

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1096858-1

Organization: Greiner Bio-One North America Inc.
4238 Capital Drive
Monroe, NC 28110
USA

Scope: Manufacture and distribution of collection systems for medical use,
for the collection of urine-, saliva- and blood samples from patients,
and distribution of blood collection sets and blood collection needles

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.: 1130379-40
Effective date: 2023-05-06
Expiry date: 2026-05-05
Issue date: 2023-04-27



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Certificate



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EN ISO 13485:2016**

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Organization: Greiner Bio-One North America Inc.
4238 Capital Drive
Monroe, NC 28110
USA

No.	Facility	Scope
/01	c/o Greiner Bio-One North America Inc. 4238 Capital Drive Monroe, NC 28110 USA	Manufacture and distribution of collection systems for medical use, for the collection of urine-, saliva- and blood samples from patients, and distribution of blood collection sets and blood collection needles
/02	c/o Greiner Bio-One North America Inc. 4218 Capital Drive Monroe, NC 28110 USA	Storage and distribution

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