	Declaration of Conformity	DoC-164 Revision Number: 102
	S1231: Blue Line Ultra (BLU) Tracheostomy Tubes	

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 - Mesto,
753 01 Hranice, Czech Republic

Product Tradename(s): Portex®, Blue Line Ultra®, BLUselect®, Suctionaid®, BLUperc®, BLUgriggs®

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: 29 Jan 2020

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN US

	Declaration of Conformity	DoC-164 Revision Number: 102
	S1231: Blue Line Ultra (BLU) Tracheostomy Tubes	

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
100	Initial Release for NPI PAEDS Project 1559 with FDA edits for home use in IFU; ISO 5366 partial compliance; and Hythe as LM.	Kristen Evenson	25-JUN-2018
101	Corrected Tijuana's address Added BLUselect tracheostomy tubes, BLUselect Suctionaid tracheostomy tubes and BLUselect tracheostomy Inner Cannulas BLUgriggs Percutaneous Dilation Tracheostomy Kits BLUperc Percutaneous Dilation Tracheostomy Kits LM Change from Hythe, UK to Minneapolis, MN US Added Hranice, Czech Republic as a Manufacturing site. Changed Signatory as Donna Semlak is no longer with Smiths Medical.	Kristen Evenson	18-JAN-2019
102	Updated to current DoC template (from 003 to 106), which includes moving the SKUs from Appendix 1 to an attached spreadsheet. Removed Kent Legal Manufacturer address as Smiths Medical ASD, Inc. is the current Legal Manufacturer. 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 notified body number (from 0086 to 2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. The EC Certificate number remains the same.	Nancy DeAngelo	28-JAN-2020

[logo:] Smiths medical bringing technology to life [zmieniamy technologię w życie]	Deklaracja zgodności	DoC-164 Wydanie numer: 102
	S1100: Rurki tracheostomijne Blue Line Ultra (BLU)	

Producent	Smiths Medical ASD, Inc., 6000 Nathan Lane North Minneapolis, Minnesota 55442, USA
Przedstawiciel w UE (jeśli dotyczy)	Smiths Medical Czech Republic a. s. Olomoucká 306, Hranice 1 – Mesto, 753 01 Hranice, Czech Republic
Nazwa handlowa Produktu	Portex [®] , Blue Line Ultra [®] , BLUselect [®] , Suctionaid [®] , BLUperc [®] , BLUgriggs [®] ,
Metoda Oceny Zgodności	Załącznik II (z wyłączeniem sekcji4)
Jednostka Notyfikowana	BSI Healthcare Certyfikacja sprzętu medycznego Jednostka Notyfikowana #0123
Numer certyfikatu CE	CE669121

Smiths Medical ASD, Inc. niniejszym oświadcza, że te produkty są zgodne z odpowiednimi przepisami dyrektywy Parlamentu Europejskiego i Rady 93/42/EWG dotyczącej Wyrobów Medycznych (MDD) oraz ze zmianami wprowadzonymi przez dyrektywę 2007/47/WE.

Autoryzowany Sygnatariusz:

<u>Podpis: /-/</u>	<u>Data: 29 stycznia 2020r.</u>
<u>Imię i nazwisko: Stacy Novak</u>	
<u>Tytuł: Dyrektor ds. Regulacyjnych</u>	
<u>Miejsce podpisania dokumentu: Minneapolis, MN, USA</u>	

[logo:] Smiths medical bringing technology to life [zmieniamy technologię w życie]	Deklaracja zgodności	DoC-164 Wydanie numer: 102
	S1100: Rurki tracheostomijne Blue Line Ultra (BLU)	

