

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:

01521-00000-06 LP SUT PS 5X1,25 TA 24 INT.
01521-00003-00 LP PLSR 1.25CMX5M TA 12 DE EN NL
01522-00000-06 LP SUT PS 5X2,5 TA 12 INT
01524-00000-06 LP SUT PS 5X5,0 TA 6 INT
01531-00000-06 LP SUT PSP 5X1,25 TA 24 INT
01532-00000-06 LP SUT PSP 5X2,5 TA 12 INT
01534-00000-06 LP SUT PSP 5X5 TA 6 INT
01536-00000-06 LP SUT PSP 9,2X1,25 TA 24 INT
01537-00000-06 LP SUT PSP 9,2X2,5 TA 12 INT
01539-00000-06 LP SUT PSP 9,2X5 TA 6 INT
01546-00000-02 LP SUT CCORE MPERF 5X10 TA 1 GB I P
01691-00000-03 LP SUT CCORE 9,2X1,25 TA 24 INT.
01692-00000-03 LP SUT CCORE 9,2X2,5 TA 12 INT
01693-00000-03 LP SUT CCORE 9,2X5 TA 6 INT
01696-00000-03 LP SUT CCORE 9,2X10 TA 4 INT
47535-00000-02 LP SUT PSP 5X7,5 TA 4 INT.
47536-00000-02 LP SUT PSP 5X10 TA 4 INT
47546-00000-01 LP SUT PSP 10X10 TA 1 IT EN
47714-00000-02 LP SUT TA PSP MPERF 5X5
47715-00000-02 LP SUT PSP MPERF 5X10 TA 4 E GB I
47725-00000-02 LP SUT PS 5X7,5 TA 1 INT.
47726-00000-02 LP SUT PS 5X10 TA 1 INT.
47826-00000-02 LP SUT PLSP 10CMX10M TA 1 ES
72668-00000-00 LP PLSR 1.25CMX4.6M TA 1 INT. 24/BOX
72668-00001-00 LP PLSR 2,5CMX4.6M TA 1 INT. 12/BOX
72668-00002-00 LP PLSR 5CMX4.6M TA 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: 04.06.2012

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.

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Compiled and released

04.06.2012, Oliver Opitz

signature

Oliver Opitz 04.06.12

The Declaration of Conformity is performed in compliance with the Quality Management System according to EN ISO 13485.

Date of Declaration: 04.06.2012

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.

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Compiled and released

04.06.2012, Oliver Opitz

signature

Oliver Opitz 04.06.12

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:

02121-00000-10 LF PLSR 1.25CMX5M MAT 1 INT. 24/BOX
02122-00000-10 LF PLSR 2.5CMX5M MAT 1 INT. 12/BOX
02122-00001-10 LF PLSP 2.5CMX5M MAT 1 ES
02124-00000-10 LF PLSR 5CMX5M MAT 1 INT. 6/BOX
02131-00000-10 LF PLSP 1.25CMX5M MAT 1 INT. 24/BOX
02132-00000-10 LF PLSP 2.5CMX5M MAT 1 INT. 12/BOX
02134-00000-10 LF PLSP 5CMX5M MAT 1 INT. 6/BOX
02136-00000-09 LF PLC 1.25CMX9.2M MAT 1 INT. 24/BOX
02137-00000-09 LF PLC 2.5CMX9.2M MAT 1 INT. 12/BOX
02138-00000-09 LF PLC 5.0CMX9.2M MAT 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: 21.07.2011

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

21.07.2011, Oliver Opitz

signature

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verbreitet werden.

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qu'avec l'accord de BSN medical GmbH

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:

02453-00000-08 LPO SUT PLC 9,2X1,25 W 24 INT
02453-40002-00 LPO SUT W PLC BU 9,2X1,25
02454-00000-08 LPO SUT PLC 9,2X2,5 W 12 INT.
02454-40002-00 LPO SUT W PLC BU 9,2X2,5
02455-00000-08 LPO SUT PLC 9,2X5 W 6 INT
02456-00000-08 LPO SUT PLC 7.5CMX9.2M W 4 INT.
02471-00000-09 LPO SUT PLSR 5X1,25 W 24 INT
02471-00003-00 LPO PLSR 1.25CMX5M W 12 DE EN NL
02471-00004-00 LPO PLSR 1.25CMX5M W 1 NL FR DE EUROHOLE
02472-00000-09 LPO SUT PLSR 5X2,5 W 12 INT.
02472-00003-00 LPO PLSR 2.5CMX5M W 1 NL FR DE EUROHOLE
02474-00000-09 LPO SUT PLSR 5X5 W 6 INT
02481-00000-09 LPO SUT PLSP 5X1,25 W 24 INT
02481-40000-00 LPO SUT W PLC BU 5X1,25
02482-00000-09 LPO SUT PLSP 5X2,5 W 12 INT
02482-40001-00 LPO SUT W PLC BU 5X2,5
02484-00000-09 LPO SUT PLSP 5X5 W 6 INT
47451-00000-04 LPO SUT PLSP 1.25CMX5M W 1 ES
47452-00000-04 LPO SUT PLSP 2.5CMX5M W 1 ES
47454-00000-04 LPO SUT PLSP 5CMX5M W 1 ES
47456-00000-04 LPO SUT PLSP 10CMX10M W 1 ES
71074-00000-01 LPO SUT PCORE 1.25CMX10M W 24 EN
71074-00001-01 LPO SUT 2.5CMX10M W 12 EN
71074-00002-01 LPO SUT PCORE 5CMX10M W 6 EN
71074-00003-01 LPO SUT PCORE 7.5CMX10M W 3 EN
72353-00000-00 LPO SUT PLC 1.25CMX5M W 24 INT.
72353-00001-00 LPO SUT PLC 2.5CMX5M W 12 INT.
72353-00002-00 LPO SUT PLC 5CMX5M W 6 INT.
72353-00003-00 LPO SUT PLC 7.5CMX5M W 4 INT.
72355-00000-00 LPO SUT DISPE 2.5CMX5M 1 FR
72355-00001-00 LPO SUT DISPE LPPR 2.5CMX5M 1 FR
72355-00002-00 LPO SUT DISPE LPPR 2.5CMX9.2M 1 FR

