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