

Declaration of Conformity Cuticell®

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We,

BSN medical GmbH Schützenstr. 1-3 22761 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 (excl. 4)** 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, 27.01.2021 Martin Spengler Director Regulatory Affairs Hamburg BSN medical GmbH Mari Kul



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Article	Description	REF
72539-00000-01	CUTICELL STERILE 7.5CMX7.5CM 1 NL EN FR DE IT JA ES 10/BOX	72539-00
72539-00001-01	CUTICELL STERILE 7.5CMX7.5CM 1	72539-01
72539-00002-01	CUTICELL STERILE 7.5CMX20CM 1	72539-02
72539-00003-01	CUTICELL STERILE 7.5CMX20CM 1	72539-03
72539-00004-01	CUTICELL STERILE 20CMX40CM 1 NL EN FR DE IT JA ES 25/BOX	72539-04