smiths medical bringing technology to life	**Declaration of Conformity** S1062: Bivona Tracheostomy Tube Inner Cannula	DoC-066 Revision Number: 107

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):	Bivona® tracheostomy tubes and connectors
Product Scope:	Sterile and non-Sterile tracheostomy accessories
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Device Certification Notified Body #2797
EC Certificate Number:	CE 669121
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: 08AUG2019

Name: Tyler Foutch

Title: Manager, Regulatory Affairs

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.	BRCA70	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 7.0MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
2.	BRCA75	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 7.5MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
3.	BRCA80	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 8.0MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
4.	BRCA85	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 8.5MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
5.	BRCA90	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 9.0MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
6.	BRC270	Bivona Replacement Inner Cannula for Size 7MM Tracheostomy Tubes	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
7.	BRC275	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 7.5MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
8.	BRC280	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 8.0MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
9.	BRC285	Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes, Size 8.5MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5
10.	BRC290	Bivona Replacement Inner Cannula for Size 9MM Tracheostomy Tubes	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	14089	IIa	5

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
002	Updating the DoC to the latest Template; Changing the Manufacturing Site for BRCA70 – BRC290 to TIJ from Gary	Mitchell Madsen	25-JAN-2017
003	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 S1062 to DoC-066 and revision from 002 to 003 and added STED # to header for traceability to STED. The Changes to this DoC include: Notified Body cert number from 551 CE to 551-01 CE and changed the effective date	Manasa Boppana	11-AUG-2017
004	Updated to new template, Rev 003, removed the product code BICSWB and added to DoC-209 as it is Class Ins/nm and is self-certified.	Manasa Boppana	07-NOV-2017
105	Updated the EC Certificate Number from 551-01 CE to 551-02 CE because the certificate 551-01 CE has expired and 551-02 CE is the replacement certificate. Removed Bivona® from the Product Scope to just Tracheostomy Tube Inner Cannula. Updated the Revision Number from 004 to 105 to follow new update to DVSOP2005.	Mitchell Madsen	26-JUN-2018
106	Intertek AMTAC closed its offices on June 30, 2018. Smiths Medical transferred certification of the products covered under this DoC from Intertek AMTAC to Intertek SEMKO AB as of July 1, 2018. Therefore, the following changes were made to the DoC. Added Notified Body Intertek SEMKO #0413. Added the Intertek SEMKO Certificate Number 41377460-00. Changed the Authorized Signatory from Stacy Novak to Gary Barrett for Regulatory Affairs approval. Changed the Start of CE Marking from July 2002 to 27 Mar 2015. Updated the Revision Number from 105 to 106.	Mitchell Madsen	27-NOV-2018

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	No other technical content review or updates were performed during the revision update.		
107	Updated to newest template revision (from rev 003 to 104). Changed the legal manufacturer from MGAR to MMSP as per FM-DVSOP8005-05. Updated STED title in header from “Bivona Tracheostomy Inner Cannula” to “Bivona Tracheostomy Tube Inner Cannula” to reflect the STED’s description 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. Changed the Notified Body from Intertek SEMKO to BSI and the EC Certificate from 41377460-00 to CE 669121 as the Notified Body for the SKUs on this DoC has changed from SEMKO to BSI. Revised the Product Scope from “Tracheostomy tube Inner cannula” to “Sterile and non-Sterile tracheostomy accessories” to match scope in EC Certificate 669121. Revised product descriptions to match the description in Agile. Revised the Tijuana Manufacturing Site address to match the address on EC 669121.	Alicia Wilson	08-AUG-2019