

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC



Product Family Name: SAM® Pelvic Sling II

Catalog Numbers:

PS300-OB-EN SAM Pelvic Sling II, Civilian; Size: Small – Hip Circumference 27"-45"

(69cm-114cm)

PS301-OB-EN SAM Pelvic Sling II, Civilian; Size: Standard – Hip Circumference 32"-50"

(81cm-127cm)

PS302-OB-EN SAM Pelvic Sling II, Civilian; Size: Large – Hip Circumference 36"-54"

(91cm-137cm)

PS301-OD-EN SAM Pelvic Sling II, Military – Olive Drab; Size: Standard – Hip

Circumference 32"-50" (81cm-127cm)

Description: The SAM Pelvic Sling[™] 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 Name: Pelvic Binder

GMDN Code: 63255

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

Conformity Assessment Route: Annex VII

Notified Body: Self-Certified

Declaration:

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 as transposed in the national laws of the Member States.

Manufacturer:

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Signature:

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