X 1-1/2	RA CATH SET: 22 GA X 1-3/8	RA CATH SET: 20 GA X 1-1/2	RA CATH SET: 22 GA X 1-3/4" (4.45 CM)	RA CATH SET: 20 GA X 1-3/4	RA CATH SET: 18 GA X 1-3/4	RA CATH SET: 22 GA x 4.45 CM	ARTERIAL CATH. KIT: 18 GA X 16 CM	ANTENIAL CALL OF THE OWN TO COL	CATH CET: 18 GA X 16 CM
03/03/14	12/01/2010	12/01/2016	0102/10/21	9102/10/21	0102/10/21	9102/10/21	0107/10/21	0.107/110/71	12/01/2016	9107/10/71	0107/10/71	010Z/10Z	12/01/2016	01/08/04	CO/91/E0	03/16/05	03/16/05	03/16/05	12/20/04	03/15/05	11/20/08	01/08/04	11/20/08	07/03/04	01/08/04	11/11/08	06/06/06	11/21/2013	04/01/04	11/11/04	10/12/04	11/11/04	07/31/06	10/12/04	50/61/90	03/14/02	91//7/50	Commit	6107/01/01

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(If applicable)	. 14 Ga	Later Co.	PARENT DOC: RAGA-098	De la Contra de la	
. 14 Ga	. 14 Ga		is for reference only	The footer information below	
14 Ga	. 14 Ga		ntial*	*Confide	
THE RESERVE OF THE PARTY OF THE		1447	S Ga ATW Needle	14 Ga X 6" (16 Cm) Cath/1	A-04014-015
Of and ited life) Device Description	Arterial Lai La (If applicable)	N/A	C W. Madla	The state of the s	(II alphicus)
	Arrerial Fail Le	(It of butterente)	(100 ) 日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日	Device Descrip	GC applicable)

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N/A	Catheter S-L: 18 Ga X 6-1/2" (16 Cm) Hydrophilic	PC-01618-001
N/A	Catheter S-L: 20 Ga X 5" (12 Cm) Hydrophilic	100-00010-001
N/N.	Catheter S-L: 18 Ga X 5" (12 Cm) Hydrophilic	PC-01218-001
NIA	Catheter S-L: 22 Ga X 3-1/4" (8 Cm) Hydrophilic	PC-00822-001
NA	Catheter S-L: 20 Ga X 3-1/4" (8 Cm) Hydrophilic	PC-00820-001
NIA	Catheter S-L: 18 Ga X 3-1/4" (8 Cm) Hydrophilic	PC-00818-001
NIA	Catheter S-L: 22 Ga X 2" (5 Cm) Hydrophilic	PC-00522-001
NA	Catheter: S-L 20 Ga X 2" (5 Cm) Hydrophilic	PC-00520-001
NA	Catheterization Dev: 20 Ga Radial Artery	P-04020-007
VIN	20ga X 1-3/4" Cath/22ga Ndi W/Coating	P-04020-005A
PCZ-02318-001	CATHETER S-L: 18 GA X 23 CM HYDROPHILIC	N/A
PCZ-01620-001	CATHETER S-L: 20 GA X 16 CM HYDROPHILIC	N/A
PCZ-01681-001	Catheter S-L: 18 Ga X 16 Cm Hydrophilic	AIN
PCZ-01222-001	CATHETER S-L: 22 GA X 12 CM HYDROPHILIC	N/A
PCZ-01220-001	CATHETER S-L: 20 GA X 12 CM HYDROPHILIC	N/A
PCZ-01218-001	CATHETER S-L: 18 GA X 12 CM HYDROPHILIC	N/N
PCZ-00820-001	Catheter S-L: 20 Ga X 8 Cm Hydrophilic	N/A
PCZ-00024-001	Catheter S-L: 24 Ga X 5 Cm Hydrophilic	NA
PCZ-00324-001	Catheter S-L: 24 Ga X 2,5 Cm Hydrophilic	NA
PCZ-008ZZ-001	CATHETER S-L: 22 GA X 8 CM HYDROPHILIC	N/A
PCZ-00818-001	CATHETER S-L: 18 GA X 8 CM HYDROPHILIC	N/A
PCZ-003ZZ-001	CATHETER S-L: 22 GA X 5 CM HYDROPHILIC	AIN
PCZ-00520-001	CATHETER S-L: 20 GA X 5 CM HYDROPHILIC	N/A
PZ-01218-003	Catheter S-L: 18 Ga X 12 Cm Hydrophilic	N/A
PZ-01218-002	Catheter S-L: 18 Ga X 12 Cm Hydrophilic	N/A
PZ-00820-002	Catheter S-L: 20 Ga X 8 Cm Hydrophilic	N/N
PZ-00818-002	Catheter S-L: 18 Ga X 8 Cm Hydrophilic	N/A
N/A	Sheath Ext Assy W/Dilator: 5 Fr	K-15511-001
NA	22 Ga X 4.45 Cm Cath /25 Ga Ndl Comm	K-14402-003
N/A	Catheterization Dev: 20 Ga Radial Artery	K-04220-003A
NA	Catheter S-L Comm: 24 Ga X 4 Cm	K-04124-001
NA	Catheter S-L Conun: 18 Ga X 12.7 Cm	K-04018-001B
NIA	Catheter/Insert Tube: 20 Ga X 8"	H-04150-004
HZ-04125-001	Catheter S-L: 20 Ga X 3-1/16"	H-04125-001
N/A	Catheter S-L: 20 Ga X 3-1/16"	H-04120-005
N/A	Catheter/Insert Tube: 20 Ga X 2-1/2"	H-04120-003B
NA	Catheterization Dev: 20 Ga Radial Artery	A-04220-009b
N/A	Catheter S-L: 22 Ga X 1-3/8"	A-04122-010
N/A	16ga X 7" Cath/19ga Ndl	A-04016-015
N/A	Catheterization Dev: 20 Ga Radial Artery	A-04220-009b
N/A	22GA X 1-3/8" CATH/23GA NDL W/COATING	A-04122-012
N/A	Catheter S-L: 22 Ga X 1-3/8"	A-04122-010
NA	22ga X 1-3/8" Cath/23ga Ndl W/Coating	A-04122-003b
N/A	20ga X 1-1/2" Cath/22ga Ndl W/Coating	A-04120-015
AZ-04022-001	22ga X 1-3/4" Cath/25ga Ndl	A-04022-001
N/A	20ga X 4-1/4" Cath/22ga Ndl	A-04020-011A
N/A	18ga X 4-1/4" Cath/20ga Ndl	A-04018-009
NIA	18ga X 1-3/4" Cath/20ga Ndl	A-04018-001
NIV	I6ga X 7" Cath/19ga Ndi	A-04016-015

