Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Greiner Bio-One GmbH
Manufacturer address	Bad Haller Straße 32 4550 Kremsmünster Austria
Single Registration Number (SRN)	AT-MF-000024608
Production Location	Nipro Medical Industries Ltd. Tatebayashi Plant 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 Japan

Notified body name	TÜV SÜD Product Service GmbH
Notified body number	0123
Directive Certificate number to which this confirmation is made	G2 029670 0035 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26th May 2024
End date of extended validity / transition period	31st December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

The Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

This document is valid until 30th June 2024.

Kremsmünster, 17th May 2024

greiner QM bio-one

Daniela Gossenreiter
Head of Regulatory Affairs
Greiner Bio-One GmbH
Bad Haller Straße 32
A-4550 Kremsmünster
Tel.: ++43(0)7583/6791-0
Fax: ++43(0)7583/6318
www.gbo.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., product category)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
VACUETTE® Multiple Use Drawing Needles	G2 029670 0035 Rev.00	26th May 2024	TÜV SÜD Product Service GmbH with identification number 0123	TÜV SÜD Product Service GmbH with identification number 0123	31st December 2028	Not applicable
VACUETTE® VISIO PLUS Need es	G2 029670 0035 Rev.00	26th May 2024	TÜV SÜD Product Service GmbH with identification number 0123	TÜV SÜD Product Service GmbH with identification number 0123	31st December 2028	Not applicable