Medtrade
Innovative Medical Products

EU DECLARATION OF CONFORMITY

IN RELATION TO THE CELOX Z-FOLD GAUZE & RAPID HAEMOSTATIC DEVICES
MDR TECHNICAL FILE 101

Medtrade Products Ltd declares that the Celox Haemostatic Devices sold within the EU conform to Regulation (EU) 2017/745 of the European Parliament and of the Council of 05th April 2017, as amended.

Legal Manufacturer:	Medtrade Products Ltd, Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL, United Kingdom	**EU Representative**:	OBELIS S.A., Bd. Général Wahis, 53 1030 Brussels, Belgium
Legal Manufacturer SRN:	GB-MF-000007864	**EU Representative SRN:**	BE-AR-000000106

Product Names	Celox Haemostatic Devices: • Celox Z-Fold Gauze 3m • Celox Z-Fold Gauze 1.5m • Celox RAPID Z-Fold Gauze
Registered Trade Name / Trademark	Celox / Omni-stat – Either of these brand name can be used for the above devices. The Omni-stat devices are the same as the Celox devices in every aspect within the EU.
Product Codes	Applicable product codes are listed in Schedule 1
Basic UDI-DI for all the Celox / Omni-stat EU devices	506020663BP00030220SU
Intended Purpose	The intended purpose of Celox / Omni-stat Z-Fold Gauzes and Celox / Omni-stat Rapid Z-Fold Gauze is: *to be used by trained emergency responders in the pre-hospital setting for temporary treatment of emergency life-threatening bleeding.*
Classification and Rule	The Celox / Omni-stat Haemostatic Devices have been classified in accordance with the rules set forth in Annex VIII Chapter III of Regulation (EU) 2017/745. The Regulation identifies that if several rules, or if within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply. The strictest rule for the Celox / Omni-stat Haemostatic Devices is Rule 18 as the devices include a material of animal origin (chitosan derived from shrimp shells): *All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.* Rule 4 is also considered to apply (second indent) as non-invasive devices which come into contact with injured skin or mucous membrane are class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent.
Conformity Assessment Route	Annex IX - Conformity assessment based on a Quality Management System and on assessment of Technical Documentation
Notified Body Name Address	British Standards Institute (BSI) Say Building, John M Keynesplein 9,

Identification number	1066 EP, Amsterdam. 2797
EU Technical Documentation Assessment Certificate Regulation (EU) 2017/745, Annex IX Chapter II Certificate First Issued Certificate Expiry Date EU Quality Management System Certificate for Regulation (EU) 2017/745, Annex IX Chapter I and III Certificate First Issued Certificate Expiry Date	MDR 756306 R000 2022-03-16 2027-03-15 MDR 756304 R000 2022-03-16 2027-03-15
GMDN Code(s)	GMDN Code: *46922* Term: *Chitosan Haemostatic Agent* Definition: *A sterile, non-bioabsorbable device that includes chitosan (a polysaccharide derived from chitin, the structural element in the exoskeleton of crustaceans) as a principal component, intended to be applied to traumatic wounds in emergency situations (e.g., road accidents, combat, emergency rescue) or during surgical intervention to produce a rapid haemostasis by forming a robust plug of gel which is removed after use. The chitosan may be intended to provide antibacterial activity, and is available in a variety of forms (e.g., fine particles in a pouch, coated on gauze). This is a single-use device.*
EMDN Code(s)	EMDN Code: *M04050* Term: *Polysaccharide Haemostatic Dressings.*

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

Issued in Crewe, U.K.

Signed for and on behalf of Medtrade Products Ltd.

Date: 16th JAN 2024.

Sue McLoughlin
Regulatory Affairs Director

Schedule 1 - Product Codes

Family Name	Celox / Omni-stat Haemostatic Devices				
Product Variant	**Product Code**	**Description**	**Pouch UDI Code**	**Inner shipper Carton UDI Code**	**Shipper Case UDI Code**
Celox Z-Fold Gauze	FG08838071	Celox Z Fold Gauze 3m CE - English Language	15060206631271	N/A	75060206631273
	FG08838191	German/Polish	15060206631400	N/A	75060206631402
	FG08838201	Spanish/Portuguese	15060206631417	N/A	75060206631419
	FG08838031	Celox Z Fold Gauze 1.5m CE – English Language	15060206630205	N/A	75060206630207
	FG08838051	German/Polish Language	15060206630236	N/A	75060206630238
	FG08838061	Swedish/English/Norwegian Language	15060206631196	N/A	75060206631198
	FG08838121	Dutch Language	15060206631202	N/A	75060206631204
	FG08838131	Finnish/Danish Language	15060206631219	N/A	75060206631211
	FG08838141	Slovak Language	15060206631226	N/A	75060206631228
	FG08838151	Hungarian/Estonian Language	15060206631233	N/A	75060206631235
	FG08838161	French/Portuguese Language	15060206631240	N/A	75060206631242
	FG08838271	Lithuanian/English	15060206631479		75060206631471
Celox RAPID Z-Fold Gauze	FG08839021	Celox RAPID Z-Fold Gauze CE – English Language	15060206630137	N/A	75060206630139
	FG08839051	Spanish Language	15060206631134	N/A	75060206631136
	FG08839101	Swedish/English/ Norwegian Language	15060206631158	N/A	75060206631150
	FG08839201	Dutch Language	15060206631172	N/A	75060206631174
	FG08839081	German/French/Italian Language	15060206631141	N/A	75060206631143
	FG05939091	French Language	15060206631127	N/A	75060206631129
	FG08839121	German /English Language	15060206630724	N/A	75060206630726
	FG08839131	Finnish Language	15060206631165	N/A	75060206631167
	FG08839221	Greek/Danish Language	15060206631189	N/A	75060206631181

Document History

Version	Comments	Date Issued
1	First issue following initial certification to the Medical Devices Regulation Including non-substantial changes to allow the gauzes sub-contractor: • use an additional bioburden test house • use an additional source of sacrificial liner for the lamination process of the gauzes Including non-substantial changes to make minor changes to specifications and artwork layout.	2nd August 2022
2	Second issue following BSi approval of non-substantial changes to make minor changes to specifications and artwork for Celox Z-Fold Gauze 1.5m and Celox RAPID Z-Fold Gauze.	12th August 2022
3	Third issue for the addition of Celox Z-Fold Gauze and Celox RAPID Z-Fold Gauze language pack codes and descriptions to Schedule 1, to allow for BSi approval of substantial change (update to EU Technical Documentation Assessment Certificate MDR 756306 R000 Device Schedule.)	16th November 2022
4	Addition of new FG08838271 code for Celox Gauze 1.5m Z-Fold - CE Lithuanian/English label & IFU Including non – substantial changes to Kolliphor specification CC23-03 458	10th July 2023
5	Additional languages on: •FG08839121 -Celox RAPID Z-Fold Gauze (Addition of English language)	21st November 2023
6	A non-significant change for the NSN/NATO stock number to be added to the shipper case label on the following FG Code FG08838031	21st December 2023
7	Additional languages on: • FG08839101- Celox RAPID Z-Fold Gauze (Addition of Norwegian language) • •FG08838061 -Celox Z Fold Gauze 1.5m (Addition of Norwegian language)	15th January 2024