Medtrade

Innovative Medical Products

EC DECLARATION OF CONFORMITY

Medtrade Products Ltd of:

Electra House
Crewe Business Park
Crewe
Cheshire
CW1 6GL
UK

Declares the class III medical device, with the GMDN code 46922 Chitosan Haemostatic Agent, described hereafter:

Celox / Omni-stat Haemostatic Granules in an Applicator

For Treatment of Life-Threatening Emergency Bleeding in Small Penetrating Wounds by Trained Emergency Responders (with 6g Celox / Omni-stat Haemostatic Granules) with part number FG0XX32YY1

Where XX is a two-digit number representing a customer, and YY is a two-digit number representing the size, language and background colour of the pouch.

Are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC (Medical Device Directive) amended by Directive 2007/47/EC.

And are subject to the procedure in Annex II of Council Directive 93/42/EEC, under the supervision of Notified Body Number 2797, British Standards Institute (BSI), Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, The Netherlands.

Signed:..... Date: 12th November 2019

Sue McLoughlin
Regulatory Director

Issued in Crewe, Cheshire, U.K.

Change History:

1. Original declaration for Celox signed by J Ranfield 1st Oct 08
2. Revised declaration to show review and compliance to Directive 2007/47/EC 16th March 10
3. Revised for new BSI address 29th Aug 12
4. Re-issued for signature by current Head of Regulatory 16th Jan 17
5. Revised following approval of additional sterilisation facility; addition of GMDN code to DoC; and signature by I Walker 6th Feb 18.
6. Revised for change to BSI number and Netherlands address, and signature by S. McLoughlin.