## DECLARATION OF CONFORMITY

DC-T-BSI-015

ROPHILIC PCZ-01020-002	CATHETER S.J.: 18 GA X Z3 CM HYDROFHLAC	
	COUNTRY OF THE PARTY OF THE PAR	
	CATHETER S.I. 20 GA X 16 CM HYDROPHILIC	
	CATHETER S-L: 18 OA X 16 CM HYDROPHILIC	
	CATHETER S-L: 22 GA X 12 CM HYDROPHILLO	
	CATHETER S-L: 20 OA A 12 OM HIDNOTHERS	
PCZ-01220-002	CATEBLER OF 10 OF A 12 OF HALL	
ROPHILIC   PCZ-01218-002	CALIFORNIA TO CA VIO CM HYDROPHILIC	
OPHILIC PCZ-00822-002	CATHETER S.I.: 22 GA X 8 CM HYDROPHILIC	
	CATHETER S-L: 20 GA X 8 CM HYDROPHILIC	
	CATHETER S-L: 18 GA X 8 CM HYDROPHILLO	
	CATHETER S-L: 24 GA X 5 CM HYDROPHILIC	
	CATHETER O-P. 27 OB CO. ST. PRODUCTION	
OPHILIC PCZ-00522-002	CONTROL OF THE OWNER	
OPHILIC PCZ-00320-002	CATHERTER S.I.: 20 GA X 5 CM HYDROPHILIC	
1	CATHETER S-L: 24 GA X 2,5 CM HYDROPHILE	
) 11) di Optioni 1007,00004,000	Calleter 3-L: 18 Ga A 3-17- (23 cm) Lijeropinion	PC-02318-001
N/A N/A	Camour our so our our free free free free free free free fr	PC-01020-001
) Hydrophilic N/A	Catheter S.I : 20 Ga X 6-1/2" (16 Cm) Hydrophilic	100 001

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 Medical Devices (EC Design Examination and Quality System), issued by The British Standards Institute, with Notified Body number 0986. This declaration authorizes Arrow International, Inc. to affix the CE-Marking with Notified Body number 0986. CERTIFICATE NUMBERS: to the products listed herein. Medical Device Directive: COUNCIL DIRECTIVE 93/42/BBC Annex 11.4 Certificate (Class II products only) N/A

