

We,

BSN medical GmbH
Quickbornstrasse 24
20253 Hamburg
Germany

hereby declare under our own responsibility, that the above mentioned product family complies with the applicable regulations 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 E.C. certificates issued by DEKRA Certification GmbH (Id. No. 0124), Handwerkstraße 15, 70565 Stuttgart, Germany.

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Hamburg, 19.11.2019
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72680-00000-00	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-00
72680-00001-00	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 7.5X10CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-01
72680-00002-00	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 10X18CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-02
72680-00003-00	CUTICELL CONTACT WOUND CONTACT LAYER STERILE 15X25CM 5 DA NL EN FI FR DE IT NO PT ES SV	72680-03
72680-00007-00	CUTICELL CONTACT STERILE 15X25CM 5 LABEL PT 72680-03	72680-07
79991-00000-01	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 NL FR DE IT AT CH FR NL	79991-00
79991-00000-02	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 NL FR DE IT AT CH FR NL	79991-00
79991-00001-01	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 IT PT ES	79991-01
79991-00002-01	LEUKOPLAST CUTICELL CONTACT WOUND CONTACT LAYER STERILE 5X7.5CM 5 DA EN FI NO SV GB SE NO FI DK	79991-02