SAM®
MEDICAL

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

CE

Product Family Name: Chest Seal (SAM®) Product Family

Description:

The SAM® Chest Seal Product Family consists of sterile, occlusive dressings comprised of a hydrogel-based adhesive bound to a clear, tough, flexible polyurethane layer, a clear flexible backing and with markings that aid with application in low light conditions (night vision visible). Vented SAM® Chest Seals include a one-way valve to allow air and fluids to passively escape from the pleural space and to prevent the ingress of air and dirt. The SAM® Chest Seal with Valve also contains a valve cap that can be used to effectively convert a vented chest seal into a non-vented chest seal if desired.

Product Catalog Numbers:

CS200-EN Chest Seal with Valve (SAM®), 1 vented dressing with valve cap & 1 absorbent pad
CS201-EN Chest Seal (SAM®), 2 non-vented dressings & 1 absorbent pad
CS202-EN Chest Seal Valved 2.0 (SAM®), 1 vented dressing (no valve cap or absorbent pad)
CS203-EN Chest Seal Combo (SAM®), 1 vented & 1 non-vented dressing (no absorbent pad)

Intended Use/Indications for Use:

The SAM® Chest Seal is placed over an open chest wound providing an air-tight and water-tight seal to convert an open pneumothorax to a closed pneumothorax. The SAM® Chest Seal has the following indications for use:

- To be used as a temporary bandage to treat penetrating chest wounds such as gunshot wounds, stab wounds and fragment wounds
- To be used as an occlusive wound dressing
- To be used in emergent situations and only left in place during transport to a hospital

Classification Name: Pneumothorax Dressing

Classification/Rule: Class IIa devices by MDD Annex IX, Rule 4, 3rd indent.

Conformity Assessment Route: Annex II, excluding Section 4

GMDN Code: 46424

Notified Body: NSAI (NB#0050)

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 and subsequent amendments thru M5.

Manufacturer:
SAM Medical Products
12200 SW Tualatin Road, Suite 200
Tualatin, OR 97062, U.S.A.
TEL: 503-639-5474
FAX: 503-639-5425

EU Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague, The Netherlands
TEL: +31 (0)70 345-8570

Signature: _____ **Date:** 2020-06-04

Jeff Lipps, Director RA/QA