

# EC Design-Examination Certificate

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

**No.****CE 669193****Issued To:**

**Smiths Medical ASD Inc.  
6000 Nathan Lane North  
Minneapolis  
Minnesota  
55442  
USA**

In respect of:

**See certificate scope page.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-07-20**

Date: **2020-08-17**

Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Certificate No: CE 669193

## Certificate Scope:

1. PORT-A-CATH II Epidural Low Profile Polysulfone / Titanium
2. PORT-A-CATH II Intraspinal Low Profile Polysulfone / Titanium
3. PORT-A-CATH Titanium Venous Access
4. PORT-A-CATH Low Profile Titanium Venous Access
5. PORT-A-CATH P.A.S. PORT T2 Titanium Venous Access
6. PORT-A-CATH II Low Profile Polysulfone / Titanium Venous Access
7. PORT-A-CATH II Polysulfone / Titanium Venous Access
8. ProPort Low Profile Plastic Venous Access
9. ProPort Plastic Venous Access
10. P.A.S Port T2 Power P.A.C. Titanium Venous Access
11. PORT-A-CATH POWER P.A.C. Low Profile Titanium Venous Access
12. PORT-A-CATH POWER P.A.C. Titanium Venous Access
13. PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone / Titanium Venous Access
14. PORT-A-CATH II POWER P.A.C. Low Profile Pre-assembled Polysulfone / Titanium Venous Access
15. PORT-A-CATH II POWER P.A.C. Polysulfone / Titanium Venous Access
16. PORT-A-CATH II POWER P.A.C. Pre-assembled Polysulfone / Titanium Venous Access
17. PORT-A-CATH P.A.S. PORT Elite Acetal Homopolymer / Titanium Venous Access
18. PORT-A-CATH II Dual-Lumen Low Profile Polysulfone / Titanium Venous Access
19. PORT-A-CATH II POWER P.A.C. Dual-Lumen Low Profile Polysulfone / Titanium Venous Access

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| Port-A-Cath II Low Profile, Intraspinal and Epidural                                                                                                                                                                                                                                                                 |                                                                                       |                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Indications for Use per IFU</b><br>The systems are intended for long-term, continuous access to the intraspinal space for the delivery of drugs approved for intraspinal delivery. The labelling for the drug governs the indications, contraindications, dosages, and warnings related to the use of medication. |                                                                                       |                                               |
| <b>Classification</b><br>Class III Implant                                                                                                                                                                                                                                                                           |                                                                                       |                                               |
| Port-A-Cath II Low Profile, Intraspinal Catalog Numbers                                                                                                                                                                                                                                                              |                                                                                       |                                               |
| Catalog Number                                                                                                                                                                                                                                                                                                       | Device Name                                                                           | Model, Type                                   |
| 21-1500-22                                                                                                                                                                                                                                                                                                           | PORT-A-CATH II Intraspinal Low Profile Polysulfone/Titanium Implantable Access System | Port-A-Cath II Low Profile, Tray, Intraspinal |
| 21-1501-22                                                                                                                                                                                                                                                                                                           | PORT-A-CATH II Epidural Low Profile Polysulfone/Titanium Implantable Access System    | Port-A-Cath II Low Profile, Tray, Epidural    |

