smiths medical bringing technology to life	**Declaration of Conformity** S1164: Pulse Oximetry	DoC-123 Revision Number: 104 Effective Date: 10-AUG-2018

Manufacturer:	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55443
EU Representative:	Smiths Medical International, Ltd. 1500 Eureka Park, Lower Pemberton Ashford, TN25 4BF, UK
Product Tradename(s):	BCI™ 3178 pediatric pulse oximetry sensor, BCI® patient vital signs monitoring
Product Scope:	Sterile & Non-Sterile Vital Sign Monitoring Probes
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Devices Certification (Notified body# 0086)
EC Certificate Number:	669121
Start of CE-Marking:	JUL, 2017

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: G. Barrett Date: 10-Aug-2018

Name: Gary Barrett

Title: VP, Quality Systems

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.	1300	Sensor, Oximetry, Disposable, Adult Finger	OSI Optoelectronics 12525 Chadron Ave Hawthorne CA, USA 90250	N/A	31658	IIa	10
2.	1301	Sensor, Oximetry, Disposable, Pediatric Finger, 15-45 kg		N/A	31658	IIa	10
3.	1302	Sensor, Oximetry, Disposable, Small Infant, <3 kg		N/A	31658	IIa	10
4.	1303	Sensor, Oximetry, Disposable, Infant, 3-15 kg		N/A	31658	IIa	10
5.	3025	Sensor, Oximetry, Wrap, Infant, 3-15 kg		N/A	37808	IIa	10
6.	3026	Sensor, Oximetry, Small Infant, <3 kg		N/A	37808	IIa	10
7.	3043	Sensor, Oximetry, Universal "Y"		N/A	37808	IIa	10
8.	3044	Sensor, Oximetry, Finger		N/A	37808	IIa	10
9.	3044S	Spot Check Sensor, Reusable, Adult		N/A	37808	IIa	10
10.	WW3078	Sensor, Oximetry, Ear		N/A	37808	IIa	10
11.	3444	Sensor, Oximetry, Finger, Comfort Clip®		N/A	37808	IIa	10
12.	3178	Pediatric Pulse Oximetry Sensor		N/A	37808	IIa	10
13.	3311	Cable, Oximetry, 1.5 m (5 feet)	Axcesor Inc 2260 Dakota Drive Grafton Wi, US 53024-9429	N/A	37808	IIa	10
14.	3311L	Cable, Oximetry, 15 ft.		N/A	37808	IIa	10
15.	3049	Strips, Adhesive	Smiths Medical ASD, Inc. 3350 Granada Ave. Oakdale, MN 55128	N/A	31658	IIa	10
16.	3134	Attachment Tape, Neonate, 50 pack		N/A	31658	IIa	10
17.	3135	Attachment Tape, Infant, 50 pack		N/A	31658	IIa	10
18.	3137	Attachment Tape, Infant, 100 pack		N/A	31658	IIa	10
19.	WW3138	Wrap, Universal "Y" Posey		N/A	37808	IIa	10

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, removed the effective by date, removed date from the Valid until statement replaced with "In conjunction with the associated notified body certificate," and Authorized Signatory. Converted document into Rev. 002 formatting. Omitted notified body address for consistency across all DoCs. Changed 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 S1164 to DoC-123 and revision from 002 to 003, removed product codes 3109, 3136 and 3178S as each of them are identified for obsolescence and added STED # to header for traceability to STED.	Brent Pearson	10-AUG-2017
104	The purpose of this revision is to reflect the changes associated with recertification of MMSP EC Cert 669121. The changes include: Updated legal manufacturer, product trademark and scope, new signatory, corrections to manufacturing site information. Update document template to currently released DoC template.	Dominique Neisz	10-AUG-2018