

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® wet wipe

Basic UDI-DI:

404280940049862AX

Intended purpose:

Leukoplast® wet wipes is intended to reduce dirt in an injection area in order to prevent contamination and prepare for disinfection. It is non-sterile and for topical, single use on intact skin. Leukoplast® wet wipes is for transient use.

Conformity assessment route: **Annex II+III**
Classification rule: **1**
Classification: **I**

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.

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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71291-00000-00	LEUKOPLAST WET WIPES NON STERILE 3X3CM WHITE 100X1 DA NL EN FI FR DE HI ID IT NO PT ES SV	71291-00