smiths medical bringing technology to life	**Declaration of Conformity** S1122: CADD-Solis® Ambulatory Infusion Pump System	DoC-101 Revision Number: 125

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®-Solis ambulatory infusion pump system/device
Conformity Assessment Route:	Annex II (excluding Section 4) & Annex VII
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: _____ Date: 24 Nov 2020

Name: LeeAnne Swiridow

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

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	15-DEC-2016
09	Added new Pumps SKUs to the DoC Appendix 1	Mitchell Madsen	08-MAR-2017
010	Additional software SKU for PGR 202 updates (22-0004-0202-51)	Breanna Fautsch	07-SEP-2017
011	The purpose of this revision update was in response to Notified Body Transfer. The changes to this DoC include: Notified Body name from Intertek 0473 to BSI 0086, the certificate number from 058-05 CE to CE 669121, changed document number format from SXXX to DoCXXX (from S1122 to DoC-101) to load documents into Agile, added STED # to header for traceability to STED and revision from 09 to 010. . Removed the following product codes from this DoC as these codes were in “Service” in Agile and “Phase Out” in Oracle which means new product cannot be commercially distributed but product in the field can be serviced: 21-2101-00, 21-2101-0100-50, 21-2101-0100-95, 21-2101-0200-02, 21-2101-0200-03, 21-2101-0200-06, 21-2101-0200-07, 21-2101-0200-08, 21-2101-0200-12, 21-2101-0200-17, 21-2101-51, 21-2102-0100-50, 21-2102-0100-95, 21-2102-0200-02, 21-02102-0200-03, 21-2102-0200-06, 21-2102-51, 21-2111-0200-12, 21-2111-0200-14, 21-2120-0100-02, 21-2120-0100-03, 21-2120-0100-06, 21-2120-0100-232, 21-2120-0100-233, 21-2120-0100-236, 21-2120-0100-50, 21-2120-0100-92, 21-2120-0100-93, 21-2120-0100-96, 21-2111-0300-09. Added the following product codes that were on DoC for S1122 for CADD-Solis Accessories, revision 08: 21-1789-24, 21-2130-51, 21-2135-25, 21-2140-25, 21-2141-0100-51, 21-2145-01, 21-2146-24, 21-2148-20, 21-2149-24, 21-2150-24, 21-2152-10, 21-2155-24, 21-2157-09, 21-2160-02, 21-2160-03, 21-2160-06, 21-2160-07, 21-2160-08, 21-2160-12, 21-2160-14, 21-2160-17, 21-2160-51, 21-2165-64, 21-2166-24, 21-2167-25, 21-2168-25, 21-2169-24, 21-2170-64, 21-2171-	Brent Pearson	14-SEP-2017

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	25, 21-2183-25, 21-2184-51, 21-2185-51, 21-2186-25, 21-2188-25, 21-2189-25, 21-2191-25, 21-2193-0200-22, 21-2193-0200-86, 21-2193-0300-22, 21-2193-0300-286, 21-2193-0401-25, 21-2194-0200-22, 21-2194-0200-86, 21-2194-0300-22, 21-2194-0300-286, 21-2194-0401-25, 21-2194-51, 21-2195-51, 21-2196-51, 21-2303-24, 21-6118-24, 21-6122-24, 21-6126-24, 21-6127-24, 21-6131-24, 21-6161-24, 21-6163-24, 21-6188-51, 22-0004-0201-51, 21-4095-0201-51, 31-0992, 67-2130-51, 67-2474-51, 21-2193-0303-25, 21-2193-0402-25, 21-2194-0303-25, 21-2194-0402-25, 67-2575-010300-01, 67-2575-010300-02, 67-2575-010300-03, 67-2575-010300-06, 67-2575-010300-07, 67-2575-010300-08, 67-2575-010300-12, 67-2575-010300-14, 67-2575-010300-17 and 67-2575-010300-50. The following product codes from DoC for S1122 for CADD-Solis Accessories, revision 08 were NOT added because these codes were in “Service” in Agile and “Phase Out” in Oracle which means new product cannot be commercially distributed but product in the field can be serviced: 21-2140-51, 21-2186-51, 21-2188-51, 21-2189-51, 21-2305-24, 21-2321-24, 21-6120-51, 21-6124-24, 21-6126-24 and 21-6127-24. The following product codes from DoC for S1122 for CADD-Solis Accessories, revision 08 were NOT added because these codes were either obsolete or identified for obsolescence: 21-2165-25, 21-2170-25, 21-2187-51, 21-2193-51, 21-6123-01, 21-6123-24 and 21-6125-24.		
012	Updated to new template from Rev 002 to Rev 003. Separated the codes 21-1789-24, 21-2183-25, 21-2184-51, 21-2185-51, 21-2188-25, 21-2189-25, 21-2303-24, 21-6118-24, 21-6122-24, 21-6126-24, 21-6127-24, 21-6131-24, 21-6161-24, 21-6163-24, 21-6188-51, 22-0004-0201-51, 22-4095-0201-51, 31-0992, 67-2130-51, 67-2474-51, 22-0004-0202-51, 21-2135-25, 21-2165-64, 21-2166-24, 21-2167-25, 21-2168-25, 21-2169-24, 21-2170-64, 21-2171-25 and added to DoC-218 as they are Class Ins/nm and are self-certified and Updated the Legal Manufacturer from St. Paul to Minneapolis	Manasa Boppana	15-NOV-2017

