

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	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066EP Amsterdam The Netherlands
Identification number	2797
(EC) Certificate Number	CE 54955
Certificate Commencement Date	22 August 2000
Certificate Expiry Date	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 TF24b

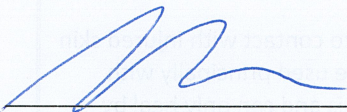
This EU declaration of conformity is issued under the sole responsibility of the legal manufacturer as named above.

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.



Susan McLoughlin
Regulatory Director

Date: 31st October 2023.

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