

## Declaration of Conformity COMPRILAN SRT STRETCH BANDAGE

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We,

BSN medical Inc. 5825 Carnegie Blvd. 28209 Charlotte, USA (SRN: NOT ISSUED YET)

hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product name: COMPRILAN SRT STRETCH BANDAGE

Basic UDI-DI: 4042809400352428L

Intended purpose: Comprilan® is intended for phlebological and

lymphological indications to support muscle pump action

and improve the haemodynamics of venous return.

Conformity assessment route: Annex II+III

Classification rule:
Classification:

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

## **European Authorized Representative:**

BSN medical GmbH Quickbornstrasse 24 20253 Hamburg Germany (SRN: NOT ISSUED YET)

Date of Issue: 04/30/2020

## Karla Worley-Ham

Digitally signed by Karla Worley-Ham. DN: Cne-Karla Worley-Ham. DN: Cne-Karla Worley-Ham, one-SBN Medical Inc., an Essity Company, ou=Regulatory Affairs, email=karla.worle. ham@essity.com. c=US
Reason.1 am approving this document

Compiled and released:

Charlotte,, 04/30/2020 Karla Worley-Ham Director Regulatory Affairs, LM NA BSN medical Inc.

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Article	Description	REF
01026-00000-06	COMPRILAN 6CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	01026-00
01026-00001-06	COMPRILAN 6CM X 5MTR TAN 20 DA NL EN FI FR DE IT JA NO PT ES SV	01026-01
01027-00000-07	COMPRILAN 8CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	01027-00
01027-00001-07	COMPRILAN 8CM X 5MTR TAN 20 DA NL EN FI FR DE IT JA NO PT ES SV	01027-01
01028-00000-06	COMPRILAN 10CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	01028-00
01028-00001-06	COMPRILAN 10CM X 5MTR TAN 20 DA NL EN FI FR DE IT JA NO PT ES SV	01028-01
01029-00000-06	COMPRILAN 12CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	01029-00
01029-00001-06	COMPRILAN 12CM X 5MTR TAN 20 DA NL EN FI FR DE IT JA NO PT ES SV	01029-01
01030-00000-05	COMPRILAN 10CM X 5MTR TAN 2 DA NL EN FI FR DE IT JA NO PT ES SV	01030-00
45381-00000-04	COMPRILAN 6CM X 5MTR TAN 10 DA NL EN FI FR DE IT JA NO PT ES SV	45381-00
45382-00000-04	COMPRILAN 8CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	45382-00
45383-00000-04	COMPRILAN 10CM X 5MTR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	45383-00
45384-00000-04	COMPRILAN 12CM X 5MTR TAN 10 DA NL EN FI FR DE IT JA NO PT ES SV	45384-00
77187-00000-02	COMPRILAN 4CM X 5MTR STRETCHED 24 DA NL EN FI FR DE IT JA NO PT ES SV	77187-00
77188-00000-02	COMPRILAN 10CM X 10MTR STRETCHED 20 DA NL EN FI FR DE IT JA NO PT ES SV	77188-00
77189-00000-02	COMPRILAN 12CM X 10MTR STRETCHED 20 DA NL EN FI FR DE IT JA NO PT ES SV	77189-00