Medtrade
Innovative Medical Products

EC DECLARATION OF CONFORMITY

IN RELATION TO FOXSEAL CHEST SEAL DRESSING TECHNICAL DOCUMENTATION TF24

Medtrade Products Ltd. declares that the FOXSEAL 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 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	Obelis S.A. Bd. Général Wahi, 53 1030, Brussels Belgium
Single Registration Number	BE-AR-000000106
EU Initial Importer	MedEnvoy Global BV Prinses Margrietplantsoen 33 Suite 123 2595 AM The Hague The Netherlands
Single Registration Number	NL-IM-000000248
Standards Applied:	Applicable standards are listed in Technical Documentation TF24

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.

Susan McLoughlin
Regulatory Director

Date: 19th JANUARY 2024

Schedule 1 - Product Codes

Product Code	Product Description
FG08814441	FOXSEAL CE Chest Dressing (English language pack)
FG08814501	FOXSEAL CE Chest Dressing (German, Italian & French language pack)
FG08814591	FOXSEAL CE Chest Dressing (Spanish & Portuguese language pack)
FG08814621	FOXSEAL CE Chest Dressing (Swedish, Norwegian & English language pack)

Document History

Version	Comments	Date Issued
1	Original Declaration.	05/May/2016
2	Change in signatory.	18/May/2017
3	Addition of GMDN code, updated description and part number. Amendment of the notified body number from "0086" to "2797" and notified body address from UK to Netherlands.	28/Sep/2020
4	Addition of Obelis SA as the EU Authorised Representative (EUAR).	23/Feb/2021
5	Added details of specific languages on FG0881450. Updates due to addition of second sterilisation dose. Change to new format for Declaration of Conformity Update to latest version of standards.	29/Apr/2021
6	Addition of MedEnvoy as the EU Initial Importer. Addition of FG08814591 (Spanish & Portuguese Pack). Addition of a second converter (BDK).	04/Nov/2021
7	Updated template and added statement regarding issuing of new revision.	09/Mar/2022
8	Reissued with reference to DC020-10-03; extension of shelf-life from 4 to 5 years for devices irradiated at 25 - 40kGy.	25/Mar/2022
9	Essential Requirements Checklist updated to reference current reports.	27/Apr/2022
10	Reissued with reference to CC22-01-407; addition of FG08814621; Swedish/Norwegian/English language pack and CC21-10-394; FG08814621 German/Italian/French language pack - addition of CH-REP details.	19/May/2022
11	Reissued with reference to CC22-01-409; addition of Sterigenics as subcontract steriliser.	20/Jul/2022
12	Reissued with reference to CC22-09-434 Raw material change for Tab in Chest Seal Dressing	17/Nov/2022
13	Reissued with reference to CC22-10-440 RM Change for Interleave Foxseal	23/Feb/2023
14	A non- significant change reference to CC23-09-475 for the NSN/NATO Stock number to be added to the shipper case label on the following FG Code – FG08814441 & FG08814621	16/Jan/2024

Medtrade Products Limited
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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:

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Electra House
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Cheshire
CW1 6GL
United Kingdom

SRN Number: GB-MF-000007864

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