

Declaration of Conformity MDR LP Compress AbsorbentProtect STE INT

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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:

Leukoplast® compress absorbent protect .

Basic UDI-DI: 404280940049853AW

Intended purpose: The device is intended for skin and wound cleansing,

absorption of secretion/exudates. As mechanical barrier it is suitable as a primary or secondary dressing in order to cover a wound and to provide cushioning. The device is

for short-term use.

Conformity assessment route: Annex IX, Chapter I

Classification rule: Classification: Is

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. This declaration is only valid in conjunction with the current E.C. certificates issued by DEKRA Certification GmbH (Id. No. 0124), Handwerkstraße 15, 70565 Stuttgart, Germany.

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Compiled and released:

Hamburg, 16.05.2023 Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH

Hadir July



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Article	D€	escription	REF
71282-00000	PF	UKOPLAST COMPRESS ABSORBENT ROTECT STERILE 20CMX20CM WHITE / BLUE X1	71282-00
71282-00001		UKOPLAST COMPRESS ABSORBENT ROTECT STERILE 20CMX40CM WHITE / BLUE X1	71282-01
71282-00002	PF	EUKOPLAST COMPRESS ABSORBENT ROTECT STERILE 10CMX10CM WHITE / BLUE X1	71282-02 E
71282-00003	PF	EUKOPLAST COMPRESS ABSORBENT ROTECT STERILE 10CMX20CM WHITE / BLUE X1	71282-03 E