Medtrade
Innovative Medical Products

EU DECLARATION OF CONFORMITY
IN RELATION TO THE CELOX GRANULES & APPLICATOR 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 Applicator 6g • Celox Granules 15g
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	506020663BP0993020037
Intended Purpose	The intended purpose of Celox / Omni-stat Granules is: *to be used by trained emergency responders in the pre-hospital setting for temporary treatment of emergency life-threatening bleeding.* The intended purpose of Celox / Omni-stat Applicator is: *to be used by trained emergency responders in the pre-hospital setting for temporary treatment of emergency life-threatening bleeding. Celox Applicator is indicated for narrow penetrating wounds.*
Classification and Rule	The Celox 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 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 756305 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 Granules and Applicator Haemostatic Devices				
Product Variant	**Product Code**	**Description**	**Pouch UDI Code**	**Inner shipper Carton UDI Code**	**Shipper Case UDI Code**
Celox Granules 15g	FG08830181	Celox Granules 15g CE – English Language	15060206630366	N/A	75060206630368
	FG08830361	Celox Granules 15g CE – Finnish Language	15060206631356	N/A	75060206631358
	FG08830611	Celox Granules 15g CE – French Language	15060206631028	N/A	75060206631020
	FG08830621	Celox Granules 15g CE – Greek Language	15060206631035	N/A	75060206631037
	FG08830631	Celox Granules 15g CE – Portuguese Language	15060206631042	N/A	75060206631044
	FG08830641	Celox Granules 15g CE – Romanian Language	15060206631059	N/A	75060206631051
	FG08830651	Celox Granules 15g CE – Spanish Language	15060206631066	N/A	75060206631068
Celox Applicator	FG08832021	Celox Applicator 6g CE – English Language	15060206630144	35060206630148	75060206630146
	FG08832041	Celox Applicator 6g CE – Spanish / Portuguese Language	15060206630298	35060206630292	75060206630290
	FG08832151	Celox Applicator 6g CE – French / Danish Language	15060206631080	35060206631084	75060206631082
	FG08832141	Celox Applicator CE – German / Czech Language	15060206631073	35060206631077	75060206631075
	FG08832161	Celox Applicator CE – Greek / Slovak Language	15060206631097	35060206631091	75060206631099
	FG08832191	Celox Applicator CE – Norwegian/English Language	15060206631516	35060206631510	75060206631518

Document History

Version	Comments	Date Issued
1	First issue following initial certification to the Medical Devices Regulation 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 updates to artwork and specifications for Celox Granules 15g.	12th August 2022
3	Updated for Spanish / Portuguese product code following substantial review and certificate update by BSI	16th November 2022
4	Updated for remaining language pack codes for both Celox Granules and Celox Applicator 6g A following substantial change review and certificate update by BSI	21st November 2022
5	Including non – substantial changes to Kolliphor CC23-03 458	11th July 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 FG08832021	21st December 2023
7	Addition of new FG code for Celox Applicator 6g in Norwegian/English label & IFU	15th January 2024