

We,

BSN medical Inc.
5825 Carnegie Blvd.
28209 Charlotte,
USA
(SRN: US-MF-000019174)

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

Product Name:

Comprinet® pro & Comprinet® S

Basic UDI-DI:

40428094003437693

Intended purpose:

The intended purpose of the COMPRINET PRO and S compression stockings are for thrombosis prophylaxis in surgical patients and patients requiring prolonged periods of immobilization.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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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
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22761 Hamburg
Germany
(SRN: DE-AR-000005791)

Declaration of conformity issued: 21.06.2024

andreas.matthies

Digitally signed by andreas.matthies
Date: 2024.06.21 14:55:06 +02'00'

Compiled and released:

Charlotte,, 21.06.2024
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
46335-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	46335-00
46335-00002-10	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46335-02
46335-00003-10	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46335-03
46335-00004-10	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46335-04
46335-00005-10	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46335-05
46335-00006-10	COMPRINET PRO THIGH HIGH OPEN TOE LARGE-REGULAR TAN 1 DA NL EN FI FR DE IT JA NO PT ES SV	46335-06
46335-00007-10	COMPRINET PRO THIGH HIGH OPEN TOE LARGE-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46335-07
46335-00012-08	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-REGULAR 1 REPK AU46335-00	46335-12
46336-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	46336-00
46336-00002-08	COMPRINET PRO THIGH HIGH OPEN TOE SMALL-LONG 1 REPK AU46336-00	46336-02
46337-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	46337-00
46337-00002-08	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-REGULAR 1 REPK AU46337-00	46337-02
46338-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	46338-00
46338-00002-08	COMPRINET PRO THIGH HIGH OPEN TOE MEDIUM-LONG 1 REPK AU46338-00	46338-02
46388-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE	46388-00

Article	Description	REF
	LARGE-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	
46388-00002-08	COMPRINET PRO THIGH HIGH OPEN TOE LARGE-REGULAR 1 REPK AU46388-00	46388-02
46389-00000-10	COMPRINET PRO THIGH HIGH OPEN TOE LARGE-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	46389-00
46389-00002-08	COMPRINET PRO THIGH HIGH OPEN TOE LARGE-LONG 1 REPK AU46389-00	46389-02
46630-00000-05	COMPRINET S KNEE HIGH SMALL-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46630-00
46631-00000-05	COMPRINET S KNEE HIGH SMALL-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46631-00
46632-00000-05	COMPRINET S KNEE HIGH MEDIUM-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46632-00
46633-00000-05	COMPRINET S KNEE HIGH MEDIUM-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46633-00
46634-00000-05	COMPRINET S KNEE HIGH LARGE-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46634-00
46635-00000-05	COMPRINET S KNEE HIGH LARGE-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46635-00
46636-00000-05	COMPRINET S KNEE HIGH EXTRA LARGE-REGULAR TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46636-00
46637-00000-05	COMPRINET S KNEE HIGH EXTRA LARGE-LONG TAN 1 DA NL EN FI FR DE IT NO PT ES SV	46637-00
77026-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE SMALL WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77026-00
77026-00002-04	COMPRINET PRO KNEE HIGH OPEN TOE SMALL WHITE 1 REPK AU77026-00	77026-02
77027-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE MEDIUM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77027-00
77027-00002-04	COMPRINET PRO KNEE HIGH OPEN TOE MEDIUM WHITE 1 REPK AU77027-00	77027-02
77028-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE	77028-00

Article	Description	REF
	LARGE WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	
77028-00002-04	COMPRINET PRO KNEE HIGH OPEN TOE LARGE WHITE 1 REPK AU77028-00	77028-02
77029-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE SMALL TAN 1 DA NL EN FI FR DE IT NO PT ES SV	77029-00
77030-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE MEDIUM TAN 1 DA NL EN FI FR DE IT NO PT ES SV	77030-00
77031-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE LARGE TAN 1 DA NL EN FI FR DE IT NO PT ES SV	77031-00
77124-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA LARGE WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77124-00
77124-00001-05	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA LARGE TAN 1 DA NL EN FI FR DE IT NO PT ES SV	77124-01
77124-00004-05	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA EXTRA LARGE TAN 1 DA NL EN FI FR DE IT NO PT ES SV	77124-04
77124-00005-03	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA LARGE WHITE 1 REPK AU77124-00	77124-05
77125-00000-06	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA LARGE-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77125-00
77125-00002-04	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA LARGE-REGULAR WHITE 1 REPK AU77125-00	77125-02
77128-00000-06	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA LARGE-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77128-00
77128-00002-04	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA LARGE-LONG WHITE 1 REPK AU77128-00	77128-02
77130-00000-06	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA EXTRA LARGE-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77130-00

Article	Description	REF
77130-00001-03	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA EXTRA LARGE-REGULAR WHITE 1 REPK AU77130-00	77130-01
77131-00000-06	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA EXTRA LARGE-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77131-00
77131-00001-03	COMPRINET PRO THIGH HIGH OPEN TOE EXTRA EXTRA LARGE-LONG WHITE 1 REPK AU77131-00	77131-01
77133-00000-05	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA EXTRA LARGE WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	77133-00
77133-00001-04	COMPRINET PRO KNEE HIGH OPEN TOE SIZE 1 SHORT WHITE 1 DA NL EN FR DE IT JA NO PT ES SV	77133-01
77133-00002-04	COMPRINET PRO KNEE HIGH OPEN TOE SIZE 2 SHORT WHITE 1 DA NL EN FR DE IT JA NO PT ES SV	77133-02
77133-00003-04	COMPRINET PRO KNEE HIGH OPEN TOE EXTRA EXTRA LARGE WHITE 1 REPK AU77133-00	77133-03
79611-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT SMALL-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79611-02
79612-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT SMALL-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79612-02
79613-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT MEDIUM-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79613-02
79614-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT MEDIUM-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79614-02
79615-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT LARGE-REGULAR WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79615-02
79616-00002-04	COMPRINET PRO DOUBLE CHAP OT WITH BELT LARGE-LONG WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	79616-02