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 Haemostatic Granules

For Treatment of Life-Threatening Emergency Bleeding by Trained Emergency Responders

In 15g packs with part number FG0XX30YY1

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) as 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 signed by J Ranfield 5th Oct 07
2. Updated for 25g and blue pouch part numbers 14th Mar 08
3. Part number system revised to allow the YY code to represent the size, pouch colour and language 30th April 08
4. Revised to show review and compliance to Directive 2007/47/EC 16th Mar 10
5. Revised for new BSI address 29th Aug 12
6. Re-issued for signature by current Head of Regulatory 16th Jan 17
7. Revised following approval of additional sterilisation facility, dose range, new packaging material and process; addition of GMDN code to DoC; removal of 25g pack (35g also no longer to be manufactured but may still be in the market); and signature by I Walker 6th Feb 18.
8. Revised for change to BSI number and Netherlands address, and signature by S. McLoughlin.