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

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TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

SARTORIUS

Sartorius Stedim Biotech GmbH

August-Spindler-Str. 11
37079 Göttingen
Germany

has established and applies
a Quality Management System for

Development, production, sales and service of products for biotechnology.

An audit was performed, Order No. **707108959**.

Proof has been furnished that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2023-05-22** until **2026-05-21**.

Certificate Registration No.: **12 100 59786 TMS**.

Head of Certification Body
Munich, 2023-03-29

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

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

Management Service

ZERTIFIKAT

Die Zertifizierungsstelle
der TÜV SÜD Management Service GmbH

bescheinigt, dass das Unternehmen

SARTORIUS

Sartorius Stedim Biotech GmbH

August-Spindler-Str. 11
37079 Göttingen
Deutschland

für den Geltungsbereich

Entwicklung, Produktion, Vertrieb und Service
von Produkten für die Biotechnologie

ein Qualitätsmanagementsystem
eingeführt hat und anwendet.

Durch ein Audit, Auftrags-Nr. **707108959**,
wurde der Nachweis erbracht, dass die Forderungen der

DIN EN ISO 9001:2015

erfüllt sind.

Dieses Zertifikat ist gültig vom **22.05.2023** bis **21.05.2026**.

Zertifikat-Registrier-Nr.: **12 100 59786 TMS**.

Leiter der Zertifizierungsstelle
München, 29.03.2023

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

BIOSERVICE
SCIENTIFIC LABORATORIES GmbH

BIOCOMPATIBILITY

CERTIFICATE

Testmaterial: **Name:** **Sartopore PLATINUM**
Order No.: **5492507H1**
Lot No.: **0017283**

Supplier: Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11, D-37079 Göttingen

Studies performed: The following studies were performed in order to determine the biocompatibility of the device. The material was produced according to the manufacturing process of Sartorius Stedim Biotech GmbH.

CYTOTOXICITY (BSL Project No. 104317)

USP BIOLOGICAL TEST
(CLASSIFICATION VI/121 °C) (BSL Project No. 104318)

Results: **The test item did not show any effect in the USP Class VI test and meets the criteria of USP Biological Tests Classification VI. No leachable substances were released in cytotoxic concentrations from the test item.**

BSL BIOSERVICE Scientific Laboratories GmbH
Behringstraße 6/8
D-82152 Planegg

BSL BIOSERVICE Scientific Laboratories GmbH ISO 17025

Dr. Daniela Stelter
Biological Safety Testing
Date: 04 November 2010
Re-issue Date: 18 May 2012

Quality Assurance Certificate

	Sartopore® Platinum
Order no.	5492507H1
Use before	10 / 2028
Pore size	0.45 + 0.2 µm
Lot no.	2341003713

This document certifies that the designated product was manufactured by Sartorius in conformance with established quality standards.

This product is developed, produced and distributed according to a Quality Management System that is certified for compliance with DIN/ISO 9001.

This product is registered with the Food and Drug Administration (FDA). The DMF number is available upon request.

This product has passed Sartorius' inhouse tests and thus meets Sartorius' stringent quality control standards.

Integrity test values: Each membrane filter element has been individually tested for integrity by means of diffusion and bubble point testing. These tests have been performed according to the procedures stated in the corresponding Validation Guide.

For this filter element the bubble point measured was ≥ 3.5 bar/ 50.7 psi.

Diffusion rate measured for this filter was found to be ≤ 25.0 ml/min, at a test pressure of 2.5 bar/ 36 psi.

For sterilizing - grade filters, these integrity test values have been fully correlated to the ASTM F 838 Bacteria Challenge test, using a challenge level ≥ 1 x 10^7 CFU/cm^2 of *Brevundimonas diminuta*.

Biosafety: All materials of this filter element meet the requirements of the current USP Biological Reactivity tests <88> for plastics Class VI, (Systemic Injection, Intracutaneous and Implantation tests).

Non fibre releasing: This filter product complies with the title21 of the Code of Federal Regulations (CFR), section 210.3(b)(6) and 211.72.

In addition to these main tests, the following is checked on a regular basis:

Bacterial Retention: Quantitative retention of *Brevundimonas diminuta* (*Serratia marcescens*) is checked for every 0.2 µm (0.45 µm) membrane lot. Additionally, the retention of *B. diminuta* (*S. marcescens*) is checked by regular sampling of all sterilizing grade (0.45 µm rated) filter elements.

Oxidizable Substances: The filtrate of these filter elements shows a negative reaction when tested according to the current USP.

Extractable Substances: The total amount of extractables is well below the limits established by the current USP under "Sterile Water for Injection".

Bacterial Endotoxins: An endotoxine free water extract of this filter product contains less than 0.25 EU/ml, which was determined by using the Limulus Amebocyte Lysate (LAL) test.

Particulate Matter: This product releases particulate matter in quantities well below the requirements established in the current USP in "Large Volume Injections for Single Dose Infusion".

Thermal Stability: Filter cartridges that underwent multiple (25) steam sterilization cycles at 134 °C showed no loss of integrity.

Note: Details of the methodologies used in the tests mentioned above as well as more detailed test results are given in the respective Validation Guide.

2023-10-17

Date

Dr. Anna Vreemann
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH
37070 Goettingen, Germany

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