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
113	The purpose of this revision is to align SKU content with the new scoping statements for recertification of the EC Certificate 669121 for MMSP. The changes include: New product scope, updated signatory, removal of 21-2120 series SKU's for VIP homecare use pumps, as well as 67-2575 series SKU's for associated VIP software updates. Removal 21-2152-10, 21-2145-01 as they are not offered in the EU. Inclusion of class Ins/nm SKU's (21-1789-24, 21-2183-25, 21-2185-51, 21-2188-25, 21-2189-25, 21-2303-24, 21-6118-24, 21-6122-24, 21-6126-24, 21-6127-24, 21-6131-24, 21-6161-24, 21-6163-24, 31-0992, 21-2135-25, 21-2166-24, 21-2167-25, 21-2168-25, 21-2169-24, 21-2170-64, 21-2171-25, 22-0004-0201-51, 22-0004-0202-51, 21-0270-25) and associated conformity assessment Annex VII, corrections to GMDN and risk classifications.	Dominique Neisz	10-AUG-2018
114	The purpose of this revision is to add new SKU's for release of CADD Solis HPCA v4.1 pump with translated software for international release in nine additional languages: French, German, Dutch, Spanish, Portuguese, Italian, Danish, Swedish, and Katakana Japanese. The new SKU's added include the Pump SKU's, CD Manuals and Electronic software update SKU's.	Aditi Dave	21-AUG-2018
115	The purpose of this revision is to add new SKU's for release CADD®-Solis VIP v1.5 pump 3 tier configuration portfolio for global launch in 11 languages complaint with 60601-1 edition 3.1.	Dominique Neisz	09-OCT-2018
116	Replaced Luton as a manufacturing site with Oakdale as all CADD pumps are manufactured in Oakdale. Removed SKUs 21-2111-0401-09, 21-2112-0401-09, and 67-2470-040100-09 as these SKUs are Japanese variants only and are not commercially distributed in the EU.	Stacy Novak	03-DEC-2018
117	Replaced the GMDN code for 21-2188-25, 21-2189-25, 21-2185-51, and 21-2303-24 from 16767 to 61952 due to 16767 not being an existing active GMDN code.	Kendall Lindenman	12-FEB-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
118	Updated STED title in header from "CADD-Solis (r) Ambulatory Infusion Pump" to "CADD-Solis Ambulatory Pump System" to reflect the STED's description in Agile. 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. Revised product descriptions to match descriptions in Agile. Removed 21-2191-0401-25 since its lifecycle phase is "preliminary," and preliminary SKUs should not be on a DoC. Removed 21-6126-24 and 21-6127-24 since they're lifecycle phase is "service," and service SKUs should not be on a DoC. Removed 21-2165-64 and 21-2170-64 since they are on DoC-273 and listed on DoC-273's related STED, S1118. Revised Oakdale Manufacturing Site address to match address listed on EC Certificate 669121. Changed Manufacturing Site for 21-6118-24 from Oakdale to Chandler Industries – Bethel Div as it is a purchased finished good. Kim Greener from Chandler Industries confirmed. Changed the Manufacturing Site for 21-2145-01, 21-2146-24, 21-2148-20, 21-2149-24, and 21-2150-24 from Oakdale to Feller LLC as they are purchased finished goods. Rod Linville from Feller LLC confirmed. Changed the Manufacturing Site for 21-2186-25 from Oakdale to TLC Electronics, Inc. as it's a purchased finished good. Tremayne Jones from TLC Electronics confirmed. Changed Manufacturing Site for 31-0092, 21-2165-64, 21-2166-24, 21-2167-25, 21-2168-25, 21-2169-24, 21-2170-64, and 21-2171-25 from Oakdale to SI Jacobson Manufacturing as they are purchased finished goods. Garette Henrick from SI Jacobson confirmed. Changed the Manufacturing Site for 21-2140-25 from Oakdale to Jerome Industries as it's a purchased finished good. James Schon from Jerome Industries confirmed. Changed Manufacturing Site for 21-2160-02, 21-2160-03, 21-2160-06, 21-2160-07, 21-2160-08, 21-2160-12, 21-2160-14, 21-2160-17, and 21-	Alicia Wilson	07-MAY-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	2160-51 from Oakdale to Ultralife to match what's listed in Agile and on S1122. Changed Manufacturing Site for 21-2183-25 from Oakdale to General Pattern Co Sunburst Division as they are purchased finished goods according to Agile and confirmed by Al Lugo, Supplier Quality Manager. Changed Manufacturing Site for 21-2135-25 from Oakdale to Nolato Contour as they are purchased finished goods according to Agile and confirmed by Al Lugo, Supplier Quality Manager. Changed Manufacturing Site for 21-0270-25 from Oakdale to Delta Products Corporation as they are purchased finished goods according to Agile and confirmed by Al Lugo, Supplier Quality Manager. Added current release of Pharmguard Reports V 2.4 SKU 22-0004-0204-25 Released as part of PGSys R1		
119	Updated to current DoC template (from rev 104 to 105). Changed the Manufacturing Site for the following SKUs from Oakdale to Luton to reflect current manufacturing activities: 21-2111-0401-51L, 21-2111-0401-02L, 21-2111-0401-03L, 21-2111-0401-06L, 21-2111-0401-07L, 21-2111-0401-08L, 21-2111-0401-12L, 21-2111-0401-14L, 21-2111-0401-17L, 21-2112-0401-51L, 21-2112-0401-02L, 21-2112-0401-03L, 21-2112-0401-06L, 21-2112-0401-07L, 21-2112-0401-08L, 21-2112-0401-12L, 21-2112-0401-14L, 21-2112-0401-17L, 21-2120-0105-02L, 21-2120-0105-03L, 21-2120-0105-06L, 21-2120-0105-07L, 21-2120-0105-08L, 21-2120-0105-12L, 21-2120-0105-13L, 21-2120-0105-14L, 21-2120-0105-15L, 21-2120-0105-17L, 21-2120-0105-50L, 21-2125-0105-02L, 21-2125-0105-03L, 21-2125-0105-06L, 21-2125-0105-07L, 21-2125-0105-08L, 21-2125-0105-12L, 21-2125-0105-13L, 21-2125-0105-14L, 21-2125-0105-15L, 21-2125-0105-17L, 21-2125-0105-50L, 21-2127-0105-02L, 21-2127-0105-03L, 21-2127-0105-06L, 21-2127-0105-07L, 21-2127-0105-08L, 21-2127-0105-12L, 21-2127-0105-13L, 21-2127-0105-14L, 21-2127-0105-15L, 21-2127-0105-17L, 21-2127-0105-50L.	Alicia Wilson	21-OCT-2019

