We,

BSN medical GmbH

Quickbornstrasse 24
20253 Hamburg

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

CE-class I

containing the products:

45470-00000-03 EM HA LAFR 4CMX4M W 1 INT.
45470-00001-03 EM HA LAFR 4CMX4M W 1 IT MUTUA 45470-0-3
45471-00000-05 EM HA LAFR 6CMX4M W 1 INT.
45471-00001-05 EM HA LAFR 6CMX4M W 1 IT MUTUA 45471-0-5
45471-00002-05 EM HA LAFR 6CMX4M W 1 FR LPPR 45471-0-5
45472-00000-05 EM HA LAFR 8CMX4M W 1 INT.
45472-00001-05 EM HA LAFR 8CMX4M W 1 IT MUTUA 45472-0-5
45472-00002-05 EM HA LAFR 8CMX4M W 1 FR LPPR 45472-0-5
45473-00000-05 EM HA LAFR 10CMX4M W 1 INT.
45473-00001-05 EM HA LAFR 10CMX4M W 1 IT MUTUA 45473--5
45473-00002-05 EM HA LAFR 10CMX4M W 1 FR LPPR 45473-00
45474-00000-05 EM HA LAFR 12CMX4M W 1 INT.
45474-00001-05 EM HA LAFR 12CMX4M W 1 IT MUTUA 45474--5
45474-00002-05 EM HA LAFR 12CMX4M W 1 FR LPPR 45474-00
45475-00000-04 EM HA LAFR 4CMX20M W 1 INT.
45475-00001-04 EM HA LAFR 4CMX20M W 1 IT MUTUA 45475--4
45476-00000-05 EM HA LAFR 6CMX20M W 1 INT.
45476-00001-05 EM HA LAFR 6CMX20M W 1 IT MUTUA 45476--5
45477-00000-04 EM HA LAFR 8CMX20M W 1 INT.
45477-00001-04 EM HA LAFR 8CMX20M W 1 IT MUTUA 45477--4
45478-00000-04 EM HA LAFR 10CMX20M W 1 INT.
45478-00001-04 EM HA LAFR 10CMX20M W 1 IT MUTUA45478--4
45479-00000-04 EM HA LAFR 12CMX20M W 1 INT.
45479-00001-04 EM HA LAFR 12CMX20M W 1 IT MUTUA45479--4
47246-00000-02 EM HA LAFR 6CMX20M W 1 INT. 6/BOX
47249-00000-02 EM HA LAFR 8CMX20M W 1 INT. 6/BOX
47303-00000-02 EM HA LAFR 10CMX20M W 1 INT. 6/BOX
76194-00000-01 EM HA HOSP LAFR 4CMX20M W 1 INT.
76194-00001-01 EM HA HOSP LAFR 6CMX20M W 1 INT.
76194-00002-01 EM HA HOSP LAFR 8CMX20M W 1 INT.
76194-00003-01 EM HA HOSP LAFR 10CMX20M W 1 INT.
76194-00004-01 EM HA HOSP LAFR 12CMX20M W 1 INT.

76194-00005-01 EM HA HOSP LAFR 6CMX20M W 1 INT. 6/BOX
76194-00006-01 EM HA HOSP LAFR 8CMX20M W 1 INT. 6/BOX
76194-00007-01 EM HA HOSP LAFR 10CMX20M W 1 INT. 6/BOX

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.

Date of Declaration: 16.08.2013
Valid until: See expiry date of the attached EN ISO 13485 certificate.

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

16.08.2013, Dr. Klaus-Steffen KSN Nippe