

CERTIFICAT



CERTIFICADO



СЕРТИФИКАТ



認證證書



CERTIFICATE



ZERTIFIKAT



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





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



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## 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  $\geq 3.5$  bar/ 50.7 psi.

Diffusion rate measured for this filter was found to be  $\leq 25.0$  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  $\geq 1 \times 10^7$  CFU/cm<sup>2</sup> 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 title 21 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

Phone +49.551.308.0  
Fax +49.551.308.3289

[www.sartorius.com](http://www.sartorius.com)

## Quality Assurance Certificate

**Sartopore® Platinum**  
Sterile Capsule

**Order no.** 5491307H4--SS--B

**Use before** 10 / 2027

**Pore size** 0.45 + 0.2 µm

**Lot no.** 2444000203  
Max. operating pressure 4 bar  
Sterilization: Autoclaving at max. 134 °C,  
no in-line steaming

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 filter capsule was sterilized using a validated process following DIN/EN ISO 17665-1 regulations, pertaining to "Sterilization of Medical Products".

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  $\geq 3.5$  bar/ 50.7 psi.

Diffusion rate measured for this filter was found to be  $\leq 1.1$  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  $\geq 1 \times 10^7$  CFU/cm<sup>2</sup> 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 title 21 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:**

**Retention of *B. diminuta*:** Quantitative retention of *Brevundimonas diminuta* is checked for every 0.2 µm membrane lot. Additionally, the retention of *B. diminuta* is checked by regular sampling of all sterilizing grade 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:** Capsules that underwent multiple (3) autoclaving 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.

2024-11-08

Date



Dr. Anna Vreemann  
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH  
37070 Goettingen, Germany

Phone +49.551.308.0  
Fax +49.551.308.3289

[www.sartorius.com](http://www.sartorius.com)

## Quality Assurance Certificate

**Sartopore® Platinum**  
Sterile Midicaps®

**Order no.** 5495307H7--SS--A

**Use before** 11 / 2027

**Pore size** 0.45 + 0.2 µm

**Lot no.** 2448007103  
Max. operating pressure: 5 bar/72.5 psig  
Sterilization: Autoclaving at max. 134 °C,  
no in-line steaming

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 filter capsule was sterilized using a validated process following DIN/EN ISO 17665-1 regulations, pertaining to "Sterilization of Medical Products".

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  $\geq 3.5$  bar/ 50.7 psi.

Diffusion rate measured for this filter was found to be  $\leq 4.0$  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  $\geq 1 \times 10^7$  CFU/cm<sup>2</sup> 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 title 21 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:**

**Retention of *B. diminuta*:** Quantitative retention of *Brevundimonas diminuta* is checked for every 0.2 µm membrane lot. Additionally, the retention of *B. diminuta* is checked by regular sampling of all sterilizing grade 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:** Capsules that underwent multiple (25) autoclaving 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.

2024-11-28

Date



Dr. Anna Vreemann  
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH  
37070 Goettingen, Germany

Phone +49.551.308.0  
Fax +49.551.308.3289

[www.sartorius.com](http://www.sartorius.com)