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:

CS062010 Chest Seal with Valve (SAM®), 1 vented dressing with valve cap & 1 absorbent pad
CS062011 Chest Seal (SAM®), 2 non-vented dressings & 1 absorbent pad
CS062013 Chest Seal Valved 2.0 (SAM®), 1 vented dressing (no valve cap or absorbent pad)
CS062014 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 IIb devices by Annex IX, Rule 4.

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
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Wilsonville, OR 97070, U.S.A.
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Signature: _____ **Date:** 22 Feb 2017

Jeff Lipps, Director RA/QA

Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

SAM Medical Products

27350 SW 95th Ave. Suite 3038
Building 30
Wilsonville
OR 97070
USA

to the Product Family

Chest Seal (SAM)

GMDN Code: 46424

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.820**
Original Approval:	**26 May 2011**
Last Amended on:	**21 February 2017**
Remains valid until:	**25 May 2020**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.