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 RAPID Z-Fold Gauze

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

In a sheet 7.6cm by 1.5m, with part number FG0XX39YY1

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.

EU Authorised Representative for this device: Obelis S.A., Bd. Général Wahis, 53, 1030, Brussels, Belgium.

Signed:..... Date: 13th April 2021

Sue McLoughlin
Regulatory Director

Issued in Crewe, Cheshire, U.K.

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Celox Z-Fold Gauze

For Treatment of Life-Threatening Emergency Bleeding Trained Emergency Responders

In a sheet 7.6cm by 1.5m, with part number FG0XX38YY1

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

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