Annex V Certificate (Class I Sterile/Measuring Function products only) Annex II.3 Certificate(s) DIRECTIVES AND STANDARDS: CE 611137, ISO 13485; FM 512674 AIN

Matt Winton
Senior Manager Quality Assurance or Designee (Print and Sign) Regulatory Management or Designee (Print and Sign)

LIGHT THE THE

13/20 C017

REVISION HISTORY:

Rev	Date	Description
Leyel	0.555	Compositive for Arterio
0	10 Nov-2009	Original issue (Created Deciaration of Contourney on Assessment Contourney DC-BSY-024, DC-BSI-045, and DC-BSI-046).
_	07 Jan- 2010	Addition of DE-01618-ZB.
2	7- Mar-2011	Addition of new SAC kit: DE-80820-RB
w	22-Jun-2011	Declaration of Conformity updated to new format. Administration of Conformity updated to new format.  kits: AA-10607-1, AA-10611-1, AA-10624-1
4	1-Sep-2011	Addition of new TransRadial Artery Acess kits AA-1940-1, AX-1020-7 and AX-1040-15 Added GMDN Codes, Added GH-04120, GH-04120-1, GH-04120-1, GH-04122, GH-04124, GH-04124, GH-04125 and GH-04150 back to DC, they were erroucously removed from the DC from Rev 0 to Rev 1.

\*Confidential\*

BACA-TOGO

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		DECLARATION OF CONFORMITY
	DC-T-BSI-015	~
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19	18	17	16	15	14	13	12	11,	10	9	∞	7	9	S	Rev Level
22-Sep-2017	1-Jun-2017	07-Apr-2017	17-Feb-2017	01-Dec-2016	10-Oct-2016	27-May-2016	29-Feb-16	19-Oct-2015	1-Apr-2014	10-Mar-2014	29-Aug-2013	4-Sep-2012	20-Dec-2011	22-Nov-2011	Date
Added DE-01618-OLD per ECR-031771	Added DE-00820-BAB per ECR-030971	Added DE-00820-VB and DE-01618-VB as per ECR-030402	Removed procedure pack # under the product name section as it is not applicable.	Added PCZ-00324-002, PCZ-00520-002, PCZ-00520-002, PCZ-00524-002, PCZ-00818-002, PCZ-00820-002, PCZ-00822-002, PCZ-01618-002, PCZ-01622-002, PCZ-01622-002, PCZ-01622-002, PCZ-01622-002, PCZ-01622-002, PCZ-01618-PBX, SAC-01618-PBX, SAC-016218-PBX, SAC-01618-PBX, SAC-016218-PBX, SAC-01620-PBX, SAC-01620-PBX	Added NL-01618-CZE and NL-00520-CZE per ECR-028596	Added NL-00820-ZUY and NL-01618-ZUY per ECR-02/939	Moved Transradial to new technical file T-BSI-058 and products to DC-1-BSI-058. Added NI_00520-MUMC per ECR-027174/ECO-038149	Updated components to include A-04122-012 used in KA-04122, updated tomain code code and separated finished goods and components by GMDN codes.	Update format to indicate market specific codes. Added DE-00820-WKKH per ECK-021126.	Added TI-0820-IR per ECR-016488, Removed KZ-04120-001, KZ-04018-001, KZ-04018-001, KZ-04018-001, KZ-04018-001, KZ-04018-001, KZ-04018-001, KZ-016402-008 per ECR-019142. Based on previous EASK trage added PCZ-0520-001, PCZ-0522-001, PCZ-0818-001, PCZ-0822-001, PCZ-01218-001, PCZ-0120-001, PCZ-01218-001, PCZ-02188-001, PCZ-0822-001, PCZ-01218-001, PCZ-02188-001, PCZ-01218-001, PCZ	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.	Added new finished goods AA-10411-1, AA-1054-1, AA-2051-1-3, AA-2067-1, AA-2067-1, AA-20507-1, AA-20507-1, AA-20507-1, AA-2067-1, AA-30407-1, AA-30411-1, AA-30411-1, AA-30511-1, AA-30511-1, AA-30524-1, AA-30507-1, AA-30624-1 per ECR-016326.	Added finished good AA-10607-ID.	Addition of new finished good DE-01618-HZO per ECR-0138/2. This product is EASN 101 Germany.	Description

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

ennsylvania Reading 2400 Bernville Road (subsidiary of Teleflex, Incorporated) Arrow International, Inc.