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| <b>PORT-A-CATH® and PORT-A-CATH® II</b>                                                                                                                                      |                                                          |                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------|
| <b>Indications for Use per IFU</b>                                                                                                                                           |                                                          |                                       |
| PORT-A-CATH® and PORT-A-CATH® II systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling |                                                          |                                       |
| <b>Classification</b>                                                                                                                                                        |                                                          |                                       |
| Class III Implant                                                                                                                                                            |                                                          |                                       |
| <b>PORT-A-CATH® and PORT-A-CATH® II Catalog Numbers</b>                                                                                                                      |                                                          |                                       |
| <b>Catalog Number</b>                                                                                                                                                        | <b>Device Name</b>                                       | <b>Model, Type</b>                    |
| 21-4000-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Kit, Venous              |
| 21-4003-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Tray, Venous             |
| 21-4008-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Kit, Venous              |
| 21-4009-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Tray, Venous             |
| 21-4022-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Kit, Venous              |
| 21-4023-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Tray, Venous             |
| 21-4024-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Kit, Venous              |
| 21-4025-24                                                                                                                                                                   | PORT-A-CATH Titanium Venous Access System                | Port-A-Cath, Tray, Venous             |
| 21-4034-24                                                                                                                                                                   | PORT-A-CATH Low Profile Titanium Venous Access System    | Port-A-Cath Low Profile, Kit, Venous  |
| 21-4035-24                                                                                                                                                                   | PORT-A-CATH Low Profile Titanium Venous Access System    | Port-A-Cath Low Profile, Tray, Venous |
| 21-4036-24                                                                                                                                                                   | PORT-A-CATH Low Profile Titanium Venous Access System    | Port-A-Cath Low Profile, Kit, Venous  |
| 21-4037-24                                                                                                                                                                   | PORT-A-CATH Low Profile Titanium Venous Access System    | Port-A-Cath Low Profile, Tray, Venous |
| 21-4050-24                                                                                                                                                                   | PORT-A-CATH II Polysulfone/Titanium Venous Access System | Port-A-Cath II, Kit, Venous           |
| 21-4051-24                                                                                                                                                                   | PORT-A-CATH II Polysulfone/Titanium Venous Access System | Port-A-Cath II, Tray, Venous          |
| 21-4052-24                                                                                                                                                                   | PORT-A-CATH II Polysulfone/Titanium Venous Access System | Port-A-Cath II, Kit, Venous           |

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|            |                                                                                  |                                                     |
|------------|----------------------------------------------------------------------------------|-----------------------------------------------------|
| 21-4053-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4054-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Kit, Venous                         |
| 21-4055-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4063-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4065-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4066-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4067-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Tray, Venous                        |
| 21-4068-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-4069-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-4070-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Kit, Venous             |
| 21-4071-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-4073-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-4082-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Kit, Venous             |
| 21-4083-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-4084-24 | PORT-A-CATH II Polysulfone/Titanium Venous Access System                         | Port-A-Cath II, Kit, Venous                         |
| 21-4085-24 | PORT-A-CATH II Low Profile Polysulfone/Titanium Venous Access System             | Port-A-Cath II Low Profile, Tray, Venous            |
| 21-8066-24 | PORT-A-CATH II Dual-Lumen Low Profile Polysulfone/ Titanium Venous Access System | Port-A-Cath II Dual-Lumen Low Profile, Tray, Venous |
| 21-8068-24 | PORT-A-CATH II Dual-Lumen Low Profile Polysulfone/ Titanium Venous Access System | Port-A-Cath II Dual-Lumen Low Profile, Tray, Venous |

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| <b>ProPort®</b>                                                                                                                                     |                                                  |                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------------------|
| <b>Indications for Use per IFU</b>                                                                                                                  |                                                  |                                   |
| ProPort® systems are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling. |                                                  |                                   |
| <b>Classification</b>                                                                                                                               |                                                  |                                   |
| Class III Implant                                                                                                                                   |                                                  |                                   |
| <b>ProPort® Catalog Numbers</b>                                                                                                                     |                                                  |                                   |
| <b>Catalog Number</b>                                                                                                                               | <b>Device Name</b>                               | <b>Model, Type</b>                |
| 21-4150-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Kit, Venous              |
| 21-4151-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Tray, Venous             |
| 21-4152-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Kit, Venous              |
| 21-4153-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Tray, Venous             |
| 21-4154-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Kit, Venous              |
| 21-4155-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Tray, Venous             |
| 21-4165-24                                                                                                                                          | ProPort Plastic Venous Access System             | ProPort, Tray, Venous             |
| 21-4170-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Kit, Venous  |
| 21-4171-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Tray, Venous |
| 21-4172-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Kit, Venous  |
| 21-4173-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Tray, Venous |
| 21-4182-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Kit, Venous  |
| 21-4183-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Tray, Venous |
| 21-4186-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Kit, Venous  |
| 21-4187-24                                                                                                                                          | ProPort Low Profile Plastic Venous Access System | ProPort Low Profile, Tray, Venous |

