720 SW Washington Street, Suite 200 Portland, OR 97205-3504 USA
TEL: +1.503.245.0459 **FAX:** +1.971.223.1000 **WEB:** www.tricolbiomedical.com

Date: 29th March 2023

Statement on compliance with the requirements of Regulation (EU) 2023/607 of the European Parliament and of the council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provision for certain medical devices and *in vitro* diagnostic medical devices.

To Whom it May Concern,

In my capacity as Vice President, Regulatory and Quality, I confirm that Tricol Biomedical, Inc., located at 720 SW Washington Street, Suite 200, Portland, OR 97205-3504, USA, has applied to The National Standards of Ireland (NSAI) for conformity assessment (CE mark) in compliance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) (EU Medical Device Regulations (MDR)) for the following devices:

- ChitoGauze XR PRO (3in x 4yds), SafeGuard Brand, Part Number 1089

Conformity assessment is under NSAI file number 745.073.

Pursuant to the requirements of Regulation (EU) 2023/607 of the European Parliament and of the council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provision for certain medical devices and *in vitro* diagnostic medical devices, Article 120 (4) of Regulation (EU) 2017/745 has been amended to allow devices lawfully placed on the market pursuant to Directive 93/43/EEC (MDD) to continue to be made available on the market or put into service until the end of the applicable transition period. The amendment applies to the medical devices supplied by

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Tricol Biomedical Inc under MDD certificate number 252.1076 and listed in this declaration. The applicable transition period deadline for the devices covered by this declaration is 31st December 2027.

Tricol Biomedical Inc. has put in place a quality management system in accordance with the requirements of Article 10(9) of Regulation (EU) 2017/745. Tricol Biomedical Inc is currently waiting Notified Body official review and certification of the quality management system in accordance with the requirements of the MDR. Tricol's quality management system is currently certified to meet the requirements of EN ISO 13485:2016 and Directive 93/34/EEC, the aspects of the quality management system per Regulation (EU) 2017/745 which came into effect on 26th May 2021 have been reviewed by NSAI during routine surveillance audits in January 2022 and September 2022.

A letter of support from NSAI confirming the MDR review status of the devices covered by this declaration is provided.

Digitally signed by
Maire E. Ni Beilliu PhD
Date: 2023.03.29
14:00:25 -07'00'

Máire E. Ní Beilliú PhD
Vice President, Regulatory & Quality

Tricol Biomedical, Inc. CORPORATE SEAL 2016

EC Design Examination Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Tricol Biomedical Inc.

720 SW Washington Street, Suite 200
Portland
OR 97205
USA

For Product Family

Chitosan haemostatic agent - wound dressings (ChitoGauze and GuardaCare)

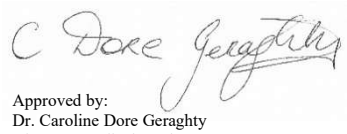
GMDN Code: 46922

CONCLUSION of EXAMINATION:

NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration Number:	**252.1076**
Original Approval:	**09 August 2011**
Last Amended on:	**05 May 2021**
Remains valid until:	**20 March 2023**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Approved model numbers are included in the associated attachment

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

February 2023

To: IGJ

Re: Tricol Biomedical Inc.
ChitoGauze XR PRO / GuardaCare PRO - Chitosan Wound Dressing
NSAI File Number 745.073

To whom it may concern

The National Standards Authority of Ireland confirms that we have accepted the signed contract for the product "ChitoGauze XR PRO / GuardaCare PRO - Chitosan Wound Dressing", NSAI File Number 745.073, and it is currently undergoing review for compliance to EU Medical Device Regulation 2017/745.

The review commenced May 2022 and our current conformity assessment procedure has an average 18-24 month timeframe.

NSAI commit to informing IGJ about major safety-related shortcomings identified during conformity assessment.

If you have any further queries, please do not hesitate to contact us.

Yours sincerely

Lisa Donlon
European Medical Device
Operations Manager
Medical Devices
NSAI

Dr Majella Geraghty
European Medical Device
Operations Manager
Medical Devices
NSAI

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