# Certificate

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| Certificate No.: | MD 1650172-1-1 |
| Manufacturer: | **Greiner Bio-One GmbH**<br>Bad Haller Str. 32<br>4550 Kremsmünster<br>Austria |
| REPs Facility ID: | F002015 |
| Certification criteria: | ISO 13485:2016<br>Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure<br>Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009<br>Canada Medical Devices Regulations – Part 1 – SOR 98/282<br>Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act<br>United States 21 CFR 820*, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D. |
| Scope: | Design, manufacture and distribution of collection systems for medical use, for the collection of urine-, saliva-, and blood samples from patients, including blood collection needles and blood collection sets, sediment screeners and timers for measurement of erythrocyte sedimentation rate. |

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

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|---|---|
| Project No.: | 1122649-230 |
| Issue Date: | 2023-02-14 |
| Effective Date: | 2023-03-01 |
| Expiry Date: | 2026-02-28 |

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105081177?locale=en or calling 1-888-743-4652.



TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

# Certificate

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Manufacturer: **Greiner Bio-One GmbH**

Bad Haller Str. 32
4550 Kremsmünster
Austria

The scope of certification includes the following additional sites:

| No. | Location | Scope |
|---|---|---|
| /01 | Greiner Bio-One GmbH<br>Bad Haller Str. 32<br>4550 Kremsmünster<br>Austria<br><br>REPs Facility ID: F002015 | Design, manufacture and distribution. |
| /02 | Greiner Bio-One GmbH<br>Plant Rainbach<br>Gewerbepark 2<br>4261 Rainbach im Mühlkreis<br>Austria<br><br>REPs Facility ID: F001092 | Manufacture. |

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