76446-00000-03 LPO SUT DISPE 9,2X1,25 W 1 NL FR DE
76446-00001-00 LPO SUT DISPE 9,2X1,25 W 1 GB I
76447-00000-03 LPO SUT DPEN 9,2X2,5 W 1 DE FR NL
76447-00001-00 LPO SUT DISPE 9,2X2,5 W 1 GB I

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: 18.07.2011

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

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Compiled and released

18.07.2011, Oliver Opitz

signature

Oliver Opitz 18.07.11

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:

01021-00000-09 LS SUT PLSR 5X1,25 W 24 INT.
01021-00002-00 LS SUT PLSR 1.25CMX5M W 1 DE EUROHOLE
01021-00003-00 LS PLSR 1.25CMX5M W 12 DE EN NL
01022-00000-09 LS SUT PLSR 5X2,5 W 12 INT
01022-00001-10 LS SUT PLSP 2.5CMX5M W 1 ES
01022-00003-00 LS SUT PLSR 2.5CMX5M W 1 DE EUROHOLE
01024-00000-09 LS SUT PLSR 5X5 W 6 INT
01031-00000-09 LS SUT PLSP 5X1,25 W 24 INT
01032-00000-09 LS SUT PLSP 5X2,5 W 12 INT
01034-00000-09 LS SUT PLSP 5X5 W 6 INT
09566-00000-01 LS SUT PLSP 9,2X1,25 W 24 INT
09567-00000-01 LS SUT PLSP 9,2X2,5 W 12 INT
09569-00000-01 LS SUT PLSP 9,2X5 W 6 INT
72669-00000-00 LS PLSR 1.25CMX4.6M W 1 INT. 24/BOX
72669-00001-00 LS PLSR 2.5CMX4.6M W 1 INT. 12/BOX
72669-00002-00 LS PLSR 5CMX4.6M 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: 22.05.2012

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

22.05.2012, Oliver Opitz

signature

 22.05.12

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:

02094-00000-02 EM WRA 4CMX4M W 20 INT.
02095-00000-02 EM WRA 6CMX4M W 20 INT.
02095-00000-03 EM WRA TIPS 4X6 W 20 INT.
02096-00000-02 EM WRA 8CMX4M W 20 INT.
02096-00000-03 EM WRA TIPS 4X8 W 20 INT.
02097-00000-02 EM WRA 10CMX4M W 20 INT.
02097-00000-03 EM WRA TIPS 4X10 W 20 INT.
02098-00000-02 EM WRA 12CMX4M W 20 INT.
02098-00000-03 EM WRA TIPS 4X12 W 20 INT.
02099-00000-02 EM 4CMX4M W 20 INT.
02100-00000-02 EM 6CMX4M W 20 INT.
02101-00000-02 EM 8CMX4M W 20 INT.
02102-00000-02 EM 10CMX4M W 20 INT.
02103-00000-02 EM 12CMX4M W 20 INT.
45250-00000-02 EM 4CMX4M W 50 INT.
45251-00000-02 EM 6CMX4M W 100 INT.
45252-00000-02 EM 8CMX4M W 100 INT.
45253-00000-02 EM 10CMX4M W 50 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: 16.05.2012

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

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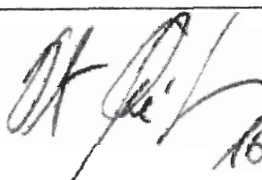
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Compiled and released

16.05.2012, Oliver Opitz

signature

 16.05.12

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:

