

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1650172-1  
Certificate Holder: Greiner Bio-One GmbH  
Bad Haller Str. 32  
4550 Kremsmünster  
Austria  
Scope: Design, manufacture and distribution of collection systems for medical use, for the collection of urine- and blood samples from patients, including blood collection needles and blood collection sets.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1201242-100  
Effective date: 2026-02-21  
Expiry date: 2029-02-20  
Issue date: 2026-02-18  
Replaces certificate SX 1650172-1 issued 2023-02-14



Dr. Matthias Fischer  
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Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Greiner Bio-One GmbH Bad Haller Str. 32 4550 Kremsmünster Austria	Design, manufacture and distribution.
/02	c/o Greiner Bio-One GmbH Plant Rainbach Gewerbepark 2 4261 Rainbach im Mühlkreis Austria	Manufacture.

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