

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:

72100-00004-00 COP 10CMX3M(6.3M) FLES 18
72100-00005-00 COP 15CMX3M(6.3M) FLES 12
72100-00006-00 COP 2.5CMX3M(6.3M) FLES 60
72100-00008-00 COP 5CMX3M(6.3M) FLES 36
72100-00009-00 COP 7.5CMX3M(6.3M) FLES 24
72101-00005-00 COP 10CMX3M(6.3M) W 18
72101-00007-00 COP 2.5CMX3M(6.3M) W 60
72101-00009-00 COP 5CMX3M(6.3M) W 36
72101-00010-00 COP 7.5CMX3M(6.3M) W 24
72101-00011-00 COP 10CMX4.5M W 16
72101-00012-00 COP 7.5CMX4.5M W 24
72101-00013-00 COP 5CMX4.5M W 36 EN
72101-00014-00 COP 10CMX4.5M W 1 FR REPACK 72101-11-0
72101-00015-00 COP 7.5CMX4.5M W 1 FR REPACK 72101-12-0
72101-00016-00 COP 5CMX4.5M W 1 FR REPACK 72101-13-0
72101-00027-00 COP 7CMX3M W 1
72101-00028-00 COP 7CM X 3M FLES 1
72101-00029-00 COP 10CM X 3.5M W 1
72101-00030-00 COP 10CM X 3.5M FLES 1
72102-00002-00 COP COLPK 10CMX3M(6.3M) ASS 18 INT.
72102-00003-00 COP COLPK 7.5CMX3M(6.3M) ASS 24 INT.
72102-00004-00 COP COLPK 5CMX3M(6.3M) ASS 36 INT.
72102-00005-00 COP 10CMX3M(6.3M) G 18 INT.
72102-00023-00 COP 10CMX3M(6.3M) DEBL 18 INT.
72102-00024-00 COP 10CMX3M(6.3M) BL 18 INT.

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: 04.03.2013

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

04.03.2013, Oliver Opitz

signature

O. Opitz 04.03.13