

	Declaration of Conformity	DoC-244 Revision Number:102 Effective Date: 15-AUG-2019
	S1252: Level 1® Convective Warmer	

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): Level 1® Convective Warmers

Product Scope: Patient Warming Units

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: BSI Healthcare
 Medical Devices Certificate
 Notified Body # 2797

EC Certificate Number: CE 669121

Start of CE-Marking: 2017-07-20

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: 15 AUG 2019

Name: Tyler Foutch _____

Title: Manager, Regulatory Affairs _____

Location of Signatory: Minneapolis, MN 55442, USA _____

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	L1-CW-220V	Level 1® Convective Warmer - 220 Volt Configuration	Minnetronix, Inc. 1635 Energy Park Drive St. Paul, MN 55108 USA	N/A	36954	IIb	9
2.	L1-PWR-EU	Power Cord for use with the Level 1® Convective Warmer - Plug Type CEE 7/7			36092		
3.	L1-PWR-G	Power Cord for use with the Level 1® Convective Warmer - Plug Type G					
4.	L1-PWR-L	Power Cord for use with the Level 1® Convective Warmer - Plug Type L					
5.	L1-PWR-I	Power Cord for use with the Level 1 Convective Warmer - Plug Type I					
6.	L1-PWR-K	Power Cord for use with the Level 1 Convective Warmer - Plug Type K					
7.	L1-PWR-J	Power Cord for use with the Level 1 Convective Warmer - Plug Type J					
8.	L1-PWR-EU-5	5m Power Cord for use with the Level 1® Convective Warmer - Plug Type CEE 7/7					
9.	L1-PWR-G-5	5m Power Cord for use with the Level 1® Convective Warmer - Plug Type G					
10.	L1-PWR-L-5	5m Power Cord for use with the Level 1® Convective Warmer - Plug Type L					
11.	L1-PWR-I-5	5m Power Cord for use with the Level 1 Convective Warmer - Plug Type I					
12.	L1-PWR-K-5	5m Power Cord for use with the Level 1 Convective Warmer - Plug Type K					
13.	L1-PWR-J-5	5m Power Cord for use with the Level 1 Convective Warmer - Plug Type J					

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	L1-HOSE	Hose for use with the Level 1® Convective Warmer	Minnetronix, Inc. 1635 Energy Park Drive	N/A	36954	Class I ns/nm	12

 bringing technology to life	Declaration of Conformity	DoC-244 Revision Number:102
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			St. Paul, MN 55108 USA				
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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
100	Initial release of Declaration of Conformity	A. Haider	26-JUL-2018
101	No Change to DoC content Revision change due to EU STED S1252 update for CE Mark additional labeling, before market release to Europe	K. Evenson	09 August 2018
102	Addition of 5m power cords. Modified product scope, authorized representative address, and notified body number to align with currently issued 669121 Certificate. Updated Authorized Signatory to Tyler Foutch.	D. Neisz	09-JUL-2019