

	Declaration of Conformity	DoC-150 Revision Number: 115
	S1216: CADD Disposables	

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 - Mesto,
753 01 Hranice, Czech Republic

Product Tradename(s): CADD™ medication cassette reservoirs, CADD® ambulatory infusion pumps and administration extension sets, NRFit™ connectors

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.

Reference Attachment 1 for list of affected SKUs.

Authorized Signatory:

Signature: Angela Kilian

Date: 22 APR 2020

Name: Angela Kilian

Title: Director of Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
08	Updated to new template, updated EC cert information	Lisa Hahne	14-DEC-2016
009	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 S1216 to DoC-150 and revision from 08 to 009 and added STED # to header for traceability to STED.	Stacy Novak	14-JUN-2017
010	The purpose of this revision update was in response to Notified Body Transfer. The changes to this DoC include: Notified Body name and number from Intertek 0473 to BSI 0086, the certificate number from 058-05 CE to CE 669121, added product codes 21-7600-24, 21-7609-24, 21-7664-24, 24-1001-64, 21-7605-24, 21-7608-24, 21-7624-24, 21-7639-24, 21-7684-24, 21-7685-24, 24-1004-64, 24-1009-64 as the NRFit™ products were added to the STED, removed product codes 21-7075-01, 21-7085-01, 21-7321-01, 21-7322-01, 21-7324-01, 21-7355-01, 21-7355-22, 21-7357-01, 21-7357-22, 21-7359-01, 21-7375-01, 21-7375-22, 21-7381-22, 21-7383-01, 21-7384-22, 21-7385-22, 21-7390-01 and 21-7391-01 as they are inactive product codes and 21-7399-01 as it is a product code that is at Service status and identified for obsolescence, renumbered remaining codes accordingly and the revision from 009 to 010. No other updates were made.	Brent Pearson	18-SEP-2017
011	Updated DoC to the latest DoC Template in Agile from Rev 002 to Rev 003. Updated the Legal Manufacturer from St. Paul to Minneapolis.	Mitchell Madsen	17-JAN-2018
112	This revision is to capture the reissuance of the Minneapolis Legal Manufacturer BSI EC Certificate for EC certificates 669121 and 669193	Sanjana Jaiswal	09-MAY-2018
113	Administrative update made to Manufacturer misspelling from Smiths Medical ASDD Inc. to Smiths Medical ASD Inc. Made formatting changes to unmerge cells. No other technical content review or updates were performed during this revision update.	Izzy Wallstein	03-DEC-2018
114	Changing the revision on the DoC template from FM-DVDP1509-01 Rev. 103 to FM-DVDP1509-01 Rev. 105. Changed the STED name in the header from "CADD Extension Sets and Disposables" to "CADD Disposables" to align with the applicable STED's description in Agile. Changed the EU Representative from the Ashford, UK facility to the Hranice, Czech Republic facility. An EU Representative is needed if a product is	Izzy Wallstein	31-OCT-2019

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	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 the Notified Body from BSI UK (0086) to BSI NL (2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. The EC Certificate number remains the same. Updated product descriptions on the DoC to match the Agile product descriptions. Revised the Tijuana, Dublin and Hranice Manufacturing Site addresses to match the addresses listed on EC Certificate 669121. Removed 21-7055V-01, 21-7057V-01 and 21-7075V-01 as they are not CE marked and are only sold in the United States. Confirmed with Global Product Manager, Nathan Walker. Changed the GMDN Code for SKUs 24-1004-64 and 24-1009-64 from 12170 to 16825 to better align with the SKUs' descriptions. Changed the GMDN Code for SKUs 21-7664-24 and 24-1001-64 from 12170 to 41222 to better align with the SKUs' descriptions. Changed the Manufacturing Site for 24-1004-64 and 24-1009-64 from Tijuana to Hranice to reflect current manufacturing activities. Addition of 8 new numbers, CR-10005685 phase 1 and 2, new GVS Filter replacing PALL Filters as part of a cost-savings project. New SKU's are: 21-7346-24, 21-7363-24, 21-7386-24, 21-7044-24, 21-7147-24, 21-7349-24, 21-7649-24, 21-7665-24.		
115	Updated to current DoC template (from rev 105 to 107), which includes moving the SKUs from Appendix I to Attachment 1. See revision history of Attachment I for additional SKU updates.	Lauren Portinga	21-APR-2020

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Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
21-7001-24	CADD Medication Cassette Reservoir	57791	IIa	2
21-7002-24				
21-7100-24				
21-7300-24				
21-7301-24				
21-7302-24				
21-7308-24				
21-7309-24				
21-7310-24				
21-7600-24				
21-7609-24				
21-7021-24	CADD Administration Sets	35833	IIa	2
21-7022-24				
21-7023-24				
21-7024-24				
21-7034-24				
21-7059-24				
21-7091-24				
21-7094-24				
21-7322-24				
21-7323-24				
21-7324-24				
21-7343-24				
21-7359-24				
21-7391-24				
21-7394-24				
21-7346-24				
21-7363-24				
21-7349-24				
21-7090-24				
21-7095-24				
21-7321-24				
21-7390-24				

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
21-7395-24	CADD High Volume Administration Sets	35833	IIa	2
21-7649-24				
21-7624-24				
21-7684-24				
21-7665-24				
21-7057-24				
21-7357-24				
21-7345-24				
21-7364-24				
21-7386-24				
21-7384-24				
21-7361-24				
21-7365-24	CADD Extension Sets	12170	IIa	2
21-7045-24				
21-7046-24				
21-7047-24				
21-7060-24				
21-7061-24				
21-7062-24				
21-7105-24				
21-7052-24				
21-7092-24				
21-7106-24				
21-7108-24				
21-7109-24				
21-7115-24				
21-7044-24				
21-7147-24				
21-7605-24				
21-7608-24				
21-1200-24	Bag Spike Set	35833	IIa	2
21-7664-24	Filling Adapter	41222	IIa	2
24-1001-64	Infusion Adapter	41222	IIa	2

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
24-1004-64	Male Cap	16825	Is	2
24-1009-64	Female Cap	16825	Is	2