

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:

Uniflex® Color

Basic UDI-DI:

404280940039695AR

Intended purpose:

Uniflex® Color, the elasticated bandage is intended to provide light support or compression as well as fixation and dressing retention in post-operative or post-traumatic usage.
Application fields include:
• **Light support in the treatment of minor soft tissue and joint injuries (e.g. sprains, strains)**
• **Light compression (e.g. in edema management to reduce effusion and swelling)**
• **Secure dressings and fixation (e.g. when treating wounds). It is to be applied on intact skin only. Wounds have to be treated before by using an appropriate wound dressing.**

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.

Declaration of conformity issued: 17.08.2023

Compiled and released:

Hamburg, 17.08.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
76970-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 10CM GREEN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76970-00
76971-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 8CM GREEN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76971-00
76972-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 6CM GREEN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76972-00
76973-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 6CM BLUE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76973-00
76974-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 8CM BLUE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76974-00
76975-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 10CM BLUE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76975-00
76976-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 6CM RED 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76976-00
76977-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 8CM RED 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76977-00
76978-00000-04	UNIFLEX UNIVERSAL BANDAGE 5M X 10CM RED 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10/BOX)	76978-00