45470-00000-02 EM HA 4X4 W 1 INT
45470-09001-02 ELASTOMULL HAFT BENDA 4X4 MUTUA
45471-00000-02 EM HA 4X6 W 1 INT
45471-00000-03 EM HA TIPS 4X6 W 1 INT.
45471-09001-02 ELASTOMULL HAFT BENDA 4X6 MUTUA
45472-00000-02 EM HA 4X8 W 1 INT
45472-00000-03 EM HA TIPS 4X8 W 1 INT.
45472-09001-02 ELASTOMULL HAFT BENDA 4X8 MUTUA
45473-00000-02 EM HA 4X10 W 1 INT
45473-00000-03 EM HA TIPS 4X10 W 1 INT.
45473-09001-02 ELASTOMULL HAFT BENDA 4X10 MUTUA
45474-00000-02 EM HA 4X12 W 1 INT
45474-00000-03 EM HA TIPS 4X12 W 1 INT.
45474-09001-02 ELASTOMULL HAFT BENDA 4X12 MUTUA
45475-00000-03 EM HA 20X4 W 1 INT
45475-09001-03 ELASTOMULL HAFT BENDA 20X4 MUTUA
45476-00000-04 EM HA 20X6 W 1 INT
45476-09001-04 ELASTOMULL HAFT BENDA 20X6 MUTUA
45477-00000-03 EM HA 20X8 W 1 INT
45477-09001-03 ELASTOMULL HAFT BENDA 20X8 MUTUA
45478-00000-03 EM HA 20X10 W 1 INT
45478-09001-03 ELASTOMULL HAFT BENDA 20X10 MUTUA
45479-00000-03 EM HA 20X12 W 1 INT
45479-09001-03 ELASTOMULL HAFT BENDA 20X12 MUTUA
47246-00000-01 EM HA 20X6 W 1 INT. 6/BOX
47249-00000-01 EM HA 20X8 W 1 INT. 6/BOX
47303-00000-01 EM HA 20X10 W 1 INT. 6/BOX
76194-00000-00 EM HA HOSP 4CMX20M W 1 INT.
76194-00001-00 EM HA HOSP 6CMX20M W 1 INT.
76194-00002-00 EM HA HOSP 8CMX20M W 1 INT.
76194-00003-00 EM HA HOSP 10CMX20M W 1 INT.
76194-00004-00 EM HA HOSP 12CMX20M W 1 INT.

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76194-00005-00 EM HA HOSP 6CMX20M W 1 INT.
76194-00006-00 EM HA HOSP 8CMX20M W 1 INT.
76194-00007-00 EM HA HOSP 10CMX20M W 1 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: 31.08.2011

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.

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Compiled and released

31.08.2011, Oliver Opitz

signature



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:

02033-00000-06 FMS 2X15 W 1 D F NL
02033-00001-06 FMS 2X15 W 1 INT.
02036-00000-08 FMS 10X5 W 1 INT.
02037-00000-08 FMS 10X10 W 1 INT.
02038-00000-08 FMS 10X15 W 1 INT.
02039-00000-08 FMS 10X20 W 1 INT.
02040-00000-08 FMS 10X30 W 1 INT.
09084-00000-02 FMS 10X5 W 1 D
09085-00000-02 FMS 10X10 W 1 D
09086-00000-02 FMS 10X15 W 1 D
09087-00000-02 FMS 10X20 W 1 D
09088-00000-02 FMS 10X30 W 1 D
47272-00000-04 FMS 5X5 W 1 D GB 1 W.O.SPLIT
47375-00000-03 FMS 20X10 W 1 INT W.O.SPLIT
47376-00000-03 FMS 20X15 W 1 INT W.O.SPLIT
47377-00000-03 FMS 20X20 W 1 INT W.O.SPLIT
70022-00000-02 FMS 2X10 W 1 D F NL
70022-00001-02 FMS 2X10 W 1 INT
70022-00003-02 FMS 2X10 W 1 S
72592-00000-00 FMS 5CMX20M W 1 DE
72592-00001-00 FMS 10CMX20M W 1 DE
72592-00002-00 FMS 15CMX20M W 1 DE
72592-00003-00 FMS 20CMX20M W 1 DE
72592-00004-00 FMS 30CMX20M W 1 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.

Date of Declaration: **18.05.2011**

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.

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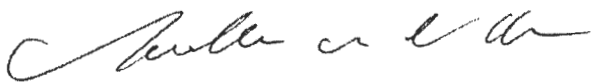
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Compiled and released

18.05.2011, Dr. Andreas Weth, von der

signature



We,

BSN medical GmbH**Quickbornstrasse 24
20253 Hamburg**

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

CE-class Is

containing the products:

72390-00000-01 LM IV STE 6CMX8CM TR 50 INT. HOSP.
72390-00003-01 LM IV STE 8.5CMX11.5CM TR 50 INT. HOSP.
72390-00004-01 LM IV STE 4.5CMX4.5CM TR 50 INT. HOSP.
72390-00005-00 LM IV STE 7CMX9CM TR 50 INT. HOSP.

comply with the applicable regulations of the Medical Device Directive (MDD) 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 V.

Date of Declaration: 13.04.2012

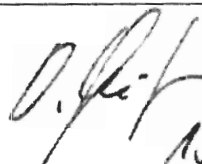
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex V.

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

13.04.2012, Oliver Opitz

signature


13.4.12

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We,

BSN medical GmbH

Quickbornstrasse 24
20253 Hamburg

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

CE-class Is

containing the products:

