

	Declaration of Conformity	DoC-178 Revision Number: 102
	S1112: CADD Legacy® Ambulatory Pumps System	

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/devices

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 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: 09 OCT 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	21-6120-24	POLEMOUNT BRACKET, LOCKABLE, CADD	Chandler Industries 1654 N 9 th St Montevideo, MN 56265 USA	41893	I ns/nm	12
2.	21-6210-24	ADAPTER, POLEMOUNT BRACKET, CADD-LEGACY	JunoPacific Inc. 1040 Lund Blvd Anoka, MN 55303 USA	41893	I ns/nm	12
3.	21-6212-24	ADAPTER, SECURITY SHELL, CADD LEGACY	JunoPacific Inc. 1040 Lund Blvd Anoka, MN 55303 USA	37685	I ns/nm	12
4.	21-6244-20	AC ADAPTER, DESKTOP, CADD-LEGACY, 240V, UNREG, UK	Smiths Medical ASD, Inc. 3350 Granada Ave. N Oakdale, MN 55128 USA	36545	I ns/nm	2
5.	21-6246-26	AC ADAPTER, DESKTOP, 240V, UNREG, EURO	Smiths Medical ASD, Inc. 3350 Granada Ave. N Oakdale, MN 55128 USA	36545	I ns/nm	2
6.	BT-05	CARRYING POUCH, COLD, CADD	Smiths Medical ASD, Inc. 3350 Granada Ave. N Oakdale, MN 55128 USA	37685	I ns/nm	12

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
000	Initial release. Added SKU's 21-6120-24, 21-6210-24, 21-6212-24, 21-6244-20, 21-6246-26 and BT-05 from Doc-093 as they are Class I ns/nm and are self-certified.	Manasa Boppana	02-OCT-2017
001	Updated DoC to the latest Template in Agile from Rev 002 to 003. Updated the Legal Manufacturer from St. Paul to Minneapolis in response to the Notified Body Transfer. Updated the Oakdale Address to reflect what is on the product certificate from Smiths Medical ASD 3350 Granada Ave. N Suite 100 to Smiths Medical ASD, Inc. 4000 Granada Ave N. Changed the GMDN code for 21-6212-24 from 16767 to 37685 due to being a non-existent GMDN code. Updated the STED Name in the Header to reflect the STED from Ambulatory Infusion Pumps to CADD-Legacy® Ambulatory Infusion Pumps.	Mitchell Madsen	05-MAR-2018
102	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. The product description in Appendix I were updated to match the product description found in Agile: The manufacturing site was updated from "Smiths Medical ASD, Inc., 4000 Granada Ave. N, Oakdale, MN 55128 USA" for the following SKUs to match the manufacturing site in Agile: 21-6120-24 to "Chandler Industries, 1654 N 9th St, Montevideo, MN 56265 USA"; 21-6210-24 and 21-6212-24 to "JunoPacific Inc., 1040 Lund Blvd, Anoka, MN 55303 USA." Alfred Mwalongo, Sr. Buyer at Oakdale, confirmed the Manufacturing locations.	Rosanna Lee	07-OCT-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	The Oakdale manufacturing site address was updated to match the address on QMS certificate MD 669191 for the following SKUs: 21-6244-20, 21-6246-26, and BT-05. Formatting and editorial changes per FM-DVDP1509-01.105. Document revision number reassigned from 0xx to 1xx to align with DVSOP2005.121.		