Dodatek 1: Historia wersji

Numer wersji	Podsumowanie zmian/ dodatków	Stworzone/ poprawione przez	data
100	Pierwsza wersja projektu NPI PAEDS 1559 z edycjami FDA dla użytku domowego w IFU; Częściowa zgodność z ISO 5366; i Hythe jako LM.	Kristen Evenson	25.06.2018
101	Poprawiono adres Tijuany Dodano rurki tracheostomijne BLUselect, BLUselect Rurki tracheostomijne z odsysaniem i BLUselect Tracheostomia Wewnętrzne kaniule BLUgriggs Zestawy do przezskórnej dylatacji tracheostomijnej BLUperc Zestawy do przezskórnej dylatacji tracheostomijnej LM Zmiana z Hythe w Wielkiej Brytanii do Minneapolis w stanie Minnesota Dodano Hranice, Republika Czeska jako miejsce produkcji. Zmieniono sygnatariusza, ponieważ Donna Semlak nie pracuje już w Smiths Medical.	Kristen Evenson	18.01.2019
102	Zaktualizowano do aktualnego szablonu DoC (od 003 do 106), który obejmuje przeniesienie jednostek SKU z Załącznika 1 do załączonego arkusza kalkulacyjnego. Usunięto adres legalnego producenta w Kent, ponieważ aktualnym legalnym producentem jest Smiths Medical ASD, Inc. Zmiana przedstawiciela UE z Ashford w Wielkiej Brytanii na Hranice w Czechach. Przedstawiciel UE jest potrzebny, jeśli produkt jest dystrybuowany komercyjnie w UE i nie jest produkowany w UE. Ponieważ Ashford nie będzie już częścią UE z powodu Brexitu, przedstawiciel UE został zmieniony z zakładu w Ashford na zakład w Hranicach. Zaktualizowano numer jednostki notyfikowanej (od 0086 do 2797), ponieważ BSI przenosi wydane certyfikaty z Wielkiej Brytanii do Holandii z powodu Brexitu. Numer Certyfikatu WE pozostaje bez zmian.	Kristen Evenson	28.01.2020

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
101/800/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 6.0mm	35404	IIb	5
101/800/060CZ				
101/800/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.0mm	35404	IIb	5
101/800/070CZ				
101/800/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.5mm	35404	IIb	5
101/800/075CZ				
101/800/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.0mm	35404	IIb	5
101/800/080CZ				
101/800/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.5mm	35404	IIb	5
101/800/085CZ				
101/800/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 9.0mm	35404	IIb	5
101/800/090CZ				
101/800/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 10.0mm	35404	IIb	5
101/800/100CZ				
101/802/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 6.0mm	35404	IIb	5
101/802/060CZ				
101/802/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 7.0mm	35404	IIb	5
101/802/070CZ				
101/802/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 7.5mm	35404	IIb	5
101/802/075CZ				
101/802/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.0mm	35404	IIb	5
101/802/080CZ				
101/802/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.5mm	35404	IIb	5
101/802/085CZ				
101/802/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 9.0mm	35404	IIb	5
101/802/090CZ				
101/802/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 10.0mm	35404	IIb	5
101/802/100CZ				
101/810/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 6.0mm	35404	IIb	5
101/810/060CZ				
101/810/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.0mm	35404	IIb	5
101/810/070CZ				
101/810/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.5mm	35404	IIb	5
101/810/075CZ				
101/810/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.0mm	35404	IIb	5
101/810/080CZ				
101/810/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.5mm	35404	IIb	5
101/810/085CZ				
101/810/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 9.0mm	35404	IIb	5
101/810/090CZ				
101/810/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 10.0mm	35404	IIb	5
101/810/100CZ				
101/811/060	BLUselect® Tracheostomy Tube, Uncuffed, 6.0mm	35404	IIb	5
101/811/060CZ				
101/811/070	BLUselect® Tracheostomy Tube, Uncuffed, 7.0mm	35404	IIb	5
101/811/070CZ				
101/811/075	BLUselect® Tracheostomy Tube, Uncuffed, 7.5mm	35404	IIb	5
101/811/075CZ				
101/811/080	BLUselect® Tracheostomy Tube, Uncuffed, 8.0mm	35404	IIb	5
101/811/080CZ				
101/811/085	BLUselect® Tracheostomy Tube, Uncuffed, 8.5mm	35404	IIb	5
101/811/085CZ				
101/811/090	BLUselect® Tracheostomy Tube, Uncuffed, 9.0mm	35404	IIb	5
101/811/090CZ				
101/811/100	BLUselect® Tracheostomy Tube, Uncuffed, 10.0mm	35404	IIb	5
101/811/100CZ				
101/812/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 6.0mm	35404	IIb	5
101/812/060CZ				
101/812/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 7.0mm	35404	IIb	5
101/812/070CZ				
101/812/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 7.5mm	35404	IIb	5
101/812/075CZ				
101/812/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.0mm	35404	IIb	5
101/812/080CZ				
101/812/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.5mm	35404	IIb	5

