

	SI-BONE Inc. Declaration of Conformity	300060 Rev B
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Manufacturer:

SI-BONE Inc.
3055 Olin Ave. Suite 2200
San Jose, Ca. 95128
USA

European Authorized Representative:

MedPass International Limited
Windsor House, Barnett Way
Barnwood
Gloucester GL4 3RT, United Kingdom

Products:

Classification per MDD 93/42/EEC: Class IIa / IIb, Annex IX

We hereby declare that the distributed CE marked products, specified above, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number:3804024CE01, first issued on 11/11/2010, ISO 13485:2003 I certificate # 3804024 first issued on 9/1/2010 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa & IIb, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers the iFuse Sacroiliac Joint Implant, Steinmann Pins, and Cannulated Drills as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s): San Jose, California USA



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300060 Rev B

Catalog Number	Description	First Lot #	Last Lot #
7030	SI-BONE Fusion Rod 7.0 x 30mm	10006	N/A
7035	SI-BONE Fusion Rod 7.0 x 35mm	10007	N/A
7040	SI-BONE Fusion Rod 7.0 x 40mm	10008	N/A
7045	SI-BONE Fusion Rod 7.0 x 45mm	10012	N/A
7050	SI-BONE Fusion Rod 7.0 x 50mm	10013	N/A
7055	SI-BONE Fusion Rod 7.0 x 55mm	11868704110	N/A
7060	SI-BONE Fusion Rod 7.0 x 60mm	7914003181009	N/A
7065	SI-BONE Fusion Rod 7.0 x 65mm	7914003181010	N/A
7070	SI-BONE Fusion Rod 7.0 x 70mm	7753003181011	N/A
4030	SI-BONE Fusion Rod 4.0 x 30mm	10014	N/A
4035	SI-BONE Fusion Rod 4.0 x 35mm	10015	N/A
4040	SI-BONE Fusion Rod 4.0 x 40mm	10016	N/A
4045	SI-BONE Fusion Rod 4.0 x 45mm	10017	N/A
4050	SI-BONE Fusion Rod 4.0 x 50mm	7987003323007	N/A
4055	SI-BONE Fusion Rod 4.0 x 55mm	7987003323008	N/A
4060	SI-BONE Fusion Rod 4.0 x 60mm	7982003323009	N/A
4065	SI-BONE Fusion Rod 4.0 x 65mm	7987003323010	N/A
4070	SI-BONE Fusion Rod 4.0 x 70mm	7987003323011	N/A
500078	Steinmann Pin, 3.2mm	R2401	N/A
500079	Steinmann Pin, 2.0mm	RCS08	N/A
500095	Blunt Steinmann Pin, 3.2	R8906	N/A
500096	Blunt Steinmann Pin, 2.0	S9K0D	N/A
500090	Push Pin, 3.2	SDB0B	N/A
500091	Push Pin, 2.0	RCS09	N/A
500082	Cannulated Drill, 4.0mm x 2.0mm	N75297	N/A
500076	Cannulated Drill, 7.0mm x 3.2mm	85638	N/A

Place of Issuance: San Jose, Ca.

Signature & Date of
Issuance

Director of Quality / Management Representative

11-19-2012

Date