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 Gauze

For Treatment of Life-Threatening Emergency Bleeding Trained Emergency Responders

In a sheet 76.2mm by 3048mm, with part number FG0XX34YY1

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 16th Mar 10
2. Revised for new BSI address 29th Aug 12
3. Declaration amended from 75.3mm to 76.2mm. This is not a change to the device as it has always been manufactured to 76.2mm. The 75.3mm was transposed from an incorrect specification. This administrative correction is not significant.
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.