CE 0123

greiner BIO-ONE

EC Declaration of Conformity

Conformity to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	
Production Location:	Nipro Medical Industries Ltd. Tatebayashi Plant 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 Japan	Nipro (Thailand) Corporation Ltd. 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110 Thailand
Product / Product Group:	VACUETTE® Luer Adapter (for details please refer to page 2)	
Classification:	Class Is, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices Annex IX, III Classification, 1.1 rule 1	
GMDN Code(s):	60579	

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex V and Annex VII of the Council Directive 93/42/EEC concerning medical devices

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München
G2S 029670 0036 Rev. 00, valid until 26 May 2024

Standards:
Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 11.04.2022

greiner QM bio-one

Signature: .....
Georg Sambs
Quality Manager GBO AT

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PRODUCT GROUP	Product name - detailed product description	Item numbers	Production Location
VACUETTE® Luer Adapter	VACUETTE® Luer Adapter 20G sterile, not made with natural rubber latex	450070	1
VACUETTE® Luer Adapter	VACUETTE® Blood Culture Holder + Luer Adapter 20G single-packed, sterile, not made with natural rubber latex	450197	2

[1] Nipro Medical Industries Ltd.
[2] Nipro (Thailand) Corporation Ltd.