

	Declaration of Conformity	DoC-104 Revision Number: 105
	S1127: Level 1® General Purpose Temperature Probes	

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):

Level 1®, Acoustascope® esophageal stethoscope, Neo-Therm®
 skin-contact thermometer for use with infants, Bi-Temp® temperature
 monitor with disposable probes

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:

112 Sept 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	ES100-9	ESOPHAGEAL STETHOSCOPE 9F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
2.	ES100-12	ESOPHAGEAL STETHOSCOPE 12F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
3.	ES100-18	ESOPHAGEAL STETHOSCOPE 18F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
4.	ES100-24	ESOPHAGEAL STETHOSCOPE 24F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
5.	ES400-9	ESOPHAGEAL STETHOSCOPE 9F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
6.	ES400-12	ESOPHAGEAL STETH 400 SERIES 12FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
7.	ES400-18	ESOPHAGEAL STETHOSCOPE 18F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
8.	ES400-24	ESOPHAGEAL STETHOSCOPE 24F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
9.	ES700-9	ESOPHAGEAL STETHOSCOPE 700 9FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
10.	ES700-12	ESOPHAGEAL STETHOSCOPE 12F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
11.	ES700-18	ESOPHAGEAL STETHOSCOPE 18F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
12.	ES700-24	ESOPHAGEAL STETHOSCOPE 24F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
13.	ES70S-12	ESOPH STETH 700 SUB 12FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
14.	ES70S-18	ESOPH STETH 700 SUB 18FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
15.	ES70S-24	ESOPH STETH 700 SUB 24FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
16.	ESTC-9	ESOPHAGEAL STETHOSCOPE 9F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
17.	ESTC-12	ESOPHAGEAL STETHOSCOPE 12F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
18.	ESTC-18	ESOPHAGEAL STETHOSCOPE 18F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
19.	ESTC-24	ESOPHAGEAL STETHOSCOPE 24F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	44120	IIB	10
20.	ER400-12	PROBE GENERAL PURPOSE 12F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
21.	ER400-9	PROBE, GENERAL PURPOSE 9F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
22.	ER700-12	PROBE GENERAL PURPOSE 700 12FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
23.	ER700-9	PROBE GENERAL PURPOSE 700 9FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
24.	ER70S-9	PROBE GP. TEMP 9FR 700 SER	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
25.	ERTC-9	PROBE, GENERAL PURPOSE 9F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
26.	ERTC-12	PROBE GENERAL PURPOSE 12F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
27.	STS-201	SKIN TEMP PROBE NEO-AIRSHIELDS (PINK) FOR USE WITH AIRSHIELDS C100,C200,C550 AND PM78s	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10
28.	STS-202	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIB	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
29.	STS-203	SKIN TEMP PROBE NEO-OHMEDA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
30.	STS-204	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
31.	STS-205	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
32.	STS-206	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
33.	STS-207	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
34.	STS-209	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10
35.	STS-400	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
36.	STS-700	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
37.	STS-70S	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
38.	STS-TC	NEO-THERM SKIN TEMP SENSOR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
39.	TTS-400	TEMP SENSORE TYMPANIC (400)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
40.	TTSP-400	PEDIATRIC TYMPANIC 400 SERIES	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
41.	TTS-70S	70S TYMPANIC	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10
42.	TTSP-TC	PEDIATRIC TYMPANIC- THEROCOUPLE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	IIb	10

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
43.	TTS-TC	TEMP SENSOR TYMPANIC (TC)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	35254	I Ib	10

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
003	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. Replaced the validity date with "In conjunction with the associated notified body certificate. Changed the EC Cert # to match product certificate, Annex and Authorized Signatory. Changed document number format from SXXX to DoCXXX (from S1127 to DoC-104) to load documents into Agile. No updates made to content of this document with the exception of removed product code ES70S-9 as this product is obsolete, ER70S-12 and TTSP-70S as these products are inactive and identified for obsolescence, the revision from 002 to 003 and added STED # to header for traceability to STED. Transferred content of document to revision 002 of the DoC template, FM-DVDP1509-01.	Brent Pearson	29-SEP-2017
104	The purpose of this revision is to reflect the changes associated with recertification of MMSP EC Cert 669121, the changes include: Update DoC template to currently Agile released form rev. 003, Legal Manufacturer changed to Nathan Lane, new signatory.	Dominique Neisz	10-AUG-2018
105	-Updated the DoC to the latest template in Agile from Rev 003 to 105 -Updated the STED Name from Level 1® Temperature Probes to Level 1® General Purpose Temperature Probes to match the STED Name 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	Mitchell Madsen	12-SEP-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-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 the Product Tradename from “N/A” to “Level 1®, Acoustascope® esophageal stethoscope, Neo-Therm® skin-contact thermometer for use with infants, Bi-Temp® temperature monitor with disposable probes” to reflect the tradenames of the affected products. -Updated the Product Descriptions of the Catalog Numbers in Appendix 1 to match their Descriptions in Agile -Modified Tijuana’s Manufacturing Site address to match the address on EC Certificate 669121 -Changed the GMDN Code for ES100-12, ES100-18, ES100-24, ES100-9, ES400-12, ES400-18, ES400-24, ES400-9, ES700-12, ES700-18, ES700-24, ES700-9, ES70S-12, ES70S-18, ES70S-24, ESTC-9, ESTC-12, ESTC-18 and ESTC-24 from 35254 to 44120 to better align with the products’ descriptions.		