19605

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:

Expiry Date: 2019-02-28 Effective Date: 2016-10-31 Carlos Pitanga, SVP, System Certification and Compliance

Page: 1 of 5

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





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Certificate No:

By Royal Charter

### 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

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.

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

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

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

Page: 2 of 5

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Certificate No: FM 512674

Location

(subsidiary of Teleflex, Incorporated)

2400 Bernville Road Arrow International, Inc.

Registered Activities

of the following catheters: intravascular, anesthesia, hemodialysis, abdominal, thoracic and pleural drainage, atherectomy, electrophysiology/pacing, themodialytion, atherectomy, electrophysiology/pacing, themodialytion. manufacturing operations for design, production and distribution of medical devices in anesthesia, surgery, cholangiography, embolectomy, vascular positioning system (VPS) stylets, consoles and accessories, plus components and urology, respiratory and gastrointestinal. wedge pressure, intra-aortic balloon, angiography, Design, development, manufacture, servicing and distribution accessories for the above product lines. Contract

19605 Pennsylvania Reading

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

Manufacture and distribution of intravascular catheters,

Prazska 209 Arrow International CR, a.s.

50004

Czech Republic

Hradec Kralove

North Carolina 27203 USA

312 Commerce Place Asheboro Arrow International, Inc.

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 CVDR regulatory clearance at distribution sites (traceability). Contract manufacturing for the above product lines. operations of ligating clips, plus components and accessories

intravascular catheters, anesthesia catheters, hemodialysis catheters, thermodilution catheters, intrautine catheterization catheters, intra-aordic 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. Design, development, manufacture and distribution of

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

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

Page: 3 of 5

This certificate remains the property of BSI and shall be noturned intends an electronic contribute that be authenticated political. Printed copies and in To be read in any junction with the scrape above at the utilished dispersion CODES CAN DE VERGERES EL PARANTES PRODUCTOR MESTA EL LA PARANTES EN PARANTES DE LA PARANTES DE L

erad Hanties 65 Goupe Andrea Inc. 1897/1 Workspale Drivo, Sone 650, nerinom, VA 70170-6007-054 ord, the 181 Grapper Comporties

Certificate No: FM 512674

Location	Registered Activities
Arrow Internacional de Chihuahua de	Manufacture and distribution of intravascular catheters,
S.A. de C.V.	percutaneous sheath introducers, spring wire guides, and
Ave. Washington 3701	packaging and distribution of anesthesia catheters, and
Alta Tecnología, Edificio 40	related components and accessories for the above product
Col. Panamericana	lines and packing and distribution of anesthesia catheters,
Chihuahua	hemodialysis catheters.
CP 31200	
MEXICO	Manufacture and distribution of intravascular catheters,
ALIOM THE HECONE OF CHILDRICE  S.A. de C.V.	abdominal, thoracic and pleural drainage catheters,
Ave. Washington 3701	percuraneous stiedul illu oducers, spring wire geneer, com-
Edificio 2	lines and packing and distribution of anesthesia catheters,
Col. Panamericana	hemodialysis catheters.
Chihuahua	
Mexico	
Arrow International CR, a.s.	Design, development, manufacture and distribution of intravacoular catheters, anesthesia catheters, hemodialysis
Jamska 2359/47	catheters, thermodilution catheters, intra-aortic balloon
Zdar Nad Sazavou	catheters, percutaneous sheath introducers, spring wire
Czech Republic	shows product lines. Contract manufacturing operations for
	design, production and distribution of medical devices in anesthesia, surgery, urology, respiratory and gastrointestinal
Arrow International, Inc.	Manufacturing material warehouse and distribution process
Berks Corporate Center	activities
760 Corporate	
Building #7	
Reading	
Pennsylvania	
19605	
Arrow International, Inc. (subsidiary of Teleflex, Incorporated)	Design, development, manufacture and distribution or Declectrophysiology / pacing, thermodilution, angiography and electrophysiology / pacing, thermodilution, angiography and electrophysiology / pacing, thermodilution and pumps;
16 Elizabeth Drive	and components and accessories for these product lines.
Massachusetts	aorticballoon pumps.

Latest Revision Date: 2018-01-08 Original Registration Date: 2006-12-19 01824 USA

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

Page: 4 of 5

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Certificate No: FM 512674

Location

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

Registered Activities

Manufacture and distribution of Intravascular catheters, 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 dearance at distribution sites. Plus components and accessories for the above product lines.