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| PORT-A-CATH P.A.S. PORT®                                                                                                                                                                      |                                                                                |                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------|
| <b>Indications for Use per IFU</b><br>P.A.S. PORT® systems are indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling. |                                                                                |                                             |
| <b>Classification</b><br>Class III Implant                                                                                                                                                    |                                                                                |                                             |
| PORT-A-CATH P.A.S. PORT® Catalog Numbers                                                                                                                                                      |                                                                                |                                             |
| Catalog Number                                                                                                                                                                                | Device Name                                                                    | Model, Type                                 |
| 21-4572-24                                                                                                                                                                                    | PORT-A-CATH P.A.S. PORT T2 Titanium Venous Access System                       | Port-A-Cath P.A.S. PORT T2, Kit, Venous     |
| 21-4573-24                                                                                                                                                                                    | PORT-A-CATH P.A.S. PORT T2 Titanium Venous Access System                       | Port-A-Cath P.A.S. PORT T2, Tray, Venous    |
| 21-4590-24                                                                                                                                                                                    | PORT-A-CATH P.A.S. PORT Elite Acetal Homopolymer/Titanium Venous Access System | Port-A-Cath P.A.S. PORT Elite, Kit, Venous  |
| 21-4591-24                                                                                                                                                                                    | PORT-A-CATH P.A.S. PORT Elite Acetal Homopolymer/Titanium Venous Access System | Port-A-Cath P.A.S. PORT Elite, Tray, Venous |

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### PORT-A-CATH POWER P.A.C.

#### Indications for Use per IFU

The Smiths Medical ASD, Inc. POWER P.A.C. implantable venous access systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling. When used with a GRIPPER PLUS® POWER P.A.C. safety huber needle or other power injectable huber needles, the Smiths Medical ASD, Inc. POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

#### Classification

Class III Implant

### PORT-A-CATH POWER P.A.C. Catalog Numbers

| Catalog Number | Device Name                                                           | Model, Type                                        |
|----------------|-----------------------------------------------------------------------|----------------------------------------------------|
| 21-4422-24     | PORT-A-CATH POWER P.A.C. Titanium Venous Access System                | Port-A-Cath Power P.A.C., Kit, Venous              |
| 21-4423-24     | PORT-A-CATH POWER P.A.C. Titanium Venous Access System                | Port-A-Cath Power P.A.C., Tray, Venous             |
| 21-4424-24     | PORT-A-CATH POWER P.A.C. Titanium Venous Access System                | Port-A-Cath Power P.A.C., Kit, Venous              |
| 21-4425-24     | PORT-A-CATH POWER P.A.C. Titanium Venous Access System                | Port-A-Cath Power P.A.C., Tray, Venous             |
| 21-4436-24     | PORT-A-CATH POWER P.A.C. Low Profile Titanium Venous Access System    | Port-A-Cath Power P.A.C. Low Profile, Kit, Venous  |
| 21-4437-24     | PORT-A-CATH POWER P.A.C. Low Profile Titanium Venous Access System    | Port-A-Cath Power P.A.C. Low Profile, Tray, Venous |
| 21-4452-24     | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C., Kit, Venous           |
| 21-4453-24     | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C., Tray, Venous          |
| 21-4454-24     | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C., Kit, Venous           |

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|------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 21-4455-24 | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System                           | Port-A-Cath II Power P.A.C., Tray, Venous                        |
| 21-4463-24 | PORT-A-CATH II POWER P.A.C. Pre-assembled Polysulfone/Titanium Venous Access System             | Port-A-Cath II Power P.A.C., Tray, Venous                        |
| 21-4465-24 | PORT-A-CATH II POWER P.A.C. Pre-assembled Polysulfone/Titanium Venous Access System             | Port-A-Cath II Power P.A.C., Tray, Venous                        |
| 21-4470-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Kit, Venous             |
| 21-4471-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4473-24 | PORT-A-CATH II POWER P.A.C. Low Profile Pre-assembled Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4474-24 | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System                           | Port-A-Cath II Power P.A.C., Tray, Venous                        |
| 21-4475-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4476-24 | PORT-A-CATH II POWER P.A.C. Polysulfone/Titanium Venous Access System                           | Port-A-Cath II Power P.A.C., Tray, Venous                        |
| 21-4477-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4482-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Kit, Venous             |
| 21-4483-24 | PORT-A-CATH II POWER P.A.C. Low Profile Polysulfone/Titanium Venous Access System               | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4485-24 | PORT-A-CATH II POWER P.A.C. Low Profile Pre-assembled Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C. Low Profile, Tray, Venous            |
| 21-4872-24 | P.A.S Port T2 Power P.A.C. Titanium Venous Access System                                        | Port-A-Cath P.A.S. Port T2 Power P.A.C., Kit, Venous             |
| 21-4873-24 | P.A.S Port T2 Power P.A.C. Titanium Venous Access System                                        | Port-A-Cath P.A.S. Port T2 Power P.A.C., Tray, Venous            |
| 21-8466-24 | PORT-A-CATH II POWER P.A.C. Dual-Lumen Low Profile Polysulfone/Titanium Venous Access System    | Port-A-Cath II Power P.A.C. Dual-Lumen Low Profile, Tray, Venous |

