

We,

BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany

hereby declare under our sole responsibility, in accordance with the regulation (EU) 2017/745 article 120, that the above mentioned product family complies with the applicable requirements of the Medical Device Directive 93/42/EEC.

Conformity assessment route acc. MDD 93/42/EEC: **Annex II**
Classification rule acc. MDD 93/42/EEC: **4**
Classification acc. MDD 93/42/EEC: **IIB**

The Declaration of Conformity is performed in accordance with the Quality Management System according to EN ISO 13485, and fulfils the essential requirements of the directive 93/42/EEC.

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

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Compiled and released:

Hamburg, 19.09.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH

A handwritten signature in blue ink, appearing to read 'Martin Spengler'.

Article	Description	REF
72680-00000-02	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-00
72680-00001-02	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 7.5X10CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-01
72680-00002-02	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 10X18CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-02
72680-00003-02	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 15X25CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-03
79991-00000-03	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 NL FR DE IT AT CH FR NL	79991-00
79991-00001-02	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 IT PT ES	79991-01
79991-00002-02	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 DA EN FI NO SV GB SE NO FI DK	79991-02