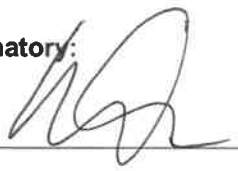
smiths medical bringing technology to life	**Declaration of Conformity** S1118: CADD-Legacy® Duodopa® Pump System	DoC-273 Revision Number: 121

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):	CADD-Legacy® Ambulatory Infusion Pump/Device
Conformity Assessment Route:	Annex VII
Notified Body:	N/A
EC Certificate Number:	N/A

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

Authorized Signatory:

Signature:  Date: 16 Oct 2019

Name: Wendy Hills

Title: Manager, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	21-6220-64	Cord, Remote Dose, Cadd-Legacy	Smiths Medical ASD Inc. 3350 Granada Avenue North, Oakdale, MN 55128 USA	N/A	61584	Ins/nm	12
2.	21-2165-64	Pouch, Pump, 50/100 Ml, Cadd-Prizm/Solis	SI Jacobson Manufacturing No. 29 Bacui Road, No. 28 Industrial Park, Shangyuan Village, Chashan Town, Dongguan City, China	N/A	37685	Ins/nm	1
3.	21-2170-64	Pouch, Pump Single Use, 50/100 Ml	SI Jacobson Manufacturing No. 29 Bacui Road, No. 28 Industrial Park, Shangyuan Village, Chashan Town, Dongguan City, China	N/A	37685	Ins/nm	1

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
100	Initial release of DoC in Agile. Moved SKUs 68-2230-28, 21-6220-24, 21-6220-64, 21-2165-64, and 21-2170-64 from DoC-097 to DoC-273 as they are EU Class 1ns/nm and have a conformity assessment route of Annex VII. DoC-097 includes class IIb SKUs that have a conformity assessment route of Annex II (excluding section 4).	Alicia Wilson	20-FEB-2019
101	Changed the EU Representative from the Ashford, UK facility to the Hranice, Czech Republic facility. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since Ashford will no longer be part of the EU, due to Brexit, the EU Representative was changed from the Ashford facility to the Hranice facility. Changed Product Scope from "Infusion Pumps for Hospital and Home Use" to "Ambulatory Infusion Pumps-Duodopa, Ambulatory Infusion Pumps" to align with the affected SKUs' product family. Removed SKU 21-6220-24 as it's in Service. DoCs list products currently manufactured and currently commercially distributed in the EU, which excludes service SKUs.	Alicia Wilson	08-APR-2019
102	Removal and movement to DoC-097 of Enteral Medication Cassette Reservoir SKU 68-2230-28 due to a classification correction as a result of a BSI audit where the cassette reservoir had been deemed incorrectly classified as a class Ins/nm device. Additional updates include updated Authorized Signatory to Tyler Foutch.	Dominique Neisz	19-JUL-2019
121	Updated template and lthe document revision to align the technical documentation (STED/ERC/DoC) are at the same revision, no updates were skipped between revision 102 and 121. Updated authorized signatory to Wendy Hills	LeeAnne Swiridow	11-OCT-2019