

smiths medical bringing technology to life	Declaration of Conformity	DoC-1122-2 Revision Number: 100
	TD-1122: CADD-Solis® Ambulatory Infusion Pump	

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

Single Registration Number (SRN): APP000006777

EU Authorized Representative: Smiths Medical Czech Republic a. s.
Olomoucká 306
Hranice 1 – Město,
753 01 Hranice, Czech Republic

Product Tradename(s): CADD®-Solis Ambulatory Infusion Pump Accessories

Conformity Assessment Route: Annex II & III

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 2017/745 on Medical Devices (MDR)

Authorized Signatory:

Signature:  Date: 26 May 2021

Name: LeeAnne Swiridow

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Controlled Copy – Verify Revision & Effective Date are current before use.

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Appendix 1: Product List

No	Catalog Number	Product Description	Basic UDI-DI	EU Risk Class	EU Rule
1.	21-2131-25	CADD-Solis – Communication Module (CM)	0610586M0216D5	I ns/nm	13
2.	21-2166-24	CADD 1-Liter Backpack	0610586M0222CY	I ns/nm	1
3.	21-2167-25	CADD 250-500-mL Pump Pouch with Waist Belt			
4.	21-2168-25	CADD 250-500-mL Pump Pouch with Waist Belt and Shoulder Strap			
5.	21-2169-24	CADD 3-Liter Backpack			
6.	21-2171-25	CADD 250-500-mL Single Use Pump Pouch			
7.	21-2165-64	CADD-Solis 50/100-mL Pump Pouch	0610586M0281DG	I ns/nm	1
8.	21-2135-25	CADD-Solis Polemount Adapter			
9.	21-6118-24	CADD-Solis Polemount Bracket			
10.	21-2183-25	CADD-Solis Polemount Swivel	0610586M0106CV	I ns/nm	1
11.	21-2172-25	CADD-Solis LockBox, Keyed, Clear			
12.	21-2174-25	CADD-Solis LockBox, Keyed, Yellow			
13.	21-2188-25	CADD-Solis LockBox, Clear			
14.	21-2189-25	CADD-Solis LockBox, Yellow			

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
100	Initial MDR release of Declaration of Conformity for CADD®-Solis Ambulatory Infusion Pump Accessories	Sinéad Walsh	26-MAY-2021