

We,

BSN medical GmbH

**Quickbornstrasse 24
20253 Hamburg**

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

CE-class IIa

containing the products:

71500-00009-02 TEC 1 INT. 400 ML

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.

Date of Declaration: 11.09.2015

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

11.09.2015, Dr. Thomas Mehler

signature

T. Mehler