smiths medical bringing technology to life	**Declaration of Conformity** S1108: Level 1 Hotline Routine Warmers and Administration Sets	DoC-090 Revision Number: 108

Legal Manufacturer: Smiths Medical ASD, Inc.,
6000 Nathan Lane N,
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): HOTLINE® fluid warmer

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: 25 NOV 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.	L-10	GAS VENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	35072	IIa	2
2.	YC-8	Y-CONN EXTENSION TUBING	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	18067	IIa	2
3.	PC-8	T-CONN EXTENSION TUBING	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	18067	IIa	2
4.	L-70	HOTLINE WARMING SET-DISP	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	41609	IIa	2
5.	L-70NI	HOTLN BLD IV NO INJEC SET	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana B.C. C.P. 22425 Mexico	41609	IIa	2
6.	HL-90-INT-230	230V CONTINENTAL EUROPE HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
7.	HL-90-DA-230	230V DANISH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
8.	HL-90-DE-230	230V GERMAN HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
9.	HL-90-EL-230	230V GREEK HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
10.	HL-90-FI-230	230V FINNISH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
11.	HL-90-FR-230	230V FRENCH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
12.	HL-90-IT-230	230V ITALIAN HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
13.	HL-90-NL-230	230V DUTCH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
14.	HL-90-NO-230	230V NORWEGIAN HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
15.	HL-90-PORT-230	230V PORTUGESE HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
16.	HL-90-SP-230	230V SPANISH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
17.	HL-90-SV-230	230V SWEDISH HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9
18.	HL-90-UK-230	230V UK HOTLINE	Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale, Minnesota 55128 USA	47620	IIb	9

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
03	Updated to new template, updated EC cert information	Lisa Hahne	15-DEC-2016
004	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 S1108 to DoC-090 and revision from 03 to 004 and added STED # to header for traceability to STED. The purpose of this revision update was in response to Notified Body Transfer. The Changes to this DoC include: Notified Body name from Intertek to BSI, updated the EU representative address, updated to new certificate number from 058 05 CE to CE66912, changed the effective date and renamed the SKU from HL-90-PT-230 to HL-90-PORT-230	Manasa Boppana	14-SEP-2017
105	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
106	Correct GMDN codes for L-70 and L-70NI that were corrupted in rev 105	Ken Meyer	16-MAY-2018
107	-Updated the DoC to the latest template in Agile from Rev 003 to 105. -Updated the STED Name on the DoC from Slow Flow Infusion Sets and Warmers to Level 1 Hotline Routine Warmers and Administration Sets -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.	Mitchell Madsen	26-SEP-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-Updated the Product Descriptions of the Catalog Numbers in Appendix 1 to match their Descriptions in Agile -Updated the Oakdale address in the Manufacturing Site column in Appendix 1 to match EC Certificate 669121 -Updated the Tijuana address in the Manufacturing Site column in Appendix 1 to match EC Certificate 669121		
108	Changed the EU Risk Class for the following SKUs from Class IIa to Class IIb as S1108 correctly classifies the SKUs as IIb: HL-90-DA-230, HL-90-DE-230, HL-90-EL-230, HL-90-FI-230, HL-90-FR-230, HL-90-INT-230, HL-90-IT-230, HL-90-NL-230. HL-90-NO-230, HL-90-PORT-230, HL-90-SP-230, HL-90-SV-230 and HL-90-UK-230.	Alicia Wilson	25-NOV-2019