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
101/812/085CZ	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.5mm	35404	IIb	5
101/812/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 9.0mm	35404	IIb	5
101/812/090CZ	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 9.0mm	35404	IIb	5
101/812/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 10.0mm	35404	IIb	5
101/812/100CZ	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 10.0mm	35404	IIb	5
101/813/060	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 6.0mm	35404	IIb	5
101/813/060CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 6.0mm	35404	IIb	5
101/813/070	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 7.0mm	35404	IIb	5
101/813/070CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 7.0mm	35404	IIb	5
101/813/075	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 7.5mm	35404	IIb	5
101/813/075CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 7.5mm	35404	IIb	5
101/813/080	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 8.0mm	35404	IIb	5
101/813/080CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 8.0mm	35404	IIb	5
101/813/085	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 8.5mm	35404	IIb	5
101/813/085CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 8.5mm	35404	IIb	5
101/813/090	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 9.0mm	35404	IIb	5
101/813/090CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 9.0mm	35404	IIb	5
101/813/100	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 10.0mm	35404	IIb	5
101/813/100CZ	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 10.0mm	35404	IIb	5
101/815/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 6.0mm	35404	IIb	5
101/815/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.0mm	35404	IIb	5
101/815/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 7.5mm	35404	IIb	5
101/815/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.0mm	35404	IIb	5
101/815/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 8.5mm	35404	IIb	5
101/815/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 9.0mm	35404	IIb	5
101/815/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, 10.0mm	35404	IIb	5
101/816/060	BLUselect® Tracheostomy Tube, Uncuffed, 6.0mm	35404	IIb	5
101/816/070	BLUselect® Tracheostomy Tube, Uncuffed, 7.0mm	35404	IIb	5
101/816/075	BLUselect® Tracheostomy Tube, Uncuffed, 7.5mm	35404	IIb	5
101/816/080	BLUselect® Tracheostomy Tube, Uncuffed, 8.0mm	35404	IIb	5
101/816/085	BLUselect® Tracheostomy Tube, Uncuffed, 8.5mm	35404	IIb	5
101/816/090	BLUselect® Tracheostomy Tube, Uncuffed, 9.0mm	35404	IIb	5
101/816/100	BLUselect® Tracheostomy Tube, Uncuffed, 10.0mm	35404	IIb	5
101/817/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 6.0mm	35404	IIb	5
101/817/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 7.0mm	35404	IIb	5
101/817/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 8.0mm	35404	IIb	5
101/817/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 9.0mm	35404	IIb	5
101/817/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Fenestrated, 10.0mm	35404	IIb	5
101/818/060	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 6.0mm	35404	IIb	5
101/818/070	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 7.0mm	35404	IIb	5
101/818/080	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 8.0mm	35404	IIb	5
101/818/090	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 9.0mm	35404	IIb	5
101/818/100	BLUselect® Tracheostomy Tube, Uncuffed, Fenestrated, 10.0mm	35404	IIb	5
101/850/060	BLUselect® Tracheostomy Tube Inner Cannula, 6.0mm	45920	IIb	5
101/850/060CZ	BLUselect® Tracheostomy Tube Inner Cannula, 6.0mm	45920	IIb	5
101/850/070	BLUselect® Tracheostomy Tube Inner Cannula, 7.0mm	45920	IIb	5
101/850/070CZ	BLUselect® Tracheostomy Tube Inner Cannula, 7.0mm	45920	IIb	5
101/850/075	BLUselect® Tracheostomy Tube Inner Cannula, 7.5mm	45920	IIb	5
101/850/075CZ	BLUselect® Tracheostomy Tube Inner Cannula, 7.5mm	45920	IIb	5
101/850/080	BLUselect® Tracheostomy Tube Inner Cannula, 8.0mm	45920	IIb	5
101/850/080CZ	BLUselect® Tracheostomy Tube Inner Cannula, 8.0mm	45920	IIb	5
101/850/085	BLUselect® Tracheostomy Tube Inner Cannula, 8.5mm	45920	IIb	5
101/850/085CZ	BLUselect® Tracheostomy Tube Inner Cannula, 8.5mm	45920	IIb	5
101/850/090	BLUselect® Tracheostomy Tube Inner Cannula, 9.0mm	45920	IIb	5
101/850/090CZ	BLUselect® Tracheostomy Tube Inner Cannula, 9.0mm	45920	IIb	5
101/850/100	BLUselect® Tracheostomy Tube Inner Cannula, 10.0mm	45920	IIb	5
101/850/100CZ	BLUselect® Tracheostomy Tube Inner Cannula, 10.0mm	45920	IIb	5
101/851/060	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 6.0mm	45920	IIb	5
101/851/060CZ	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 6.0mm	45920	IIb	5
101/851/070	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 7.0mm	45920	IIb	5
101/851/070CZ	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 7.0mm	45920	IIb	5
101/851/075	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 7.5mm	45920	IIb	5
101/851/075CZ	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 7.5mm	45920	IIb	5
101/851/080	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 8.0mm	45920	IIb	5
101/851/080CZ	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 8.0mm	45920	IIb	5

