EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices,
Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HX 1036347-1
Manufacturer:	**Greiner Bio-One GmbH** Maybachstr. 2 72636 Frickenhausen Germany
EUDAMED Single Registration No.:	DE-MF-000032396
Products:	Products of class A, sterile: DEVICES FOR SAMPLES TRANSPORT (non-generic laboratory products) IVR 0803: Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746 W05020199 - SAMPLES TRANSPORT, CONTAINERS - OTHER The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
Authorised representative(s):	N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market. If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.:	1123030-40
Effective date:	2023-08-28
Expiry date:	2028-08-27
Issue date:	2023-08-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices,
Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1036347-1

Manufacturer: **Greiner Bio-One GmbH**
Maybachstr. 2
72636 Frickenhausen
Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-08-28

Report No.: 1123030-40

Effective date: 2023-08-28

Expiry date: 2028-08-27

Issue date: 2023-08-28

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.