

	Declaration of Conformity	DoC-107 Revision Number: 111
	S1131: Convective Warming Blankets	

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 - Mesto
753 01 Hranice, Czech Republic

Product Tradename(s): Snuggle Warm® patient warming blanket

Product Scope: Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets

Conformity Assessment Route: Annex VII (for Non-Sterile Versions)
Annex II (excluding Section 4) (for Sterile Versions)

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

EC Certificate Number: CE 669121 (for Sterile Versions)

Start of CE-Marking: MAR, 2015

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: 05 AUG 2019

Name: Wendy Hills

Title: Manager, Regulatory Affairs

Location of Signatory: Minneapolis, MN, 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.	SWU-2001	SNUGGLE WARM, ADULT FULL BODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman KM 21.7 Parque Industrial Monterrey, Apodaca Nuevo Leon 666003 Mexico	N/A	47681	I	1
2.	SWU-2002	SNUGGLE WARM, PEDIATRIC FULL BODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
3.	SWU-2003	SNUGGLE WARM, UPPER BODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman KM 21.7 Parque Industrial Monterrey, Apodaca Nuevo Leon 666003 Mexico	N/A	47681	I	1
4.	SWU-2004	SNUGGLE WARM, LOWER BODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman KM 21.7 Parque Industrial Monterrey, Apodaca Nuevo Leon 666003 Mexico	N/A	47681	I	1
5.	SWU-2007	SNUGGLE WARM, TUBE CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
6.	SWU-2008	SNUGGLE WARM, STERILE CARDIAC CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47682	Is	1
7.	SWU-2009	SNUGGLE WARM, PEDIATRIC UNDERBODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
8.	SWU-2010	SNUGGLE WARM, SMALL UPPER BODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
9.	SWU-2011	SNUGGLE WARM, LARGE PEDIATRIC UNDERBODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
10.	SWU-2013	SNUGGLE WARM, ADULT UNDERBODY CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
11.	SWU-2014L	SNUGGLE WARM, LEFT LATERAL ACCESS CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
12.	SWU-2014R	SNUGGLE WARM, RIGHT LATERAL ACCESS CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
13.	SWU-2016	SNUGGLE WARM, FULL BODY SPLIT ACCESS CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
14.	SWU-2018	SNUGGLE WARM, MULTI-ACCESS CONVECTIVE WARMING BLANKET 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
15.	SWU-2113	SNUGGLE WARM, ADULT UNDERBODY CONVECTIVE	Smiths Healthcare Manufacturing S.A. de C.V.	N/A	47681	I	1

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
		WARMING BLANKET WITH ARM OPENINGS 10/BX	Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico				
16.	SWU-2119	SNUGGLE WARM CONVECTIVE WARMING PONCHO BLANKET WITH ARM OPENINGS 10/BX	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	N/A	47681	I	1
17.	SWU-9001	ADAPTER ASSEMBLY, BH 505 1/EA	Adaero Precision Components Ltd, Downend, Lords Meadow Industrial Estate, Crediton, Devon, EX17 1HN, England	N/A	47681	I ns/nm	1
18.	SWU-9002	HOSE ADAPTER ASSEMBLY, BH 750 1/EA	Adaero Precision Components Ltd, Downend, Lords Meadow Industrial Estate, Crediton, Devon, EX17 1HN, England	N/A	47681	I ns/nm	1
19.	SWU-9003	HOSE ADAPTER ASSEMBLY, MA PLUS 1/EA	Adaero Precision Components Ltd, Downend, Lords Meadow Industrial Estate, Crediton, Devon, EX17 1HN, England	N/A	47681	I ns/nm	1
20.	SWU-9004	HOSE ADAPTER ASSEMBLY, COVIDIEN 1/EA	Adaero Precision Components Ltd, Downend, Lords Meadow Industrial Estate, Crediton, Devon, EX17 1HN, England	N/A	47681	I ns/nm	1

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
05	Updated to New Template; Updated EC Cert Info	Lisa Hahne	14-DEC-2017
06	Updating the EU Representative to Ashford from N/A	Mitchell Madsen	30-MAR-2017
007	Change document number format from SXXX to DoCXXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1131 to DoC-107 and revision from 006 to 007 and added STED # to header for traceability to STED. Removed Notified Body address for consistency across all DoCs.	Callie Frick	05-JUN-2017
108	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
109	Modify Product Scope to include Non-Sterile versions. Modify Conformity Assessment Route to be Annex VII for Sterile Versions, in addition to Annex II. Correct classifications to Class I for Non-Sterile and Class Is for Sterile Versions.	Ken Meyer	17-MAY-2018
110	Expand Scope statement to include 'Non-Sterile'. Clarify that the CE certificate applies to Sterile version only. Correct Manufacturing locations for SWU-2001, SWU-2003 and SWU-2004.	Ken Meyer	25-OCT-2018
111	Updated to latest template revision (from 003 to 104). 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. Updated Scope per Ken Meyer from Non-Sterile and Sterile Convective Warming Blankets to "Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets" to align with EC Certificate 669121	Alicia Wilson	25-JUL-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	Changed formatting by unmerging cells in Appendix 1. Changed SKU descriptions to match descriptions in Agile. 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 remains 669121. Added SWU-9001, SWU-9002, SWU-9003, SWU-9004 from DoC-176 as all SKUs are Class I and relate to the same STED (S1131). Removed SW-2001, SW-2002, SW-2003, SW-2004, SW-2007, SW-2008, SW-2009, SW-2011, SW-2013, SW-2014R, SW-2113 as they have been in phase out for 2 years, there's no inventory, they are blocked in the EU, and they are going end of life.		