SAM®
MEDICAL

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

CE

Product Family Name: SAM® XT Extremity Tourniquet

Description:

The SAM® XT Extremity Tourniquet is a device that includes a self-adhering strap, an autostop buckle and a windlass tightening mechanism that is placed around an injured extremity/limb proximal to a site of vascular hemorrhage and manually tightened to stop arterial bleeding.

Product Catalog Numbers:

XT600-OR-EN	SAM® Extremity Tourniquet – Hi-Viz Orange
XT600-BL-EN	SAM® Extremity Tourniquet – Hi-Viz Blue
XT600-BK-EN	SAM® Extremity Tourniquet – Tactical Black

Intended Use/Indications for Use:

The SAM® XT Extremity Tourniquet has the following Intended Use:

- The SAM® XT Extremity Tourniquet is to be applied around a limb to occlude arterial blood flow.

Classification Name: Arm/Leg Tourniquet, Single-Use

GMDN Code: 58128

Classification/Rule: Class I by Rule 1

Conformity Assessment Route: Annex VII of MDD 93/42/EEC Council Directive

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.

The SAM® XT Extremity Tourniquet is composed of biocompatible fabric, polymers and aluminum, the device is manufactured in the United States.

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Jeff Lipps, Director RA/QA

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