EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

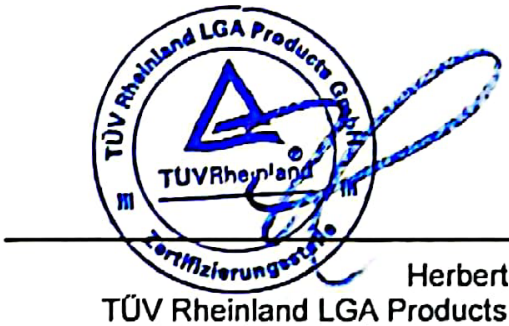
TÜVRheinland®

Registration No.:	HZ 2336171-1
Manufacturer:	**Suzhou Shengtian Biotechnology Co., Ltd.** Room 301, F3, B5, No.35 Dongfu Road, Suzhou Industrial Park, Suzhou, 215000 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000009632
Products:	Products of class I, sterile: A1101 Sample Collection Neutral Swabs - Disposable Sampling Swabs The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
Authorised representative(s):	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-03-22

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 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. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	244334808-200
Effective date:	2022-03-22
Expiry date:	2027-01-20
Issue date:	2022-03-22



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2336171-1

Organization: Suzhou Shengtian Biotechnology Co., Ltd.
Room 301, F3, B5, No.35 Dongfu Road, Suzhou Industrial Park,
Suzhou,
215000 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Sampling Swabs

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.: 244334808-200
Effective date: 2022-03-22
Expiry date: 2025-01-20
Issue date: 2022-03-22

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02