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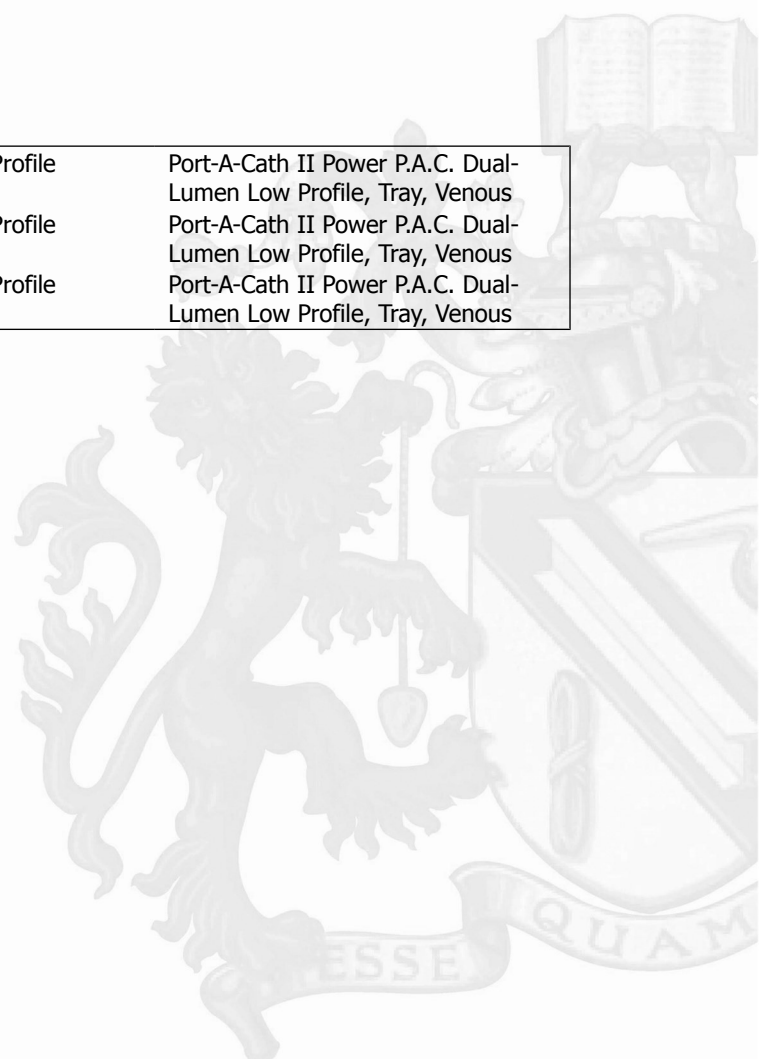
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| 21-8468-24 | PORT-A-CATH II POWER P.A.C. Dual-Lumen Low Profile Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C. Dual-Lumen Low Profile, Tray, Venous |
| 21-8469-24 | PORT-A-CATH II POWER P.A.C. Dual-Lumen Low Profile Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C. Dual-Lumen Low Profile, Tray, Venous |
| 21-8470-24 | PORT-A-CATH II POWER P.A.C. Dual-Lumen Low Profile Polysulfone/Titanium Venous Access System | Port-A-Cath II Power P.A.C. Dual-Lumen Low Profile, Tray, Venous |



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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 669193

Issued To:

**Smiths Medical ASD Inc.**  
**6000 Nathan Lane North**  
**Minneapolis**  
**Minnesota**  
**55442**  
**USA**

## Certificate History

| Date          | Reference Number | Action                                                                                                                                                                   |
|---------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20 July 2017  | 8750865          | First issue, transferred from another notified body.<br>Change Notification for Manufacturing Site Transfer, Sterilization Site Transfer, and Legal Manufacturer Change. |
| 22 March 2019 | 8603491          | Traceable to NB 0086.                                                                                                                                                    |
| Current       | 3105704          | Certificate renewal. Removal of Port-A-Cath Titanium Peritoneal Access model. Format update to product tables.                                                           |

First Issued: **2017-07-20**Date: **2020-08-17**Expiry Date: **2024-05-26**

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