

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

**DECLARATION OF CONFORMITY**

Document Number: DC-TPM65      Revision: N      Page: 1 of 1

Reference Product Family: Dynacast Ankle Splint Kit

Reference Documents

Product Family Description: PFD-TPM65

Essential Requirements Checklist: ER-TPM65

Risk and Biological Safety Assessment: RA-TPM65

Clinical Assessment: CA-TPM65

Legal Manufacturer

BSN medical Inc.  
100 Beiersdorf Drive  
P.O. Box 390  
Rutherford College, NC 28671

EU Representative

BSN medical GmbH  
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 Regulatory Affairs

17 Sept. 2010  
Date

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