smiths medical bringing technology to life	**Declaration of Conformity** S1136: Subcutaneous Infusion Sets	DoC-109 Revision Number: 103

Legal Manufacturer:	Smiths Medical ASD Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
EU Representative:	Smiths Medical Czech Republic a. s. Olomoucká 306, Hranice 1 - Město, 753 01 Hranice, Czech Republic
Product Tradename(s):	Cleo®90 infusion set
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.

Authorized Signatory:

Signature: Stacy Novak Date: 18 Sept 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	21-7220-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 24" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7
2.	21-7221-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 31" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7
3.	21-7222-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 42" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7
4.	21-7230-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 24" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7
5.	21-7231-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 31" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7
6.	21-7232-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 42" BUCKLE AY	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	63262	IIa	7

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
001	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 and the replaced the valid until date with “In conjunction with the associated notified body certificate”. No updates to content were made to this document, with the exception of the change document number format from SXXX to DoCXXX (from S1136 to DoC-109) to load documents into Agile, the revision from 000 to 001, added UMDNS, GIVD and IVD Classification columns to Appendix 1 to align with DoC template and added STED # to header for traceability to STED.	Brent Pearson	11-OCT-2017
102	This revision is to capture the reissuance of the Minneapolis Legal Manufacturer BSI EC Certificate for EC certificates 669121 and 669193.	Mitchell Madsen	09-MAY-2018
103	Updated to current template revision (from 003 to 105). Changed STED title from "Subcutaneous Infusion Systems" to "Subcutaneous Infusion Sets" to match the STED's title 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 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. Revised Tijuana's Manufacturing Site address to match the address listed on EC Certificate 669121.	Thomas Saladin	16-SEP-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	The GMDN code for the following SKUs were changed from 35833 to 63262 to better match the product description: 21-7220-24, 21-7221-24, 21-7222-24, 21-7230-24, 21-7231-24, and 21-7232-24.		