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

Colonia Complejo Industrial Las Americas Chihuahua CP 31114 Mexico

Arrow Internacional de Chihuahua S.A. de C.V. Avenida Washington # 3701 Edificio 36

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

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

Page: 5 of 5

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An electronic certificate can be automated <u>online</u>. Finited copies can be valvelted at symbolignoup constitution for the need in the statement of the respiration on the statement appeadus.

Americas Headquerteis: 853 Carous Amerika Inc., 12959 Wolldgate Onve. Koro XXX, Herm. n. VA. 36170-6607 USA. A Member of the 353 Carous Amerika

#### bsi



# EC Certificate - Full Quality Assurance System

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

ĕ.

Issued To:

6464 Sycamore Court North CE 647900 Minneapolis Vascular Solutions LLC

55369

Minnesota

In respect of:

Peripheral Use, Fluid Delivery Kits, Surgical Laser Procedure Kits, Intravascular Catheters Used for Diagnostic, Angiographic, Embolic Delivery and/or Embolectomy, Support and Design, Development, and Manufacturing of Guidewires, Hemostatic and Embolic Agents for 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):

h

Stewart Brain, Head of Compliance & Risk -

First Issued: 2016-06-10

Date: 2018-07-06

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Validity of this confliction is conditional on the surrealisation activities of the Notified Body. The control of this confliction in the surrealisation of the surrealisation o A STANDARD OF THE PROPERTY OF A STANDARD OF THE CONTROL OF THE PROPERTY OF THE

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### <u>bsi</u>



# 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

Issued To:

2018-07-06 6464 Sycamore Court North Vascular Solutions LLC

Minnesota Minneapolis

55369 USA

Subcontractor:

Service(s) supplied

Manufacture

Biomerics LLC 2560 Fletcher Lane, Suite 300

Rogers MN 55374

6550 Wedgwood Road North Suite 300 Cartika Medical, Inc.

Manufacture

Maple Grove

55311 Minnesota

아io E-Beam Services, Inc. 2775 Henkle Drive Lebanon

E Beam Sterilization

Expiry Date: 2022-07-01

Page 1 of 1

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Page 1 of 7



# 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:

Issued To: Certificate No: 2018-07-06 CE 647900

Vascular Solutions LLC 6464 Sycamore Court North 55369 Minnesota Minneapolis

Subcontractor:

Lafayette

Manufacture

Harland Medical Systems 7418 Washington Ave S Eden Prairie MN 55344 USA

Service(s) supplied

E Beam Sterilization

E-Beam Services, Inc. 3400 Union Street

Indiana 47905 USA

Galt Medical Corp 2220 Merritt Drive Garland, TX 75041

Manufacture

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Page 2 of 7

#### bsi



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:

Issued To:

CE 647900 2018-07-06

Minneapolis 6464 Sycamore Court North Vascular Solutions LLC

**NSA** 55369 Minnesota

Service(s) supplied

Subcontractor: Harmac Medical Products IDA Business Park Manufacture

Ireland Roscommon Castlerea

Minneapolis MN 55433 Isomedix Operations, Inc. 380 90th Avenue NW

**ETO Sterilization** 

340 Lake Hazeltine Drive Lake Region Medical

Minnesota 55318 Chaska

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 2018-07-06

6464 Sycamore Court North Vascular Solutions LLC

Issued To:

55369 Minnesota Minneapolis

Subcontractor:

1600 West Merit Parkway South Jordan UT 84095 Merit Medical Systems, Inc.

Merit Medical Systems, Inc. 14646 Kirby Drive

Texas 77047

High Road Phillips-Medisize Ireland

Service(s) supplied

Manufacture

Manufacture

Manufacture

Letterkenny Co. Donegal Ireland

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Page 4 of 7

### bsi.



# 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 2018-07-06

Vascular Solutions LLC 6464 Sycamore Court North

Issued To:

55369 USA Minneapolis Minnesota

Service(s) supplied

Manufacture

Subcontractor:

Polymicro Technologies a Subsidiary of Molex 18019 N. 25th Ave.

