smiths medical bringing technology to life	**Declaration of Conformity** S1228:Pain Management Kits	DoC-159 Revision number: 107

Legal Manufacturer:	Smiths Medical ASD Inc. 6000 Nathan Lane North Minneapolis, Minnesota 55442 USA
EU Representative:	Smiths Medical Czech Republic a. s. Olomoucká 306, Hranice 1 - Město, 753 01 Hranice, Czech Republic
Product Tradename(s):	Portex® Minipack epidural trays and kits
Conformity Assessment Route:	Annex II (excluding Section 4)
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.

Authorized Signatory:

Signature: Stacy Novak Date: 28AUG2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN USA

Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	100/391/016	100/391/016CZ	Epidural Minipack System 1 16G Terminal Eye	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
2.	100/391/018	100/391/018CZ	Epidural Minipack System 1 18G Terminal Eye	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
3.	100/391/019	100/391/019CZ	Epidural Minipack Paediatric 19G Terminal Eye	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
4.	100/391/116	100/391/116CZ	Epidural Minipack System 1 16G 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
5.	100/391/118	100/391/118CZ	Epidural Minipack System 1 18G 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
6.	100/391/126	100/391/126CZ	16G Epidural Minipack With Clamp	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
7.	100/391/128	100/391/128CZ	18G Epidural Minipack With Clamp	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
8.	100/391/318	100/391/318CZ	Epidural Minipack System 1 HD 18G 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
9.	100/391/816	100/391/816CZ	Epid. Minipack Sys.1 (CTE), 16G	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
10.	100/391/818	100/391/818CZ	Epidural Minipack System 1 18G 3 Closer Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
11.	915/216/0023	915/216/0023CZ	16G Epidural Custom Pack	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
12.	915/218/0023	915/218/0023CZ	18G Epidural Custom Pack	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
13.	100/392/116	100/392/116CZ	Epidural Minipack System 2 16G 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
14.	100/392/118	100/392/118CZ	Epidural Minipack System 2 18G 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
15.	915/018/0002	915/018/0002CZ	18G Epidural Minipack System 2with Pre-Attached Tuohy Wing	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
16.	100/393/116	100/393/116CZ	Epidural Minipack System 3 16G Clear, 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
17.	100/393/118	100/393/118CZ	Epidural Minipack System 3 18G Clear, 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
18.	100/394/116	100/394/116CZ	Epidural Minipack System 4 16G Clear, 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
19.	100/394/118	100/394/118CZ	Epidural Minipack System 4 18G Clear, 3 Lateral Eyes	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
20.	100/382/116	100/382/116CZ	Epidural Catheter 16g Lateral Eyes Clear	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
21.	100/382/118	100/382/118CZ	Epidural Catheter 18G Lateral Eyes Clear	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
22.	100/382/816	100/382/816CZ	Epidural Catheter 16G Closer 3 Eyes Clear	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7
23.	100/382/818	100/382/818CZ	Epidural Catheter 18G Closer 3 Eyes Clear	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	34842	IIb	7

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
24.	100/386/010	100/386/010CZ	Epidural Flat Filter Luer Lock	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	31245	IIa	3

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
003	Updated to new Template, Updated EC Cert Info	Mitchell Madsen	20-JAN-2017
004	Change document number format from SXXX to DoC-XXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1228 to DoC-159 and revision from 003 to 004 and added STED # to header for traceability to STED.	Stacy Novak	30-MAY-2017
005	Updating Cert Issued Date from 19 JAN 2017 to 21 JAN 2016	Mitchell Madsen	14-JUL-2017
006	The purpose of this revision update was to remove part 4892CSCZ as this is a Class Is device and is covered under a different CE certificate (reference new DoC - DoC-174). Updated the authorized signatory from Jack Kromenhoek to James Taufen and the revision from 005 to 006. No other updates were made.	Brent Pearson	15-AUG-2017
107	Updated to current template revision (from 002 to 105). Changed revision from 006 to 107 due to DVSOP2005 revision formatting requirements. Changed the Legal Manufacturer from MCZH to MMSP as per FM-DVSOP8005-05. Changed the Notified Body from Intertek AMTAC to BSI and the EC Certificate from 1201-09 A CE to EC 669121 as the Notified Body for the SKUs on this DoC has changed from AMTAC to BSI. Added Hranice, Czech Republic as EU Representative. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since the Legal Manufacturer is changing to MMSP, an EU Representative is needed. Split the “Product Code” column into “External Reference Number” and “Internal Reference Number” columns as the	Alicia Wilson	27-AUG-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	external number is what's listed on the label, while the internal number is used for our internal reference. Revised the Hranice Manufacturing Site address to match the address listed on EC Certificate 669121. Changed the GMDN Code for 100/382/116CZ, 100/382/118CZ, 100/382/816CZ, and 100/382/818CZ from 35795 to 34842 as 35795 was obsoleted by the GMDN Agency, and 34842 is an appropriate replacement term.		