ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 055425 0007 Rev. 01

Manufacturer:	**PreAnalytiX GmbH** Feldbachstrasse 8634 Hombrechtikon SWITZERLAND
SRN Manufacturer:	Not available at issuance date of this certificate
Authorized Representative:	Qiagen GmbH Qiagen Str. 1, 40724 Hilden, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:V11 055425 0007 Rev. 01

Report No.:	713249633
Preceding Certificate No.:	V11 055425 0007 Rev. 00
Valid from:	2022-04-27
Valid until:	2026-04-14
Date of Initial Issuance:	2021-04-15

Issue date: 2022-04-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 055425 0007 Rev. 01

Classification:	A
Device Group:	W0501 - SAMPLES COLLECTION DEVICES
Intended Purpose:	IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746
The validity of this certificate depends on conditions and/or is limited to the following:	The audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Revision History:

Rev.	Dated	Report
00	2021-04-15	713194664 / 713206051

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®