

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)

Manufacturer name	Smiths Medical ASD Inc
Manufacturer address and contact details	6000 Nathan Lane North Minneapolis MN55442, USA
Single Registration Number (SRN) (if available)	US-MF-000002566

Authorised Representative name (if applicable)	Smiths Medical
Authorised Representative address and contact details	Smiths Medical Czech Republic a.s. Olomoucká 306, Hranice 1 - Město, 753 01 Hranice, Czech Republic
Single Registration Number (SRN) (if available)	CZ-AR-000002443

Notified body name (if applicable)	BSI Group, The Netherlands <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	2797 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 669121 CE 685113 CE 669193 <input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	18 March 2023 26 May 2024 <input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	31 December 2027 (Class III Devices) 31 December 2028 (Class I(S), Class IIa and IIb Devices) <input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
- Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the devices covered by the expired certificate or in respect of a devices intended to substitute that/those devices

➤ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Smiths Medical ASD Inc

Date: 13 DEC 2023

Signature, Print Name, Title:



JENNIFER COOKE

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ¹ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
NRFit Cap	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Needle Protection Point-Lok	CE 685113	26 May 2024	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex LOCKIT Plus Regional Anaesthesia Catheter Securement Device	CE 685113	26 May 2024	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Loss of Resistance (L.O.R.) Syringe with NRFit Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Catheter Connector Key	CE 685113	26 May 2024	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Snuggle Warm® Convective Warming Blanket	CE 685113	26 May 2024	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

CADD-Solis VIP Ambulatory Infusion Pump	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD-Solis Ambulatory Infusion Pump - HPCA	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
PharmGuard Administrator Medication Safety Software (MSS)	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Administration Sets	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD High Volume Administration Sets	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Yellow High Volume Administration Sets with NRFit connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Extension Set	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Medication Cassette Reservoir	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Bag Spike Set	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Filling Adapter	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
CADD Infusion Adapter	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Blood Draw Hypodermic Needle-Pro	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

Jelco Hypodermic Needle-Pro Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Hypodermic Needle-Pro with Syringe Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Hypodermic Needle-Pro Fixed Needle Insulin Syringe	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Insulin Syringe with Jelco Hypodermic Needle-Pro Edge	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Hypodermic Needle-Pro Edge	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Hypodermic Needle-Pro Edge with Syringe	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Port-A-Cath Subcutaneous Tunneling Tool	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Peel-Away Introducer Set	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Port-A-Cath Needles Plastic Hub	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Gripper Power P.A.C. Plus Non-Coring Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Gripper Micro Non-Coring Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Gripper Plus Non-Coring Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Deltec Gripper Non-Coring Needles	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

Port-A-Cath Implantable Access Systems - Deltec P.A.S Ports	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath & Port- A-Cath II Ports	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-A-Cath Implantable Access Systems - Deltec ProPort Ports	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath II P.A.C. Dual-Lumen	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath II Power P.A.C. Dual-Lumen	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath Power P.A.C.	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Port-a-Cath Implantable Access Systems - Epidural and Intraspinal	CE 669121 CE 669193	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2027	N/A
Jelco Safety ProtectIV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

ViaValve ViaValve -W Safety I.V. Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Radiopaque I.V. Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Optiva Radiopaque I.V. Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Optiva 2 Radiopaque IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Jelco Clear IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Optiva Winged IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Jelco Radiopaque IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Optiva IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Conventional Plus IV Catheters	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Jelco Convention Jelco 2 IV Catheter	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex ABS Pulsator Liquid Heparin	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex ABS Pulsator Dry Heparin - With Needle	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Cleo 90 Infusion Set	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

EchoGlo Peripheral Nerve Block Needle: Continuous System	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
EchoGlo Peripheral Nerve Block Needle: Single Shot	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Epidural Tuohy and Hustead Needles with NRFit Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Epidural Flat Filter with NRFit Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
EpiFuse Catheter Connector with NRFit Connector and Key	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Epidural Minipack with NRFit Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Epidural Catheter Kit with NRFit Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Epidural Single Shot Trays	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Hotline Fluid Warming Sets	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Hotline Routine Fluid Warmer	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Level 1® Convective Warmer	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Level 1 Neo-Therm Skin Temperature Sensor	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

Level 1 Tympanic Temperature Sensor	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Level 1 Esophageal/Rectal Temperature Probes	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Level 1 Skin Temperature Sensor	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Flex Tubes	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Thermovent O2	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Thermovent T Heat & Moisture Exchanger	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Thermovent T2 Heat & Moisture Exchanger with Oxygen & Suction Port	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Thermovent 600/1200 Heat & Moisture Exchangers	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Filtered Heat & Moisture Exchangers	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Heat & Moisture Exchangers	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
BLUselect Tracheostomy Tubes	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
BLUselect Suctionaid Tracheostomy Tubes	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

BLUselect Inner Cannula	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
BLUgriggs Percutaneous Dilation Tracheostomy Procedural Kit with BLUselect Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
BLUperc Percutaneous Dilation Tracheostomy Procedural Kit with or without BLUselect Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
EzPAP Positive Airway Pressure Therapy Device with Mask	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
EzPAP Positive Airway Pressure Therapy Device with Mouthpiece	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Custom Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Neonatal/Pediatric Hyperflex Uncuffed Adjustable Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Neonatal/Pediatric Uncuffed Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A

Bivona Neonatal/Pediatric TTS Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Neonatal/Pediatric Flexend TTS Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Cuffless Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Tracheostomy Tube	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Bivona Inner Cannula	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Pneupac paraPAC Plus Disposable CPAP Circuit	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
paraPAC plus ventilator	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Swivel Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex 15mm Double Swivel Connector	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Portex Catheter Mount	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Hotline Gas Vent	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A
Hotline Connector Extension	CE 669121	18 March 2023	BSI Group, The Netherlands (2797)	BSI Group, The Netherlands (2797)	31 December 2028	N/A