72380-00000-01 LM STE 5CMX7.2CM W 50 INT. HOSP.
72380-00001-01 LM STE 8CMX10CM W 50 INT. HOSP.
72380-00002-01 LM STE 8CMX15CM W 50 INT. HOSP.
72380-00003-01 LM STE 10CMX20CM W 50 INT. HOSP.
72380-00004-01 LM STE 10CMX25CM W 50 INT. HOSP.
72380-00005-01 LM STE 10CMX30CM W 50 INT. HOSP.
72380-00006-01 LM STE 10CMX35CM W 50 INT. HOSP.
72380-00007-01 LM STE 5CMX7.2CM W 5 INT. PHARM.
72380-00008-01 LM STE 8CMX10CM W 5 INT. PHARM.
72380-00009-01 LM STE 8CMX15CM W 5 INT. PHARM.
72380-00010-01 LM STE 10CMX20CM W 5 INT. PHARM.
72380-00011-01 LM STE 10CMX25CM W 5 INT. PHARM.
72380-00012-01 LM STE 10CMX30CM W 5 INT. PHARM.
72380-00013-01 LM STE 10CMX35CM W 5 INT. PHARM.
72380-00018-00 LM STE 5CMX7.2CM W 50 INT. HOSP NO PHARM
72380-00019-00 LM STE 8CMX10CM W 50 INT. HOSP NO PHARM
72380-00020-00 LM STE 8CMX15CM W 50 INT. HOSP NO PHARM
72380-00021-00 LM STE 10CMX20CM W 50 INT. HOSP NO PHARM
72380-00022-00 LM STE 10CMX25CM W 50 INT. HOSP NO PHARM
72380-00023-00 LM STE 10CMX30CM W 50 INT. HOSP NO PHARM
72380-00024-00 LM STE 10CMX35CM W 50 INT. HOSP NO PHARM
72380-09007-01 LM STE 5CMX7.2CM W 5 FR LPPR
72380-09008-01 LM STE 8CMX10CM W 5 FR LPPR
72380-09009-01 LM STE 8CMX15CM W 5 FR LPPR
72380-09010-01 LM STE 10CMX20CM W 5 FR LPPR
72380-09011-01 LM STE 10CMX25CM W 5 FR LPPR
72380-09012-01 LM STE 10CMX30CM W 5 FR LPPR
72380-09013-01 LM STE 10CMX35CM W 5 FR LPPR

comply with the applicable regulations of the Medical Device Directive (MDD) 93/42/EEC,
including change directive 2007/47/EC, and that the products fulfil the essential requirements

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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 V.

Date of Declaration: 13.07.2012

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 V.

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Compiled and released

13.07.2012, Oliver Opitz

signature

OK Opitz
13.07.2012

We,

BSN medical GmbH**Quickbornstrasse 24
20253 Hamburg**

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

CE-class Is

containing the products:

72382-00000-01 LM T PL STE 5CMX7.2CM TR 50 INT. HOSP.
72382-00001-01 LM T PL STE 8CMX10CM TR 50 INT. HOSP.
72382-00002-01 LM T PL STE 8CMX15CM TR 50 INT. HOSP.
72382-00003-01 LM T PL STE 10CMX25CM TR 50 INT. HOSP.
72382-00004-01 LM T PL STE 10CMX30CM TR 50 INT. HOSP.
72382-00005-01 LM T PL STE 10CMX35CM TR 50 INT. HOSP.
72382-00006-01 LM T PL STE 5CMX7.2CM TR 5 INT. PHARM.
72382-00007-01 LM T PL STE 8CMX10CM TR 5 INT. PHARM.
72382-00008-01 LM T PL STE 8CMX15CM TR 5 INT. PHARM.
72382-00009-01 LM T PL STE 10CMX25CM TR 5 INT. PHARM.
72382-00010-01 LM T PL STE 10CMX30CM TR 5 INT. PHARM.
72382-00011-01 LM T PL STE 10CMX35CM TR 5 INT. PHARM.
72382-00014-01 LM T PL STE 10CMX20CM TR 50 INT. HOSP.
72382-00015-01 LM T PL STE 10CMX20CM TR 5 INT. PHARM.
72382-00016-01 LM T PL STE 5CMX7.2CM TR 5 NL EN PHARM.
72382-09006-01 LM T PL STE 5CMX7.2CM TR 5 FR LPPR
72382-09007-01 LM T PL STE 8CMX10CM TR 5 FR LPPR
72382-09008-01 LM T PL STE 8CMX15CM TR 5 FR LPPR
72382-09009-01 LM T PL STE 10CMX25CM TR 5 FR LPPR
72382-09010-01 LM T PL STE 10CMX30CM TR 5 FR LPPR
72382-09011-01 LM T PL STE 10CMX35CM TR 5 FR LPPR
72382-09015-01 LM T PL STE 10CMX20CM TR 5 FR LPPR
72382-09908-01 LM T PL STE 8CMX15CM TR 5 PHARM. BELGIUM

comply with the applicable regulations of the Medical Device Directive (MDD) 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 V.

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Date of Declaration: 26.04.2012

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 V.

This Declaration of Conformity is only valid in conjunction with the current certificate(s) issued
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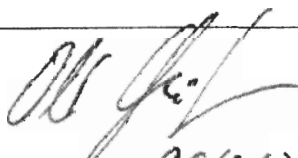
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Compiled and released

26.04.2012, Oliver Opitz

signature


26.4.12

We,

BSN medical GmbH

Quickbornstrasse 24
20253 Hamburg

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

CE-class Is

containing the products:

72381-00000-01 LM T STE 5CMX7.2CM TR 50 INT. HOSP.
72381-00001-01 LM T STE 8CMX10CM TR 50 INT. HOSP.
72381-00002-01 LM T STE 11CMX14CM TR 50 INT. HOSP.
72381-00003-01 LM T STE 5CMX7.2CM TR 5 INT. PHARM.
72381-00004-01 LM T STE 8CMX10CM TR 5 INT. PHARM.
72381-00005-01 LM T STE 11CMX14CM TR 5 INT. PHARM.
72381-00008-01 LM T STE 10CMX12.5CM TR 50 INT. HOSP.
72381-00009-01 LM T STE 15CMX20CM TR 50 INT. HOSP.
72381-00010-01 LM T STE 15CMX25CM TR 50 INT. HOSP.
72381-00011-01 LM T STE 10CMX12.5CM TR 5 INT. PHARM.
72381-00012-01 LM T STE 15CMX20CM TR 5 INT. PHARM.
72381-00013-01 LM T STE 15CMX25CM TR 5 INT. PHARM.
72381-00014-01 LM T STE 10CMX25CM TR 50 INT. HOSP.
72381-00015-00 LM T STE 10CMX25CM TR 5 INT. PHARM.
72381-09003-01 LM T STE 5CMX7.2CM TR 5 FR LPPR
72381-09004-01 LM T STE 8CMX10CM TR 5 FR LPPR
72381-09005-01 LM T STE 11CMX14CM TR 5 FR LPPR
72381-09011-01 LM T STE 10CMX12.5CM TR 5 FR LPPR
72381-09012-01 LM T STE 15CMX20CM TR 5 FR LPPR
72381-09013-01 LM T STE 15CMX25CM TR 5 FR LPPR
72381-09015-00 LM T STE 10CMX25CM TR 5 INT. PHARM. LPPR

comply with the applicable regulations of the Medical Device Directive (MDD) 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 V.

CONFIDENTIEL
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Date of Declaration: 21.05.2012

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 V.

This Declaration of Conformity is only valid in conjunction with the current certificate(s) issued
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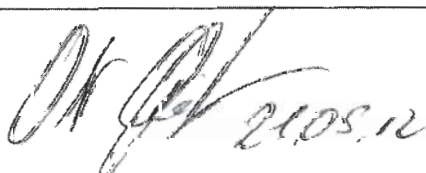
CONFIDENTIEL

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qu'avec l'accord de BSN medical GmbH

Compiled and released

21.05.2012, Oliver Opitz

signature

Handwritten signature of Oliver Opitz, dated 21.05.12.

We,

BSN medical GmbH**Quickbornstrasse 24
20253 Hamburg**

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

CE-class Is

containing the products:

72628-00000-00 LSAN STR STE 6X38MM W 60 INT. PHARM
72628-00001-00 LSAN STR STE 3X75MM W 50 INT. PHARM
72628-00002-00 LSAN STR STE 6X75MM W 30 INT. PHARM
72628-00003-00 LSAN STR STE 6X100MM W 100 INT. PHARM
72628-00004-00 LSAN STR STE 12X100MM W 60 INT. PHARM
72628-00005-00 LSAN STR STE 25X100MM W 40 INT. PHARM
72628-00006-00 LSAN STR STE 6X38MM W 12 INT. PHARM
72628-00007-00 LSAN STR STE 3X75MM W 10 INT. PHARM
72628-00008-00 LSAN STR STE 6X75MM W 6 INT. PHARM
72628-00009-00 LSAN STR STE 6X100MM W 10 INT. PHARM
72628-00010-00 LSAN STR STE 12X100MM W 12 INT. PHARM
72629-00000-00 LSAN STR STE 6X38MM W 300 INT. HOSP
72629-00001-00 LSAN STR STE 3X75MM W 250 INT. HOSP
72629-00002-00 LSAN STR STE 6X75MM W 150 INT. HOSP
72629-00003-00 LSAN STR STE 6X100MM W 500 INT. HOSP
72629-00004-00 LSAN STR STE 12X100MM W 300 INT. HOSP
72629-00005-00 LSAN STR STE 25X100MM W 100 INT. HOSP
72629-09003-00 LSAN STR STE 6X100MM W 500 FR HOSP ACL

comply with the applicable regulations of the Medical Device Directive (MDD) 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 V.

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Date of Declaration: 05.05.2011

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 V.

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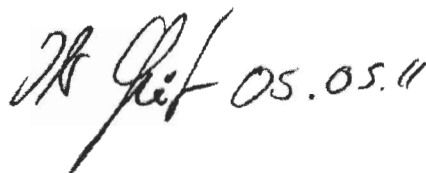
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Compiled and released

05.05.2011, Oliver Opitz

signature

Handwritten signature of Oliver Opitz, dated 05.05.11.

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:

72541-00000-00 LSAN AD STE 0.7ML 10 INT. HOSP

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: 16.09.2010

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

16.09.2010, Oliver Opitz

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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:

72539-00000-00 CCE STE 7.5CMX7.5CM 1
72539-00001-00 CCE STE 7.5CMX7.5CM 1
72539-00002-00 CCE STE 7.5CMX20CM 1
72539-00003-00 CCE STE 7.5CMX20CM 1
72539-00004-00 CCE STE 20CMX40CM 1 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 10.01.2012

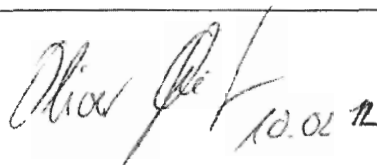
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

10.01.2012, Oliver Opitz

signature


10.01.12

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:

72538-00000-01 CCE CLC STE 5CMX5CM 1 INT.
72538-00001-01 CCE CLC STE 5CMX5CM 1 INT.
72538-00002-01 CCE CLC STE 10CMX10CM 1 INT.
72538-00003-01 CCE CLC STE 10CMX10CM 1 INT.
72538-00004-01 CCE CLC STE 10CMX40CM 1 INT.
72538-00005-01 CCE CLC STE 10CMX10CM 36 INT.
72538-00006-01 CCE CLC STE 10CMX7M 1 INT.
72538-00007-02 CCE CLC STE 15CMX2M 1 INT.
72538-09000-01 CCE CLC STE 5CMX5CM 1 FR LPPR
72538-09002-01 CCE CLC STE 10CMX10CM 1 FR LPPR
72538-09004-01 CCE CLC STE 10CMX40CM 1 INT. LPPR