AZ 85023 Phoenix

Oregon 97062 USA Precision Wire Components 10230 SW Spokane Court Tualatin

Manufacture

Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527

ETO Sterilization

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Page 5 of 7



# 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 2018-07-06

Vascular Solutions LLC

Issued To:

Minnesota 55369 USA Minneapolis 6464 Sycamore Court North Service(s) supplied

Subcontractor:

Synergy Health Westport Ltd Lodge Road

**Gamma Sterilization** 

Westport County Mayo Ireland

Teleflex Medical IDA Business and Technology Park **Dublin Road** 

**EU Representative** 

Co. Westmeath Athlone

Vascular Solutions LLC 14005 13th Avenue

Manufacture

Plymouth Minnesota

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Page 6 of 7

#### bsi.

## EC Certificate - Full Quality Assurance System By Royal Charter

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 2018-07-06

Vascular Solutions LLC 6464 Sycamore Court North

Issued To:

Minneapolis Minnesota 55369 USA

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cular Solutions LLC	Regulatory Compliance	
ole Grove Inesota		
)69 A		
xcular Solutions LLC 20 Sycamore Lane North meapolis mesota	Manufacture	
369		

Vasc 640. Map Minn S53 USA Vasc 642 Vasc 642 Vasc 642 Vasc 053

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Certificate No:

Issued To:

CE 647900

Certificate History

2018-07-06

Vascular Solutions LLC 6464 Sycamore Court North Minneapolis Minnesota 55369

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."  Change of multiple subcontractor names from "Vascular Solutions, Inc." to "Vascular Solutions LLC."  Change EU Representative to Teleflex Medical (Ireland).  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.

Issued To:

CE 678707

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):

In sta

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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Page 1 of 3

Validated this conflicted is conditional to the parally system being maintained to the requirements of the Directive as demonstrated through the required accordance the Notifice bear.

This certificate was asked declarated and in Count in the complians of the Contract.

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### bsi.

## EC Design-Examination Certificate



Supplementary Information to CE 678707

Issued To:

Vascular Solutions LLC 64,64 Sycamore Court North Minneapolis Minnesota 55369

USA

## Twin-Pass Dual Access Catheters

Catalog Number   Device Name 5200   Twin-Pass Dual
5201

...ma

Expiry Date: 2023-09-25

Date: 2018-09-26

First Issued: 2018-09-26

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Page 2 of 3

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Supplementary Information to CE 678707

Issued To:

Vascular Solutions LLC 6464 Sycamore Court North Minneapolis Minnesota 55369 USA

## **Certificate History**

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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Page 3 of 3

Validity of this conditional on the quality system being maintained to the requirements of the cheather as demonstrated through the required surveillance are vides of the Neetfeet Budy. This continuous assued electronizaty and is bound by the conditions of the contract.

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# EC Design-Examination Certificate

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



No.

Issued To:

CE 678708
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis
Minnesota
55369

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):

In stan

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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Page 1 of 3

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## To Josian Examination of



## EC Design-Examination Certificate

Supplementary Information to CE 678708

Issued To:

Vascular Solutions LLC 6464 Sycamore Court North Minneapolis Minnesota 55369 USA

SuperCross Microcatheters

5309	5308	5307	5306	5305	5304	5303	5302	5341	5340	5301	5300	Model Number	
	93					SuperCross SuperCross FT							
2	1X 605	17.0	1200	Č	മറം	1	450	110000	flexible	or original	Straight	Distal Tip	
150cm	130cm	150cm	130cm	150cm	130cm	150cm	130cm	150cm	130cm	150cm	130cm	Working Length	
agents.	subselectively infuse/deliver	interventional devices and to	placement and other	lilay be used to lacilitate	penpheral vasculature: It	the colonary and/or	access discrete regions of	steerable guidewires to	be used in conjunction with	microcatheter is intended to	The SuperCross	Intended purpose per IFU	
*					H				THE COURT OF THE PERSON NAMED IN	THE STATE OF THE S		Classification	

Date: 2018-09-26 Expiry Date: 2023-09-25

First Issued: 2018-09-26

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Page 2 of 3

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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

Current	Date
8780397	Reference Number
First issue.	
	Action

First Issued: 2018-09-26

Date: 2018-09-26

Expiry Date: 2023-09-25

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Page 3 of 3

Waiding of this cardificits is cardificial on the quality system being maintained to the requirements of the Directive as denunstrated through the required surveiting a cardificial of the testing first recommendation of the testing first recommendation of the contract.

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

liter smallin mit Corbog 1931, Kibenava Courf, Dacy Awatuer Kinnelfall, Petron Keynes Kfg, 959 febr. 44, 495 (93) 48(b) 951 Assurance Un-literbed, registerer of England in the number 79073(2) to 350 (Cilisade k Hoch Kond, condon 994 43). HK A remoter of 651 (Schoop of Chimichan)

# 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 53369 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.

55369

In sia

For and on behalf of BSI:

Effortion Date: 2017 07 16

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

Page: 1 of 2

on Date: 2018-08-23

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This certificate was bound electroments and remains the property of SSI and is braind by the conditions of unitract, an electronic confidence of the entire conditions of unitract.

