EC DECLARATION OF CONFORMITY

IN RELATION TO FOXSEAL VENTED CHEST SEAL DRESSING TECHNICAL DOCUMENTATION TD24b

Medtrade Products Ltd. declares that the FOXSEAL Vented Chest Seal Dressing conforms to the essential requirements and provisions of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, concerning medical devices.

Legal Manufacturer: Medtrade Products Ltd.
Electra House
Crewe Business Park
Crewe CW1 6GL
Cheshire
United Kingdom

Legal Manufacturer Single Registration Number: GB-MF-000007864

Product Name (Registered Trade Name/Trademark)	FOXSEAL Vented Chest Seal Dressing
Product Codes	Applicable product codes are listed in Schedule 1
Basic UDI-DI	N/A
Intended Purpose	An occlusive dressing for open chest wounds
Classification and Rule	Class IIb, as defined by Rule IV, laid down in Annex IX of Council Directive 93/42/EEC All non-invasive devices which come into contact with injured skin are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent
Conformity Assessment Route	Annex II Full Quality Assurance System
Notified Body Name Address Identification number	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066EP Amsterdam The Netherlands 2797
(EC) Certificate Number Certificate Commencement Date Certificate Expiry Date	CE 54955 22 August 2000 26 May 2024
GMDN Code(s)	46424 - Pneumothorax dressing A sterile covering applied to a chest wound that has penetrated the pleura (serous membrane covering the lungs and lining the pleural cavity) in order to temporarily treat and prevent pneumothorax (collapsed lung). The device may be self-adhesive and have a one-way valve that enables internal pressure release while preventing air entry. It is typically used by first responders [emergency medical services (EMS)] in the management of penetrating chest trauma (e.g., bullet or stab wounds). This is a single-use device.

EU Authorised Representative Single Registration Number	Obelis S.A. Bd. Général Wahi, 53 1030, Brussels Belgium BE-AR-000000106
EU Initial Importer Single Registration Number	MedEnvoy Global BV Prinses Margrietplantsoen 33 Suite 123 2595 AM The Hague The Netherlands NL-IM-000000248
Standards Applied:	Applicable standards are listed in Technical Documentation TF24b

This EU declaration of conformity is issued under the sole responsibility of the legal manufacturer as named above.

Note: Original Declaration of Conformity is still valid and has not been invalidated with the update.

Changes are allowed as per MDR Article 120, Transitional Provisions.

Issued in Crewe, U.K.

Signed for and on behalf of Medtrade Products Ltd.

Date: 31st October 2023.

Susan McLoughlin
Regulatory Director

Schedule 1 - Product Codes

Product Code	Product Description
FG08814541	FOXSEAL CE & US Vented Chest Dressing (English language pack)
FG08814601	FOXSEAL CE Vented Chest Dressing (French, German & English language pack)
FG08814611	FOXSEAL CE Vented Chest Dressing (Swedish, Norwegian & English language pack)
FG08814631	FOXSEAL CE Vented Chest Dressing (Lithuanian, Polish & English language pack)
FG08814641	FOXSEAL CE Vented Chest Dressing (Spanish, Finnish & English language pack)

Document History

Version	Comments	Date Issued
1	Original document - Draft not signed.	28/Mar/2019
2	Addition of Obelis as EU Rep - Draft not signed.	05/Nov/2020
3	Revised due to move to new sub-contractor with new manufacturing processes and validations; extension to shelf life to 3 years; and increase in sterilization dose. To view all changes, see the Amendments section of the Technical File R3.	11/Jun/2021
4	Added language pack variants to Schedule 1.	18/Aug/2021
5	Updated template and added statement regarding issuing of new revision.	09/Mar/2022
6	Reissued with reference to DC083-14-02; extension of shelf-life from 3 to 5 years.	25/Mar/2022
7	Reissued with reference to CC22-02-409; addition of Sterigenics as a subcontract steriliser.	21/Apr/2022
8	Reissued with reference to CC22-09-434 Raw material change for Tab in Chest Seal Dressing	17/Nov/2022
9	Added language pack variants to Schedule 1	09/May/2023
10	Reissued with reference to CC21-12-402	01/June/2023
11	Added Spanish, Finnish & English Language pack	12/October/2023

Medtrade Products Limited
Electra House
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Electra Way
Crewe
Cheshire
CW1 6GL
United Kingdom

25 March 2024

Notified Body Confirmation Letter
Reference: EU2023-607/819150

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Medtrade Products Limited
Electra House
Crewe Business Park
Electra Way
Crewe
Cheshire
CW1 6GL
United Kingdom

SRN Number: GB-MF-000007864

NB 2797

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
Foxseal Chest Seal Dressing	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: CE 54955 NB#: 2797
Foxseal Vented Chest Seal Dressing	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate: CE 54955 NB#: 2797

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	Action
2024/03/25	Initial issue

NB 2797