

We,

BSN medical GmbH

**Quickbornstrasse 24
20253 Hamburg**

hereby declare under our own responsibility, that the above mentioned product family

CE-class IIb

containing the products:

79929-00000-02	CMED	SLC	SOR	STE	7.5X7.5CM	10	INT.
79929-00000-04	CMED	SLC	SOR	STE	7.5X7.5CM	10	INT.
79929-00001-02	CMED	SLC	SOR	STE	12.5X12.5CM	10	INT.
79929-00001-04	CMED	SLC	SOR	STE	12.5X12.5CM	10	INT.
79929-00002-02	CMED	SLC	SOR	STE	15X15CM	10	INT.
79929-00002-04	CMED	SLC	SOR	STE	15X15CM	10	INT.
79929-00003-02	CMED	SLC	SOR	STE	17.5X17.5CM	5	INT.
79929-00003-04	CMED	SLC	SOR	STE	17.5X17.5CM	5	INT.
79929-00004-04	CMED	SLC	SOR	STE	22.5X22.5CM	5	INT.
79929-00005-04	CMED	SLC	SOR	SAC	17.5X17.5CM	5	INT.
79929-00006-02	CMED	SLC	SOR	SAC	23X23CM	5	INT.
79929-00006-04	CMED	SLC	SOR	SAC	23X23CM	5	INT.
79929-00007-00	CMED	SLC	SOR	STE	7.5X7.5CM	12	DE
79929-00008-00	CMED	SLC	SOR	STE	12.5X12.5CM	12	DE
79929-00009-00	CMED	SLC	SOR	STE	15X15CM	12	DE
79929-00010-00	CMED	SLC	SOR	STE	17.5X17.5CM	6	DE
79929-00011-00	CMED	SLC	SOR	STE	22.5X22.5CM	6	DE
79929-00012-00	CMED	SLC	SOR	SAC	17.5X17.5CM	6	DE
79929-00013-00	CMED	SLC	SOR	SAC	23X23CM	6	DE

comply with the applicable regulations of the Medical Device Directive 93/42/EEC, including change directive 2007/47/EC, and that the products fulfil the essential requirements as defined in Annex I.

The Declaration of Conformity is performed in compliance with the Quality Management System according to EN ISO 13485 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

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BSN medical GmbH

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20253 Hamburg**

hereby declare under our own responsibility, that the above mentioned product family

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containing the products:

Date of Declaration: 13.10.2015

Valid until: See expiry date of the attached EN ISO 13485 Quality
Management Certificate and the Quality Assurance Certificate
according to MDD 93/42/EEC Annex II.

This Declaration of Conformity is only valid in conjunction with the current certificate(s) issued by
0124 DEKRA Certification GmbH, Handwerkstrasse 15, D-70565 Stuttgart, Germany.

Compiled and released

13.10.2015, Dr. Thomas Mehler