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Certificate No: MD 648016

By Royal Charter

55441 55369 Vascular Solutions LLC 6401 Sycamore Court North ASU Plymouth Vascular Solutions LLC 14005 13th Avenue NSN 55369 Minnesota 6464 Sycamore Court North 6420 Sycamore Lane North Maple Grove Minnesota Minneapolis Location Minnesota Minneapolis Vascular Solutions LLC Minnesota Vascular Solutions LLC Receiving, Kit Manufacturing (Vari-Lase), Final Inspection and Release, Warehousing/Distribution snare loops, braiding, and laser processing Sales, HR, Marketing, Finance Devices and Retrieval Devices. Design, Development, and Manufacturing of Guidewires, Vascualir and Topical Hemostasis Devices, Embolectomy Catheters, Intravascular Catheters, Vascular Access Devices, Vascular Introducer Kits, Fluid Delivery Kits, Embolization Registered Activities Catheter Component Manufacturing including extrusion, coils,

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

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

Page: 2 of 2

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Ostronom and Covenit 250, Kromius – ur. Savy Švenius Krominā, Mitra Noykos 1945 (949 Tg.) + 44 345 (949 900) O Apou aro LIK Limbol, rejultorio miligrafo suodai murbai 180522) i ki sol Chavada Agrikada, Kojepa Wi-44, jul Memby ol 196 (35) (1900) ol Kromius i

## Declaration of Conformity

Date of legie:	USA	Minneapolis, MN 55369	Place of Issuance: Vascular Solutions and		Date CE Mark Affixed: June 13, 2013	EC Certificate #647900	EC Certificate(s) ISO 13485:2003 and ISO 13485:2012 # 648016	Notified Body Number: 0086	Milton Keynes, MK5 8PP, UK	Knowlhill	Kitemark Court, Davey Avenue,	Notified Body: BSI	Standards Applied: (see attached)			ation of	Route:	Conformity, According to the FC-Directive (Council Directive 93/42/EEC of 14 June 1993)	Classification: Class III	ne win-Pass torque catheter is interined to access unsurer exposition in a peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.	to subselectively infuse/deliver diagnostic or therapeutic agents.	devices, and for use during two guidewire procedures. The Twin-Pass catheter is also used	guidewires in order to access discrete regions of the coronary and peripheral arterial .	Generic Indication(s): The Twin-Pass catheters are intended to be used in conjunction with steerable	Reference/Catalog 5200, 5201	Product Name: Twin-Pass V2 dual access catheter	Co. Westmeath, Ireland	Representative: IDA Business and Technology Park	European Teleflex Medical	Minneapolis, MN 55369 USA	6464 Sycamore Court North
November 25, 2018														3, concerning medical devices	ccordance with Annex II of the	cts, specified on this Declarati		of 14 June 1993)		nent and exchange of guidewi	agents.	e Twin-Pass catheter is also us	nary and peripheral arterial wires and other intervention	nction with steerable							

