

BSN medical Inc.
100 Beiersdorf Drive
Rutherford College, NC 28671 USA

DECLARATION OF CONFORMITY

Document Number: DC-TPM06 Revision: 8 Page 1 of 1

Reference Product Family: Compridur, Comprihaft, Comprilan, Comprilan S

Reference Documents

Product Family Description: PFD-TPM13
Essential Requirements Checklist: ER-TPM05
Risk and Biological Assessment: RA-TPM05
Clinical Assessment: CA-902
Product Dossier: TPD-F

Legal Manufacturer

BSN medical Inc.
100 Beiersdorf Drive.
Rutherford College, NC 28671

EU Representative

BSN medical
Quickbornstrasse 24
Hamburg, Germany 20253

We, BSN medical Inc. hereby certify that the above product family was produced at a third party manufacturer and is controlled by the Legal Manufacturer according to an approved and controlled Quality System compliant to ISO 13485:2003 + AC 2007, the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC and FDA QSR 21CFR Part 820.

Carroll D. Hoyle
Global SRA



6 Nov. 2013
Date

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