

We,

**BSN medical GmbH
Quickbornstr. 24
20253 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: **Ib**

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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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72610-00000-02	CUTIMED GEL STERILE 8G 10 DE EN FR ES	72610-00
72610-00001-02	CUTIMED GEL STERILE 15G 10 DE EN FR ES	72610-01
72610-00002-02	CUTIMED GEL STERILE 25G 10 DE EN FR ES	72610-02
72610-00003-01	CUTIMED GEL STERILE 15G 1 NL EN FR DE ES PHARM	72610-03
72610-00032-00	CUTIMED GEL STERILE 25G 1 REPACK 72610-2-1 MX	72610-32