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	Removed SKUs 21-2141-0100-51 and 21-2191-25 because they are not medical devices (CD with the manuals and metadata software). Added current release of Pharmguard Reports V 2.4 SKUs 22-4095-0204-25 and 22-0117-0201-25. Released as part of PGSys R1. Added 21-6126-24 and 21-6127-24 back onto the DoC as they were previously removed for being in Service. DVDP1509 is currently being revised to indicate Service SKUs are to be included on DoCs. Changed the GMDN Code for 21-2130-51 from 36534 to 32547 to better align with the SKU's intended use.		
120	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. Remove 21-2120-0102-232, 21-2193-0200-86, 21-2194-0200-86, 21-2194-0300-286, 21-2193-0300-286 as they are Demo SKUs, which are not required on DoCs. Changed the EU Rule for "1" to "12" for the following SKUs: 21-2130-51, 21-2140-25, 21-2145-01, 21-2146-24, 21-2148-20, 21-2149-24, 21-2150-24, 21-2160-02, 21-2160-03, 21-2160-06, 21-2160-07, 21-2160-08, 21-2160-12, 21-2160-14, 21-2160-17, 21-2160-51, 21-2186-25 and 21-0270-25 as they are active devices. Changed the EU Risk Class from "Ins/nm" to "IIa" for the following SKUs: 22-0004-0204-25, 22-4095-0204-25 and 22-0117-0201-25 as they are considered a system within the infusion pump.	Alicia Wilson	28-OCT-2019
121	Remove 21-2185-51 and 21-2303-24 from DoC as they are spare parts. Confirmed with LeeAnne Swiridow. Add the following SKUs as part of the CADD-Solis version 4.2 release: 21-2111-0402-02, 21-2111-0402-02L, 21-2111-0402-	Alicia Wilson	08-NOV-2019

