Certificate

Standard

ISO 9001:2015

Certificate Registr. No.

01 100 1412516

Certificate Holder:

Greiner Bio-One GmbH

Bad Haller Str. 32 4550 Kremsmünster

Austria

including the locations according to annex

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, products for general laboratory use and accessories for industrial, medical and research use

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2023-02-21 until 2026-02-20. First certification 2014

2023-02-02

P.Z

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln







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Annex to certificate

Standard

ISO 9001:2015

Certificate Registr. No.

01 100 1412516

2023-02-02

No.	Location	Scope
/01	c/o Greiner Bio-One GmbH Bad Haller Str. 32 4550 Kremsmünster Austria	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, products for general laboratory use and accessories for industrial, medical and research use
/02	c/o Greiner Bio-One GmbH Plant Rainbach Gewerbepark 2 4261 Rainbach im Mühlkreis Austria	Manufacture 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, products for general laboratory use and accessories for industrial, medical and research use
		No

Page 1 of 1

TÜV Rheinland Cert GmbH

Am Grauen Stein · 51105 Köln





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

DAkkS Akkreditierungsstelle D-ZM-14169-01-02

Dipl.-Ing. (FH) Daniéle Wiedemuth TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜVAhelnland