

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 | 26 th May 2024 |
| End date of extended validity / transition period | 31 st 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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.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



Daniela Gossenreiter
Head of Regulatory Affairs

Greiner Bio-One GmbH
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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 | 26 th May 2024 | TÜV SÜD Product Service GmbH with identification number 0123 | TÜV SÜD Product Service GmbH with identification number 0123 | 31 st December 2028 | Not applicable |
| VACUETTE® VISIO PLUS Needles | G2 029670 0035 Rev.00 | 26 th May 2024 | TÜV SÜD Product Service GmbH with identification number 0123 | TÜV SÜD Product Service GmbH with identification number 0123 | 31 st December 2028 | Not applicable |



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 029670 0035 Rev. 00

Manufacturer: **Greiner Bio-One GmbH**
Bad Haller Straße 32
4550 Kremsmünster
AUSTRIA

Facility(ies): Greiner Bio-One GmbH
Bad Haller Straße 32, 4550 Kremsmünster, AUSTRIA

Product Category(ies): **VACUETTE® Blood Collection System:
VACUETTE® Multiple Use Drawing Needles,
including VACUETTE® VISIO PLUS Needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713152781

Valid from: 2019-09-19
Valid until: 2024-05-26

Date, 2019-09-19

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICADO ◆ CERTIFICADO

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認證契約

認證は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとします。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認證書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
 - 定期的な工場監査を実施している

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.