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	03L, 21-2111-0402-06L, 21-2111-0402-07L, 21-2111-0402-08, 21-2111-0402-08L, 21-2111-0402-09, 21-2111-0402-12L, 21-2111-0402-14L, 21-2111-0402-17L, 21-2111-0402-51, 21-2111-0402-51L, 21-2111-0402-78, 21-2111-0402-92, 21-2112-0402-02, 21-2112-0402-02L, 21-2112-0402-03L, 21-2112-0402-06L, 21-2112-0402-07L, 21-2112-0402-08, 21-2112-0402-08L, 21-2112-0402-09, 21-2112-0402-12L, 21-2112-0402-14L, 21-2112-0402-17L, 21-2112-0402-51, 21-2112-0402-51L, 21-2112-0402-78, 21-2112-0402-92, 21-2131-25, 67-2470-040200-02, 67-2470-040200-03, 67-2470-040200-06, 67-2470-040200-07, 67-2470-040200-08, 67-2470-040200-09, 67-2470-040200-12, 67-2470-040200-14, 67-2470-040200-17, and 67-2470-040200-51.		
122	Fixed error from rev 120: changed the EU Risk Class to IIb, rule 11 for 22-0004-0204-25 and changed the EU Risk Class back to Ins/nm for 21-0270-25. Changed 22-4095-0204-25 and 22-0117-0201-25 from Class IIa. Rule 12 to Class IIb, Rule 11 as they take the classification of the infusion pump, which is Class IIb, Rule 11. Changed GMDN Code for 21-2171-25 from 31072 (personal device holder, single-use) to 37685 (personal device holder, reusable) since 21-2171-25 is single patient reusable. Removed 21-2194-51 since CE Marking, Legal Manufacturer and EU Representative were not updated to align with Notified Body/Legal Manufacturer consolidation activity. The Notified Body Number found on device labeling is no longer supported by EC Certificate or DoC. Confirmed by Dominique Neisz. Removed 21-2194-51 and 21-2196-51 as they're version 1.1 and 1.2 of the admin CD. Newer version is available. Confirmed with Andrea Grabanski. Removed SKU 31-0992 as it's a component included in a kit and is not sold on its own. Confirmed with Nathan Walker and LeeAnne Swiridow.	Alicia Wilson	18-DEC-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Removed 22-0004-0201-51 as its version 2.1 of the CD, PharmGuard Device Reports. Version 2.2 and 2.4 are available. Confirmed with Global Product Manager.		
123	Updated to current DoC template (from rev 105 to 106), which includes moving the SKUs from Appendix 1 to an attached spreadsheet.	Alicia Wilson	23-JAN-2020
124	Updated to current DoC template (from rev 106 to 107). See Attachment 1 (DoC-101.Attachment 1.124) for SKU changes.	Alicia Wilson	26-MAR-2020
125	Added SKU 67-2470-040201-51 to enable software upgrade in the EU.	Alicia Wilson	24-NOV-2020