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: 08.07.2011

Valid until:

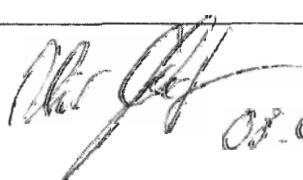
See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

08.07.2011, Oliver Opitz

signature


08.07.11

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:

72650-00001-01 CCE EPIG STE 7.5X10CM 10 INT.
72650-00003-01 CCE EPIG STE 10X15CM 10 INT.
72650-00004-01 CCE EPIG STE 15X20CM 10 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 04.08.2011

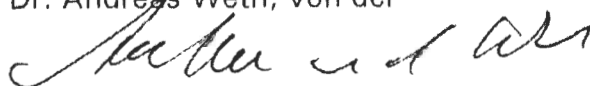
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

04.08.2011, Dr. Andreas Weth, von der

signature



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:

72161-00000-03 CMED SOR STE 7CMX9CM 40 INT.
72161-00001-03 CMED SOR STE 7CMX9CM 5 INT.
72162-00000-03 CMED SOR STE 10CMX10CM 40 INT.
72162-00001-03 CMED SOR STE 10CMX10CM 5 INT.
72163-00000-03 CMED SOR STE 10CMX20CM 20 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 02.05.2012

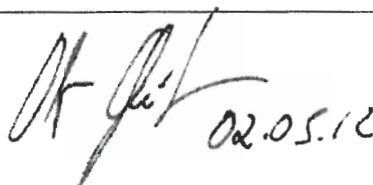
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

02.05.2012, Oliver Opitz

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02.05.12

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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:

72164-00000-02 CMED SOR SW STE 4CMX6CM 40 EN ES

72164-00001-02 CMED SOR SW STE 4CMX6CM 5 EN ES

72165-00000-02 CMED SOR SW STE 7CMX9CM 40 EN ES

72165-00001-02 CMED SOR SW STE 7CMX9CM 5 EN ES

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: 14.05.2012

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

14.05.2012, Oliver Opitz

signature


14.05.2012

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:

72166-00000-02 CMED SOR RGAU STE 2CMX50CM 20 INT.

72167-00000-02 CMED SOR RGAU STE 5CMX200CM 10 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 05.06.2012

Valid until:

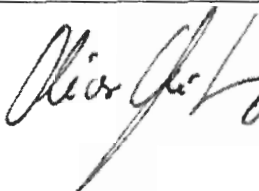
See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

05.06.2012, Oliver Opitz

signature

 05.06.2012**CONFIDENTIEL**
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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:

72168-00000-02 CMED SOR BAL STE 70 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 27.06.2012

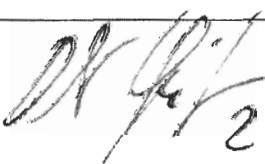
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

27.06.2012, Oliver Opitz

signature


27.06.12

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:

72611-00000-01 CMED SOR GEL STE 7.5CMX7.5CM G 10 INT.
72611-00001-01 CMED SOR GEL STE 7.5CMX15CM G 10 INT.
72611-09001-00 CMED SOR GEL STE 7.5CMX15CM G 10 FR LPPR

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: 25.01.2012

Valid until:

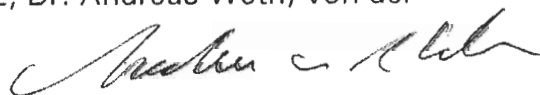
See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

25.01.2012, Dr. Andreas Weth, von der

signature



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:

72610-00000-01 CMED GEL STE 10X8 GRAMS INT.
72610-00001-01 CMED GEL STE 10X15 GRAMS INT.
72610-00002-01 CMED GEL STE 10X25 GRAMS INT.
72610-00003-00 CMED GEL STE 1X15 GRAMS INT. PHARM

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: 10.08.2012

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

10.08.2012, Oliver Opitz

signature

 10.08.12

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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:

72635-00000-00 CMED HY B STE 7.5CMX7.5CM 5 INT.
72635-00001-00 CMED HY B STE 10CMX10CM 5 INT.
72635-00002-00 CMED HY B STE 15CMX15CM 5 INT.
72635-00003-00 CMED HY B STE SACRAL 15CMX18CM 3 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 22.07.2011

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

22.07.2011, Oliver Opitz

signature

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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:

72636-00000-00 CMED HY L STE 5CMX25CM 12 INT.
72636-00001-00 CMED HY L STE 7.5CMX7.5CM 10 INT.
72636-00002-00 CMED HY L STE 10CMX10CM 10 INT.
72636-00003-00 CMED HY L STE 15CMX15CM 5 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 22.07.2011

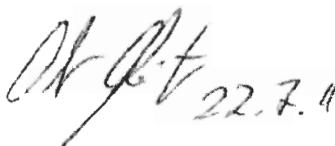
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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

22.07.2011, Oliver Opitz

signature

22.7.11

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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:

72634-00000-01 CMED ALG STE 5X5CM 10 INT.
72634-00001-01 CMED ALG STE 10X10CM 10 INT.
72634-00002-01 CMED ALG STE 10X20CM 10 INT.
72634-00003-01 CMED ALG STE 2.5X30CM FLAT ROPE 5 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 02.04.2012

