smiths medical bringing technology to life	**Declaration of Conformity** S1136: Subcutaneous Infusion Systems	DoC-109 Revision Number: 102 Effective Date: 09-MAY-2018

Manufacturer:	Smiths Medical ASD Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
EU Representative:	Smiths Medical International Limited 1500 Eureka Park, Lower Pemberton, Ashford Kent TN25 4BF UK
Product Tradename(s):	Cleo® infusion set
Product Scope:	Sterile Disposable Infusion Kits including cassette, tubes, connectors, needles
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Devices Certification Notified Body #0086
EC Certificate Number:	CE 669121
Start of CE-Marking:	5 December 2013

We hereby declare that the products listed in Appendix 1 conform with the relevant provisions of Directive 93/42/EEC of June 14, 1993 as transposed into UK law by Statutory Instrument S.I. 2008 No. 2936 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of September 5, 2007 concerning medical devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations. We are hereby exclusively responsible for the contents found on this declaration of conformity. All supporting documentation is retained under the premise of the Manufacturer.

Authorized Signatory:

Signature: _____ Date: 09/MAY/2018

Name: Tyler Foutch

Title: Manager, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	21-7220-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 24" BUCKLE AY 10-10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	35833	IIa	7
2.	21-7221-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 31" BUCKLE AY 10-10/BX					
3.	21-7222-24	SET, INSULIN, 6MM INSERTER/RETRACTOR, 42" BUCKLE AY 10-10/BX					
4.	21-7230-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 24" BUCKLE AY 10-10/BX					
5.	21-7231-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 31" BUCKLE AY 10-10/BX					
6.	21-7232-24	SET, INSULIN, 9MM INSERTER/RETRACTOR, 42" BUCKLE AY 10-10/BX					

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
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	11OCT2017
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