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greiner BIO-ONE

EU Declaration of Conformity

to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: AT-MF-000024608
Production Location:	Surge Industrial Co., Ltd. 4F., No.258, Sec. 3, BeiShen Rd., ShenKeng District, New Taipei City 22204, Taiwan (R.O.C.)	Starlim Spritzguss GmbH Mühlstraße 21 4614 Marchtrenk Austria
Product / Product Group:	VACUETTE® Tourniquets (for details please refer to page 2)	
Basic UDI-DI (GMN):	912001757G00000069K	
Classification:	Class I according to Regulation (EU) 2017/745 of the european parliament and of the council of 5 April 2017 on medical devices, Annex VIII - Chapter III Classification Rules - 4.1. Rule 1	
GMDN Code(s):	67048	

We herewith declare under our sole responsibility that the products specified above meet the provisions of the above-mentioned Regulation. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure according to Annex IV of the Regulation (EU) 2017/745.

Standards / common specifications:
Refer to the list of applicable (harmonized) standards and common specifications in the Technical Documentation.

Kremsmünster, 23.09.2024

greiner QM bio-one

Georg Sambs
Director Quality Management

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Product Group	Product name - detailed product description	Item numbers	Production Location
VACUETTE® Tourniquets Single-use	VACUETTE® Disposable Tourniquet latex-free, synthetic rubber, non-sterile	840053	1
VACUETTE® Tourniquets Single-use	VACUETTE® Super-T Disposable Tourniquet latex-free	840056	2

[1] Surge Industrial Co., Ltd.

[2] Starlim Spritzguss GmbH