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

April 2024

Notified Body Confirmation Letter

Reference: NBCL0040.01

Re: SAM Medical Products
Chest Seal (SAM)
NSAI File Number 252.820

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To whom it may concern

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SAM Medical Products
12200 SW Tualatin Road
Suite 200
Tualatin
OR 97062, USA
SRN Number : US-MF-000002589

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB

has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Pamela Burdette Miller
European Medical Devices Operations Manager
Medical Devices, NSAI

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Chest Seal (SAM)	IIa	252.820 0050	n/a

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
n/a	n/a	n/a	n/a

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023.07.06	NBCL0040.01	Initial issue
2024.04.19	NBCL0040.02	Correction to Table 1