

## **European Declaration of Conformity**

## to the Medical Device Directive, 93/42/EEC



Classification Name: Orthosis, Sacroiliac, Soft

Product Name: SAM Pelvic Sling II™

Product Model Number:

SL556652 SAM Pelvic Sling II<sup>TM</sup>, Civilian; Size: Standard – Hip Circumference 32"-50"

SL556652-SM SAM Pelvic Sling II<sup>TM</sup>, Civilian; Size: Small – Hip Circumference 27"-47"

SL556652-LG SAM Pelvic Sling II<sup>TM</sup>, Civilian; Size: Large – Hip Circumference 36"-60"

SL55652-MIL-OD SAM Pelvic Sling II<sup>TM</sup>, Military – Olive Drab; Size: Standard – Hip Circumference 32"-50"

Description: The SAM Pelvic Sling<sup>TM</sup> is a non-invasive, circumferential pelvic belt intended for application by

pre-hospital and medical professionals or trained personnel to individuals who have, or are

suspected of having, a pelvic ring fracture where hemorrhage might occur.

Classification/Rule: Class I, by Annex IX, Rule 1

Conformity Assessment Route: Annex VII

SAM Medical Products declares under its sole responsibility that the above products to which this declaration relates, and which bear the CE Marking, are in conformity with the applicable requirements of EC Directive 93/42/EEC of 14 June 1993 all of the amendments thru M5.

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Date: April 16, 2014

Signature:

Kasey Griffin, Director of Quality Assurance & Regulatory Affairs