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
101/851/085	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 8.5mm	45920	IIb	5
101/851/085CZ				
101/851/090	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 9.0mm	45920	IIb	5
101/851/090CZ				
101/851/100	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 10.0mm	45920	IIb	5
101/851/100CZ	BLUselect® Tracheostomy Tube Inner Cannula, Fenestrated, 10.0mm	45920	IIb	5
101/856/060	BLUselect® Tracheostomy Tube Inner Cannula, 6.0mm	45920	IIb	5
101/856/070	BLUselect® Tracheostomy Tube Inner Cannula, 7.0mm	45920	IIb	5
101/856/075	BLUselect® Tracheostomy Tube Inner Cannula, 7.5mm	45920	IIb	5
101/856/080	BLUselect® Tracheostomy Tube Inner Cannula, 8.0mm	45920	IIb	5
101/856/085	BLUselect® Tracheostomy Tube Inner Cannula, 8.5mm	45920	IIb	5
101/856/090	BLUselect® Tracheostomy Tube Inner Cannula, 9.0mm	45920	IIb	5
101/856/100	BLUselect® Tracheostomy Tube Inner Cannula, 10.0mm	45920	IIb	5
101/858/060	BLUselect® Tracheostomy Tube Inner Cannula, 6.0mm	45920	IIb	5
101/858/070	BLUselect® Tracheostomy Tube Inner Cannula, 7.0mm	45920	IIb	5
101/858/075	BLUselect® Tracheostomy Tube Inner Cannula, 7.5mm	45920	IIb	5
101/858/080	BLUselect® Tracheostomy Tube Inner Cannula, 8.0mm	45920	IIb	5
101/858/085	BLUselect® Tracheostomy Tube Inner Cannula, 8.5mm	45920	IIb	5
101/858/090	BLUselect® Tracheostomy Tube Inner Cannula, 9.0mm	45920	IIb	5
101/858/100	BLUselect® Tracheostomy Tube Inner Cannula, 10.0mm	45920	IIb	5
101/860/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 6.0mm	35404	IIb	5
101/860/060CZ				
101/860/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.0mm	35404	IIb	5
101/860/070CZ				
101/860/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.5mm	35404	IIb	5
101/860/075CZ				
101/860/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.0mm	35404	IIb	5
101/860/080CZ				
101/860/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.5mm	35404	IIb	5
101/860/085CZ				
101/860/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 9.0mm	35404	IIb	5
101/860/090CZ				
101/860/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 10.0mm	35404	IIb	5
101/860/100CZ				
101/870/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 6.0mm	35404	IIb	5
101/870/060CZ				
101/870/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.0mm	35404	IIb	5
101/870/070CZ	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.0mm	35404	IIb	5
101/870/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.5mm	35404	IIb	5
101/870/075CZ				
101/870/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.0mm	35404	IIb	5
101/870/080CZ				
101/870/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.5mm	35404	IIb	5
101/870/085CZ				
101/870/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 9.0mm	35404	IIb	5
101/870/090CZ				
101/870/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 10.0mm	35404	IIb	5
101/870/100CZ				
101/875/060	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 6.0mm	35404	IIb	5
101/875/070	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.0mm	35404	IIb	5
101/875/075	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 7.5mm	35404	IIb	5
101/875/080	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.0mm	35404	IIb	5
101/875/085	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 8.5mm	35404	IIb	5
101/875/090	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 9.0mm	35404	IIb	5
101/875/100	BLUselect® Tracheostomy Tube, Soft-Seal® Cuff, Suctionaid®, 10.0mm	35404	IIb	5
101/561/070	BLUperc® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/561/080	BLUperc® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/561/090	BLUperc® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5
101/562/000	BLUperc® Percutaneous Dilation Tracheostomy Kit, 10.0mm	14099	IIb	5
101/563/070	BLUperc® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/563/080	BLUperc® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/563/090	BLUperc® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5
101/541/070	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/541/080	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/541/090	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
101/543/070	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/543/080	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/543/090	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5
101/891/070	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/891/080	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/891/090	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5
101/893/070	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 7.0mm	14099	IIb	5
101/893/080	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 8.0mm	14099	IIb	5
101/893/090	BLUgriggs® Percutaneous Dilation Tracheostomy Kit, 9.0mm	14099	IIb	5