

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:

Leukotape® Foam

Basic UDI-DI:

404280940037870A5

Intended purpose:

**Leukotape® Foam is a textile laminated padding material which provides protection from pressure from dressings.
Application fields include:
- Supports orthopaedic treatment as a padding and hollow support for areas at risk from pressure
- Protects against pressure caused by all types of dressings
- Helps to increase pressure with bandages.**

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: 30.11.2023

Compiled and released:

Hamburg, 30.11.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
09776-00000-07	LEUKOTAPE FOAM 20CM X 30CM NATURAL 10 DE EN ES	09776-00