

EC Declaration of Conformity

according to the Regulation (EU) 2017/745

of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Class I Medical Device
(non-sterile, without measuring function)

Manufacturers Name:	Sanctuary Health Sdn Bhd
Manufacturers Address:	No 16, Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak, Malaysia.
Manufacturer's SRN (Single Registration Number):	MY-MF-000002197
Authorized Representative Name (if applicable):	cosiMed GmbH
Authorized Representative Address (if applicable):	Pyrmonter Straße 9, 31860 Emmerthal GERMANY
Authorized Representative's SRN (Single Registration Number):	TBD
Basic UDI-DI:	Refer to Attachment 1
Name of the Device (s):	Comprefloss™ Flossband
Product code:	Refer to Attachment 1
Classification:	Class 1 (Non-Sterile, Without Measuring Function)
Rule	1
Notified Body name:	N/A
Notified Body Address:	N/A

Notified Body Identification number: N/A

Intended use Increase joint mobility, training recovery, rehab and stretch.

Conformity assessment route: SANCTUARY HEALTH SDN. BHD. uses the following procedures for the CE-labeling of the products according to the Regulation MDR 2017/745:

Class 1: EC conformity declaration according to Annex IV + Annex II and III Technical Documentation

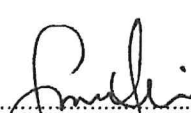
This declaration of conformity is issued under the sole responsibility of SANCTUARY HEALTH SDN. BHD. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DQS.

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

This declaration of conformity is valid for 5 years from the issued date.

for SANCTUARY HEALTH SDN BHD

Place and date of issue:


SUMETHI SELVARAJU
QAQC cum RA Deputy Manager



Sanctuary Health, Chemor, Malaysia.
04 MAY 2021

Attachment 1

Product Code	UDI Barcode		Description
	Colour Box	Carton	
FB003H-DASB0	09555514005115	19555514005112	Comprefloss™ Flossband Lime Green Size: 1.10mm(T) X 2.5cm(W) X 2m(L)
FB003J-DASB0	09555514005122	19555514005129	Comprefloss™ Flossband Blueberry Size: 1.30mm(T) X 2.5cm(W) X 2m(L)
FB003K-DASB0	09555514005139	19555514005136	Comprefloss™ Flossband Plum Size: 1.60mm(T) X 2.5cm(W) X 2m(L)
FB003M-DASB0	09555514005146	19555514005143	Comprefloss™ Flossband Gray Size: 1.80mm(T) X 2.5cm(W) X 2m(L)
FB005H-DASB0	09555514005016	19555514005013	Comprefloss™ Flossband Lime Green Size: 1.10mm(T) X 5cm(W) X 2m(L)
FB005J-DASB0	09555514005023	19555514005020	Comprefloss™ Flossband Blueberry Size: 1.30mm(T) X 5cm(W) X 2m(L)
FB005K-DASB0	09555514005030	19555514005037	Comprefloss™ Flossband Plum Size: 1.60mm(T) X 5cm(W) X 2m(L)
FB005M-DASB0	09555514005047	19555514005044	Comprefloss™ Flossband Gray Size: 1.80mm(T) X 5cm(W) X 2m(L)
FB004H-DASB0	09555514005405	19555514005402	Comprefloss™ Flossband Lime Green Size: 1.10mm(T) X 5cm(W) X 3.5m(L)
FB004J-DASB0	09555514005412	19555514005419	Comprefloss™ Flossband Blueberry Size: 1.30mm(T) X 5cm(W) X 3.5m(L)
FB004K-DASB0	09555514005429	19555514005426	Comprefloss™ Flossband Plum Size: 1.60mm(T) X 5cm(W) X 3.5m(L)
FB004M-DASB0	09555514005436	19555514005433	Comprefloss™ Flossband Gray Size: 1.80mm(T) X 5cm(W) X 3.5m(L)
FB008J-DASB0	09555514005214	19555514005211	Comprefloss™ Flossband Blueberry Size: 1.30mm(T) X 7.5cm(W) X 2m(L)
FB008M-DASB0	09555514005221	19555514005228	Comprefloss™ Flossband Gray Size: 1.80mm(T) X 7.5cm(W) X 2m(L)
FB075H-DASB0	09555514005443	19555514005440	Comprefloss™ Flossband Lime Green Size: 1.10mm(T) X 7.5cm(W) X 3.5m(L)
FB075J-DASB0	09555514005450	19555514005457	Comprefloss™ Flossband Blueberry Size: 1.30mm(T) X 7.5cm(W) X 3.5m(L)
FB075K-DASB0	09555514005467	19555514005464	Comprefloss™ Flossband Plum Size: 1.60mm(T) X 7.5cm(W) X 3.5m(L)
FB075M-DASB0	09555514005474	19555514005471	Comprefloss™ Flossband Gray Size: 1.80mm(T) X 7.5cm(W) X 3.5m(L)