

EC DECLARATION OF CONFORMITY

Manufacturer: Tricol Biomedical, Inc.
720 SW Washington Street, Suite 200
Portland, OR 97205
USA

Product Name: ChitoGauze / GuardaCare – Chitosan Wound Dressing

Description: Chitosan gauze medical dressing

Classification: Class III, device per Annex IX Rule 17 of Council Directive 93/42/EEC Concerning Medical Devices

CE Certification #: 252.1076

Tricol Biomedical, Inc., being the manufacturer/distributor hereby declares that the products covered by the declaration conform to the Essential Requirements of EC Directive 93/42/EEC as amended by EC Directive 2007/47/EC and have been subject to the Conformity Assessment procedures defined in Annex II under the supervision of National Standards Authority of Ireland (NSAI), a Notified Body carrying the number 0050.

This declaration is valid for all devices described in this document. The date of the first shipment of the device into the EU is provided below.

Tricol agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Tricol confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Tricol confirms that animal tissue derivatives are incorporated in the device as defined in EN ISO 22442-1.

Tricol agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Tricol agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, including significant design change to devices.

Tricol has appointed as our EU Authorised Representative:
CEPartner4U BV Esdoornlaan 13, 3951 DB Maarn, The Netherlands

The declaration is supported by a Certificate of Quality Assurance issued by National Standards Authority of Ireland (NSAI), Notified Body Number 0050.

The date of shipment of the first ChitoGauze / GuardaCare product into the EU was 2011-10-05.

Signed _____

Date 11th November 2021

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



Product Name: ChitoGauze / GuardaCare – Chitosan Wound Dressing

Device Schedule: List of Product Codes covered by this Declaration:

Classification	Annex IX Rule	GMDN
III	17	46922

Product Code	Name
1017	HemCon ChitoGauze PRO, 4in x 4yds (10cm x 37m)
1012	HemCon GuardaCare PRO, 2in x 2in, 8ply (5cm x 5cm, 8 ply)
1013	HemCon GuardaCare PRO, 4in x 4in, 8ply (10cm x 10cm, 8 ply)
1089	HemCon ChitoGauzeXR PRO, 3in x 4 yds, Prometheus (7.5cm x 37m)
1090	HemCon ChitoGauzeXR PRO, 3in x 4yds (7.5cm x 37m)

Basic UDI-DI Information		
Device Family	GS1 Company Prefix	Basic UDI-DI
Gauze	087005300	087005300GauzeGH