

smiths medical bringing technology to life	Declaration of Conformity	DoC-291 Revision Number: 103
	S1276: Pain Management with NRFit™ Connector Products Class Is and Class IIa	

Legal Manufacturer: Smiths Medical, ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA

EU Representative: Smiths Medical Czech Republic a. s.
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Hranice 1 - Mesto,
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Product Tradename(s): Portex® Epidural Needles with NRFit Connector. Portex® Catheter Connector with NRFit™ Connector. Portex® Loss of Resistance Syringe with NRFit™ Connector. Portex® Epidural Flat Filter with NRFit™ Connector, Portex® Filter Needle with NRFit™ Connector, Portex® Epidural Catheter Kit with NRFit™ Connector, Portex® Epidural Single Shot Pack with NRFit™ Connector, Portex® Epidural Minipack with NRFit™ Connector, Portex® Epidural Maxipack with NRFit™ Connector.

Conformity Assessment Route: Annex II for Class IIa products
Annex VII combined with Annex II for Class Is products

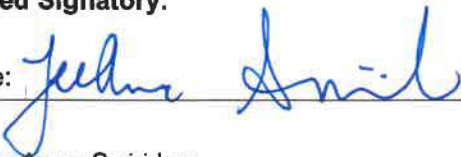
Notified Body: BSI Healthcare
Medical Devices Certification
Notified Body #2797

EC Certificate Number: CE 669121

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC.

Reference Attachment 1 for list of affected SKUs.

Authorized Signatory:

Signature: 

Date: 13 Jan 2021

Name: LeeAnne Swiridow

Title: Director of Regulatory Affairs

Location of Signatory: Minneapolis, Minnesota, USA

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Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
100	Release Pain Management with NRFit™ Connector products as part of a split of S1177 into Luer based Pain Management products (S1177), EchoGlo Peripheral Pain Management products (S1274) and Pain Management with NRFit™ Connector products (S1276)	Ken Meyer	02-AUG-2019
101	Update for new format. Add 24-1356-64 filter needle	Ken Meyer	9-APR-2020
102	Add Catheter Kits, Epidural Single Shot Packs, Epidural Minipacks, and Epidural Maxipacks	Ken Meyer	29-JUL-2020
103	Add description of update in GMDN code to the revision history. GMDN code 46115 was obsoleted by the GMDN Agency and replaced by 63607; that change was implemented in revision 102 but not reflected in the Summary of Changes/Additions for revision 102.	Ken Meyer	11-JAN-2021