RG2093 Rev. A

	g	Area Quality System	Standard  Standard  EN ISO 13485:2012/AC:2012: Medical Devices -Quality management systems - Requirements for regulatory purposes.  EN ISO 14071-2012: Medical Devices - Application of risk management to medical devices.
			EN ISO 109931:2009/AC:2010: Biological evaluation of medical devices—Part 1, Guidance on selection of tests
			EN SO 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—
		in a salinity	vitro methods
2	₹   a   .	siocompationity	EN ISO 10993-10:2010: Biological evaluation of medical devices -
a n	er and an		skin sensitization
ž,	etc.		EN ISO 10993-11:2009: Biological evaluation of medical devices-
<u>g</u>	ξ, add .		toxicity
£	ffc na :		EN ISO 10993-12:2012: Biological evaluation of medical devices
E a .	ffc and c		reference materials.
<u>g</u>	₹     a   1		The local transfer of the property and associated controlled e
g .	fic a		EN ISO 14644-1: 2015: Cleanrooms and associated controlled e
<u>s</u>	₹ a	ontrolled	Of Sit Cleaniness by particle concentration
£ .	gr.	nylronments	EN ISO 14644-2: 2015: Cleanrooms and associated controlled e
a n	etc.		(ISO 14644-2:2015)
icity ng	icity	Freedom from manufacturing	EN ISO 109937:2008/AC:2009: Biological evaluation of medical sterilization residuals
			EN ISO 11138-1:2017: Sterilization of Health Care Products – Bio requirements
			EN ISO 11138-2:2017: Sterilization of health care products - Bio
			Biological indicators for ethylene oxide sterilization processes
		Sterilization and	EN ISO 11135:2014: Sterilization of health care products - Ethyle
chic	cffic	Duraganicity	development, validation and routine control of a sterilization pro
ng ng	ng 3	ryiogenicity	EN ISO 11737-1:2006: Sterilization of Medical Devices - Microbic
ng 3	ng 3		Determination of a population of microorganisms on assembly
ng g	ng 3		EN ISO 11737-2:2009: Sterilization of Medical Devices - Microbi
ng g	ng 3		sterility performed in the definition, validation and maintenance
ng g	ng 3		EN 556-1: 2002: Sterilization of medical devices. Requirements
ng g	ng 3		designated "STERILE" —Part 1, Requirements for terminally steri
ng g	ng g		EN ISO 116071:2009+A1:2014: Packaging for terminally steriliz
t Specific	z Specific	Packaging	Requirements for materials, sterile barrier systems and package
t Specific	t Specific	Labeling	EN 1041: 2013: Specification for information supplied by the m
t Specific	t Specific	raccing	EN ISO 15223-1:2016: Medical devices—Symbols to be used v
t Specific	t Specific		and information to be supplied - Part 1, General Requiremen
t Specific	t Specific	Clinical	EN ISO 14155:2011: Clinical investigation of medical devices for
TT		Cilina	EN ISO 10555-1:2013: Sterile, single-use intravascular catheter
1 1			EN ISO 62366: 2009: Medical devices-Application of usability en
-1			ISO 594-1:1986: Conical fittings with a 6% (Luer) taper for syring
ISO 594-2:1998: Conical fittings with a 6% (Luer) taper for syring	ISO 594-2:1998: Conical fittings with a 6% (Luer) taper for syring medical equipment—Part 2, Lock fittings		medical equipment—Part 1, General requirements
	medical equipment—Part 2, Lock fittings	Product Specific	ISO 594-2:1998: Conical fittings with a 6% (Luer) taper for syring

ION HISTORY

RG2093 Rev. A

RG2098 Rev. A

## Declaration of Conformity

	Signature of Authorized Individual:	Place of Issuance: Vasc 6464 Minr USA	Date CE Mark Sup- Affixed: Sup- Sup-	EC Certificate(s) ISO EC (		Standards Applied: (see		GMDN Code 1784 Conformity Ann Assessment Route:	Classification; Clas	tion(s):	Number: 5300		European Tele Representative: IDA Dubl	NSU
fi Munsinger, Sr. Director, Regulatory Affairs	hillywarizer	Vascular Solutions, Inc. 6464 Sycamore Court North Minneapolis, MN 55369 USA	SuperCross microcatheter: September 14, 2010 SuperCross Flexible Tip microcatheter: July 30, 2012 SuperCross Angled Tip microcatheter: September 22, 2014	ISO 13485:2003 and ISO 13485:2012 # MD 648016 EC Certificate #CE 647900 DE Certificate # CE 678708	BSI Kitemark Court, Davey Avenue, Knowlhill Milton Keynes, MK5 8PP, UK Notified Body Number: 0086	(see attached)	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 REC – Directive, the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.	17846 - Vascular guide-catheter, single-use Annex II of the EC-Directive (Council Directive 93/42/EEC of 14 Juno 1993)	Class III, Rule 6	The Super-Cross 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.	5340, 5341 5340, 5341 5302, 5303, 5304, 5305, 5306, 5307, 5308, 5309	SuperCross microcatheter SuperCross Flexible Tip microcatheter SuperCross Angled Tip microcatheter	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone	USA
Affairs	1 29/18		, 2010 uly 30, 2012 eptember 22, 2014	MD 648016			E marked products, specified one required documentation in a cil Directive 93/42/EEC of 14	se irective 93/42/EEC of 14 Juno		to be used in conjunction with the coronary and/or peripheral that coronary and/or peripheral that coronary and/or peripheral that coronary and other coronary and ot	8, 5309		11 (11 (1) (1) (1) (1) (1) (1) (1) (1) (	
******	November 29, 2018						n this ccordance with June 1993,	1993)		h steerable vasculature. It eer ed therapeutic				

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### Standards Applied:

RG2098 Rev. A

Number	Title
EN ISO 13485:2012	Medical Devices - Quality management systems - Requirements for regulatory nurroses
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	Slerilization 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

RG2098 Rev. A