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

02.04.2012, Dr. Andreas Weth, von der

signature



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:

72621-00000-00 CMED CAV STE 5CMX6CM 10 INT.
72621-00001-00 CMED CAV STE 10CMX10CM 10 INT.
72621-00002-00 CMED CAV STE 15CMX2CM 10 INT.
72621-00003-00 CMED CAV STE 15CMX15CM 5 INT.
72663-00000-00 CMED FO STE 5CMX6CM 10 INT.
72663-00001-00 CMED FO STE 10CMX10CM 10 INT.
72663-00002-00 CMED FO STE 15CMX15CM 10 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 21.03.2011

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

21.03.2011, Oliver Opitz

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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:

72632-00000-01 CMED SLC STE 5X6CM 10 INT.
72632-00001-01 CMED SLC STE 10X10CM 10 INT.
72632-00002-01 CMED SLC STE 10X20CM 10 INT.
72632-00003-01 CMED SLC STE 15X15CM 10 INT.
72632-00004-01 CMED SLC STE 20X20CM 5 INT.
72632-09000-01 CMED SLC STE 5X6CM 10 NORDIC
72632-09001-01 CMED SLC STE 10X10CM 10 NORDIC
72632-09002-01 CMED SLC STE 10X20CM 10 NORDIC
72632-09003-01 CMED SLC STE 15X15CM 10 NORDIC
72632-09004-01 CMED SLC STE 20X20CM 5 NORDIC

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: 30.03.2011

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.

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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:

72631-00000-02 CMED SLC B STE 7.5X7.5CM 10 INT.
72631-00001-02 CMED SLC B STE 12.5X12.5CM 10 INT.
72631-00002-02 CMED SLC B STE 15X15CM 10 INT.
72631-00003-02 CMED SLC B STE 17.5X17.5CM 5 INT.
72631-00004-02 CMED SLC B STE 22.5X22.5CM 5 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 and in compliance with the Quality Assurance System according to MDD 93/42/EEC Annex II.

Date of Declaration: 29.06.2012

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

29.06.2012, Oliver Opitz

signature

 29.06.12

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:

72630-00000-01 CMED SLC L STE 5X6CM 10 INT.
72630-00001-01 CMED SLC L STE 10X10CM 10 INT.
72630-00002-01 CMED SLC L STE 15X15CM 10 INT.

comply with the applicable regulations of the Medical Device Directive 93/42/ECC 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 Medical Device Directive (MDD) 93/42/ECC Annex II.

Date of Declaration: 16.01.2009

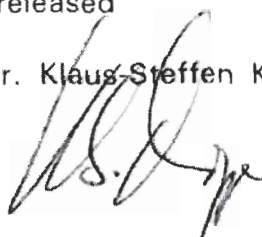
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/ECC Annex II.

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

16.01.2009, Dr. Klaus Steffen KSN Nippe

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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:

72639-00000-02 CSB ULT STE 10CMX10CM 20 INT.
72639-00001-02 CSB ULT STE 10CMX20CM 20 INT.
72639-00002-02 CSB ULT STE 20CMX20CM 20 INT.
72639-00003-02 CSB ULT STE 20CMX30CM 20 INT.
72640-00000-02 CSB ULT STE 10CMX10CM 50 INT. HOSP
72640-00001-02 CSB ULT STE 10CMX20CM 50 INT. HOSP
72640-00002-02 CSB ULT STE 20CMX20CM 50 INT. HOSP
72640-00003-02 CSB ULT STE 20CMX30CM 50 INT. HOSP
72644-00000-02 CSB ULT STE 10CMX10CM 5 INT. HOSP
72644-00001-02 CSB ULT STE 10CMX20CM 5 INT. HOSP
72644-00002-02 CSB ULT STE 20CMX20CM 5 INT. HOSP
72644-00003-02 CSB ULT STE 20CMX30CM 5 INT. HOSP

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: 13.02.2012

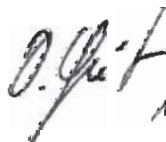
Valid until: See expiry date of the attached EN ISO 13485 Quality Management Certificate and the Quality Assurance Certificate according to MDD 93/42/EEC Annex II.

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Compiled and released

13.02.2012, Oliver Opitz

signature


13.02.12

Date of Declaration: 22.07.2010

Valid until:

See expiry date of the attached EN ISO 13485 certificate.

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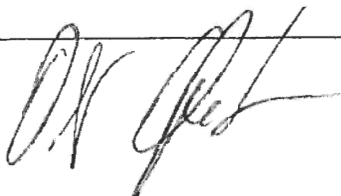
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22.07.2010, Oliver Opitz

signature



We,

BSN medical GmbH

Quickbornstrasse 24
20253 Hamburg

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

CE-class Is

containing the products:

72594-00000-00 CSB LAD STE 5CMX5CM 10 INT.
72594-00001-00 CSB LAD STE 5CMX5CM 25 INT.
72594-00002-00 CSB LAD STE 5CMX5CM 100 INT.
72594-00003-00 CSB LAD STE 7.5CMX7.5CM 12 INT.
72594-00004-00 CSB LAD STE 10CMX10CM 10 INT.
72594-00005-00 CSB LAD STE 10CMX10CM 100 INT.
72594-00006-00 CSB LAD STE 7.5CMX20CM 10 INT.
72594-00007-00 CSB LAD STE 10CMX20CM 5 INT.
72594-00008-00 CSB LAD STE 10CMX20CM 10 INT.
72594-00009-00 CSB LAD STE 10CMX20CM 100 INT.

comply with the applicable regulations of the Medical Device Directive (MDD) 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 V.

