

We,

BSN medical GmbH Schützenstr. 1-3 22761 Hamburg Germany (SRN: DE-MF-000005787)

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:

Cover-Roll® stretch

Basic UDI-DI: 4042809400329299A

Intended purpose: Cover-Roll® stretch is intended for wide area fixation of

wound dressings, particularly on joints as well as on frequently moved and contoured parts of the body. The product can also be used to secure fixation of tubes, catheters, measuring devices and instruments and can be used for one day to several days depending on the status of the wound and on the skin condition.

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.

Declaration of conformity issued: 07.02.2025

Compiled and released:

Hamburg, 07.02.2025 Martin Spengler Director Regulatory Affairs Hamburg BSN medical GmbH

Gallin July

Declaration of Conformity Cover-Roll® stretch

Article	Description	REF
45547-00000-11	COVERROLL STRETCH 5CMX1.84M WHITE 1 EN FR ES	45547-00
45548-00000-11	COVERROLL STRETCH 10CMX1.84M WHITE 1 EN FR ES	45548-00
45549-00000-11	COVERROLL STRETCH 15CMX1.84M WHITE 1 EN FR ES	45549-00
45550-00000-11	COVERROLL STRETCH 20CMX1.84M WHITE 1 EN FR ES	45550-00
45551-00000-11	COVERROLL STRETCH 30CMX1.84M WHITE 1 EN FR ES	45551-00
45552-00000-11	COVERROLL STRETCH 5CMX9.2M WHITE 1 EN FR ES	45552-00
45553-00000-11	COVERROLL STRETCH 10CMX9.2M WHITE 1 EN FR ES	45553-00
45554-00000-11	COVERROLL STRETCH 15CMX9.2M WHITE 1 EN FR ES	45554-00
45555-00000-11	COVERROLL STRETCH 20CMX9.2M WHITE 1 EN FR ES	45555-00
45556-00000-11	COVERROLL STRETCH 30CMX9.2M WHITE 1 EN FR SV	45556-00