BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan. 24888
☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
✉ : info@besmed.com 🌐 : www.besmed.com

EC Declaration of Conformity

Manufacturers Name:	Besmed Health Business Corp.
Manufacturers Address:	No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
SRN (Single Registration Number) of Manufacturer:	TW-MF-000007246
Authorized Representative Name (if applicable):	Casus Europe B.V.
Authorized Representative Address	Lange Viestraat 2b, Utrecht, 3511 BK, The Netherlands.
SRN (Single Registration Number) of Authorized Representative:	NL-AR-000037688
Basic UDI-DI:	4716770PN08400KY
Name of the Device Group (s):	SILICONE PENROSE TUBE (STERILE)
Product (MDN) code:	1202
European Medical Device Nomenclature (EMDN):	A0601010403
Conformity assessment route:	Conformity assessment based on a Quality Management System, and technical documentation (Annex IX of MDR 2017/745).
Intended use:	Besmed Silicone Penrose Tube (Sterile) is a surgical device placed in a wound to drain fluid. It consists of a soft silicone tube placed in a wound area, to prevent to buildup of fluid.
Classification:	CLASS IIa, **Rule 7**: Besmed Silicone Penrose Tube (Sterile) belongs to surgical invasive device intended for short term use
Notified Body Name:	DEKRA Certification B.V.
Notified Body Address:	Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands
Notified Body Identification number:	NB 0344
Harmonized standards or CS are applied:	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 20417:2021, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-18:2020, EN ISO 10993-11:2020 , EN ISO 15223-1:2021, ISTA 2A-2011, ASTM F1140/F1140M-13, ASTM F88-23, ASTM F1929-15, ASTM F1980-21, ASTM F1608-21, EN ISO 20697:2018
CE certificate no.	6170840CE01

This declaration of conformity is issued under the sole responsibility of Besmed Health Business Corp. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR

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2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V.

All supporting documentation is retained at the premises of the manufacturer.

Place and date (yyyy.mm.dd) of issue: Taipei, 2024.07.09

Signature:

Sarah Lu

……
Sarah Lu
Vice President
For and on behalf of Besmed

Steven Wong

…….
Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [Silicone Penrose Tube (Sterile)]

SILICONE PENROSE TUBE (STERILE)

Device	Reference number	PJ Ref No.	Description
Silicone Penrose tube	PN-84106	05.000.22.995	Silicone Penrose tube, Round, OD:6mm, L:100mm
	PN-84306	05.000.22.760	Silicone Penrose tube, Round, OD:6mm, L:300mm
	PN-84308	05.000.22.761	Silicone Penrose tube, Round, OD:8mm, L:300mm
	PN-84310	05.000.22.762	Silicone Penrose tube, Round, OD:10mm, L:300mm
	PN-84312	05.000.22.748	Silicone Penrose tube, Round, OD:12mm, L:300mm
	PN-84314	05.000.22.766	Silicone Penrose perforated tube, Round, OD: 12mm, L: 300mm
	PN-84506	-	Silicone Penrose tube, Round, OD:6mm, L:500 mm
	PN-84508	-	Silicone Penrose tube, Round, OD:8mm, L:500 mm
	PN-84510	-	Silicone Penrose tube, Round, OD:10mm, L:500 mm
	PN-84512	05.000.22.874	Silicone Penrose tube, Round, OD:12mm, L:500 mm
	PN-84206	9781692135	Silicone Penrose tube, Flat, OD:6mm, L:300 mm
	PN-84208	9781692127	Silicone Penrose tube, Flat, OD:8mm, L:300 mm
	PN-84210	9781692151	Silicone Penrose tube, Flat, OD:10mm, L:300 mm
	PN-84212	9781692143	Silicone Penrose tube, Flat, OD:12mm, L:300 mm
	PN-8424	9781692224	Silicone Penrose tube, Flat, OD:40mm, L:300 mm

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	PN-84006	9900005006	Silicone Penrose Tube, Flat, O.D: 6mm, L:500 mm
	PN-84008	9900005008	Silicone Penrose Tube, Flat, O.D:8mm, L:500 mm
	PN-84010	9900005010	Silicone Penrose Tube, Flat, O.D: 10mm, L:500 mm
	PN-84012	9900005012	Silicone Penrose Tube, Flat, O.D: 12mm, L:500 mm