

**EU DECLARATION OF CONFORMITY AS PER ANNEX IV OF THE REGULATION (EU) MDR 2017/745**

**Manufacturer:**



**SAM® Medical Products**

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 Single Registration Number (SRN): US-MF-000002589

**EU Authorized Representative:**



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Prinsessegracht 20, 2514 AP The Hague, The Netherlands  
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 Single Registration Number (SRN): NL-AR-000000116

**Product Family Name**

SAM® Pelvic Sling II

**Basic UDI-DI:**

0822045SL01U6 (see details in Table 1 attached)

**Device(s) concerned:**

This Declaration applies to all devices and variants included within the *SAM® Pelvic Sling II Product Family* (see details in Table 1 attached).

**Intended Purpose**

The SAM Pelvic Sling II is a non-invasive, circumferential pelvic belt intended to stabilize pelvic fractures during transport to a definitive care facility.

**Risk Class per Annex VIII:**

Class I (non-sterile) as per Rule 1

**GMDN Code**

63496 (Pelvic binder, single use)

**EMDN Code**

M0305099 (Immobilization Systems and devices – Other)

**Notified Body:**

Not applicable. Class I (non-sterile, non-measuring, non-reusable) devices are not reviewed by a Notified body.

**Conformity Assessment Route:**

SAM Medical® Products utilizes Annex II and Annex III Technical Documentation (including PMS) for Class I EU medical devices and issues a Declaration of Conformity (self-certification).

**Applicable CE Certificate(s):**

Not applicable – Class I (non-sterile) devices are self-certified.

**Standards and Common Specifications (CS):**

This certificate further declares that the products covered herein also comply with the applicable requirements of relevant standards and Common Specifications specified in Table 2.

This declaration of conformity is issued under the sole responsibility of SAM® Medical Products. We hereby declare that the medical devices specified above meet the applicable provisions of the Medical Devices Regulation (EU) MDR 2017/745. All supporting documentation is retained at the premises of the manufacturer.

**Person authorized to sign on behalf of SAM® Medical Products:**

**Signature & date:**

2021-06-23

**Name:** Jeff Lipps

**Position:** Director RA/QA, SAM® Medical Products

**Place of Issue:** 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

Table 1: Medical devices and variants included in the SAM® Pelvic Sling II Product Family

| Basic UDI-DI   | GTIN   | Product   | Packaging Level | SKU         |
|----------------|--|---|-----------------|-------------|
| 0822045SL01U6  | 00822045428621                                       | SAM Pelvic Sling II Small 27 in-45 in (69 cm-114 cm)                  | Each            | PS300-OB-EN |
|                | 10822045428628                                       |   | Case            |             |
|                | 00822045428638                                       | SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm)              | Each            | PS301-OB-EN |
|                | 10822045428635                                       |   | Case            |             |
|                | 00822045428614                                       | SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm) – Olive Drab | Each            | PS301-OD-EN |
|                | 10822045428611                                       |   | Case            |             |
| 00822045428645 | SAM Pelvic Sling II Large 36 in-54 in (91 cm-137 cm) | Each  | PS302-OB-EN     |             |
| 10822045428642 |  | Case  |                 |             |

Table 2: Standards and Common Specifications (CS) applied

| Standard #                      | Title  | Year / Version                    |
|---------------------------------|--|-----------------------------------|
| <b>Applied Standards</b>        |  |                                   |
| EN 1041                         | Information supplied by the manufacturer of medical devices  | 2008+A1:2013                      |
| EN ISO 10993-1                  | Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process                                 | 2020                              |
| EN ISO 10993-18                 | Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process | 2020                              |
| EN ISO 13485                    | Medical devices - Quality management systems - Requirements for regulatory purposes  | 2016+AC:2018                      |
| EN ISO 14971                    | Medical Devices - Application of Risk Management to Medical Devices  | 2019                              |
| EN ISO 15223-1                  | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements   | 2016                              |
| EN ISO 16061                    | Instrumentation for use in association with non-active surgical implants - General requirements  | 2015<br>See Footnote <sup>1</sup> |
| EN 62366-1                      | Medical devices – Part 1: Application of usability engineering to medical devices  | 2015+A1:2020                      |
| <b>Other relevant standards</b> |  |                                   |
| EN ISO 17100                    | Translation services — Requirements for translation services   | 2015+A1:2017                      |
| ASTM F2052-15                   | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment   | 2015                              |
| ASTM F2503-20                   | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment                             | 2020                              |
| <b>Common Specifications</b>    |  |                                   |
| -                               | No common specifications relevant to the device family have been published in OJ at this time.   |                                   |

<sup>1</sup>Annex A was utilized for biocompatibility considerations.






# EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)

Final Audit Report

2021-06-23

|                 |  |
|-----------------|--|
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## "EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)" History

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