Date of Declaration: 14.06.2011

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 V.

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

14.06.2011, Oliver Opitz

signature

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:

72978-00010-01 LT K 2.5CM X 5M FLES 1 INT.
72978-00011-01 LT K 5CM X 5M FLES 1 INT.
72978-00012-01 LT K 7.5CM X 5M FLES 1 INT.
72978-00015-01 LT K 2.5CM X 5M R 1 INT.
72978-00016-01 LT K 5CM X 5M R 1 INT.
72978-00017-01 LT K 7.5CM X 5M R 1 INT.
72978-00020-01 LT K 2.5CM X 5M BLUE 1 INT.
72978-00021-01 LT K 5CM X 5M BLUE 1 INT.
72978-00022-01 LT K 7.5CM X 5M BLUE 1 INT.
72978-00023-00 LT K 5CM X 5M BL 1 INT.
72978-00024-00 LT K 5CM X 5M LIB 1 INT.
72978-00025-00 LT K 5CM X 5M LRED 1 INT.
72978-09023-00 LT K 5CM X 5M BL 1 FR ACL

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: 02.05.2011

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

02.05.2011, Oliver Opitz

signature

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:

72100-00014-00 CO LAFR 2.5CM X 2M(4.5M) FLES 60 INT.
72100-00016-00 CO LAFR 5CM X 2M(4.5M) FLES 36 INT.
72100-00017-00 CO LAFR 7.5CM X 2M(4.5M) FLES 24 INT.
72100-00018-00 CO LAFR 10CM X 2M(4.5M) FLES 18 INT.
72100-00019-00 CO LAFR 15CM X 2M(4.5M) FLES 12 INT.
72100-00020-00 CO LAFR COLPK 7.5CM X 2M(4.5M) ASS 24
72100-00021-00 CO LAFR COLPK 10CM X 2M(4.5M) ASS 18 INT
72100-00022-00 CO 7X3 W 24 FR LATEX FREE 2020602010BA
72100-00025-00 CO 7X3 G 24 FR LATEX FREE 2020602010CA
72100-00026-00 CO 10X3,5 W 18 FR LATEX FREE 2020602010B
72100-00027-00 CO 10X3,5 TA 18 FR LATEX FREE 2020602010
72100-00028-00 CO LAFR 2.5CM X 2M(4.5M) W 72 FR
72100-00029-00 CO LAFR 5CM X 2M(4.5M) W 36 EN FR
72100-00030-00 CO LAFR 7.5CM X 2M(4.5M) W 24 EN FR
72100-00031-00 CO LAFR 10CM X 2M(4.5M) W 16 FR EN
72100-00032-00 CO LAFR 15CM X 2M(4.5M) W 12 FR
72100-00033-00 CO LAFR COLPK 5CM X 2M(4.5M) 36 INT.
72100-00034-00 CO LAFR 7.5CM X 4.5M R 1 INT.
72100-00035-00 CO LAFR 10CM X 4.5M R 1 INT.
72100-00036-00 CO LAFR 7.5CM X 4.5M B 1 INT.
72100-00037-00 CO LAFR 10CM X 4.5M B 1 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.

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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:

09831-00000-00 TEG 6.25CM X 1M B 1 NL
09832-00000-00 TEG 12CM X 1M SIZE G 1 NL
09833-09001-01 TEG 6.75CM X 1M C 1 INT.
09835-09001-01 TEG 8.75CM X 1M E 1 INT.
09838-09001-01 TEG 7.5CM X 1M D 1 INT.
09840-09001-01 TEG 10CM X 1M F 1 INT.
71513-00000-01 TEG TU BA 4.5CM X 10M A 1 INT.
71514-00000-01 TEG TU BA 6.25CM X 10M B 1 INT.
71514-00001-01 TEG 6.25CM X 10M B FLES 1 INT.
71515-00000-01 TEG TU BA 7.5CM X 10M D 1 INT.
71515-00001-01 TEG 7.5CM X 10M D FLES 1 INT.
71516-00000-01 TEG TU BA 10CM X 10M F 1 INT.
71516-00001-01 TEG F FLES 1 INT.
71517-00000-01 TEG 17.5CM X 10M 1 INT. SIZE J
71519-00000-01 TEG TU BA 6.75CM X 10M C 1 INT.
71519-00001-01 TEG 6.75CM X 10M C FLES INT.
71520-00000-01 TEG TU BA 8.75CM X 10M E 1 INT.
71520-00001-01 TEG 8.75CM X 10M E FLES 1 INT.
71521-00000-01 TEG TU BA 12CM X 10M 1 INT. SIZE G
71521-00001-01 TEG 12CM X 10M FLES 1 INT. SIZE G
71522-00000-01 TEG TU BA 32.5CM X 10M 1 INT. SIZE L
71523-00000-01 TEG TU BA 21.5CM X 10M K 1 INT.
71524-00000-01 TEG 37.5CM X 10M 1 INT. SIZE M

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: 07.09.2011

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.

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Compiled and released

07.09.2011, Oliver Opitz

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07.09.11