

# Certificate



**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 1650172-1

Organization: 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-, saliva-, and blood samples from patients, including blood collection needles and blood collection sets, sediment screeners and timers for measurement of erythrocyte sedimentation rate.

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.: 1122649-40  
Effective date: 2023-02-21  
Expiry date: 2026-02-20  
Issue date: 2023-02-14



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Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification also covers the following:

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

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