CE	OriginalSartoriusEG-/EU-KonformitätserklärungSartoriusEC / EU Declaration of Conformity
Hersteller <i>Manufacturer</i>	Sartorius Lab Instruments GmbH & Co. KG 37070 Goettingen, Germany
	erklärt in alleiniger Verantwortung, dass das Betriebsmittel declares under sole responsibility that the equipment
Geräteart <i>Device type</i>	Sartocheck <sup>®</sup> Integritäts-Testgerät / Sartocheck <sup>®</sup> Integrity tester (Sartocheck <sup>®</sup> 5)
Modell / <i>Model</i>	26787Ғ, 26787ҒР
	in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien – einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen – entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen erfüllt: <i>in the form as delivered fulfils all the relevant provisions of the following European Directives –</i> <i>including any amendments valid at the time this declaration was signed – and meets the applicable</i> <i>requirements of the harmonized European Standards listed below:</i>
2014/30/EU	Elektromagnetische Verträglichkeit / Electromagnetic compatibility EN 61326-1:2013
2011/65/EU	Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS) Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) EN 50581:2012
2014/34/EU	Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen Equipment and protective systems intended for use in potentially explosive atmospheres
	EN 60079-0:2012 + A11:2013, EN 60079-11:2012, EN 60079-15:2010
	Kennzeichnung / Marking.II 3 (1)GEx nA [ia Ga] IIB T4 GcEG-Baumusterprüfbescheinigung Nummer/EC-Type Examination Certificate number.DEKRA 17ATEX0084 X
2006/42/EG	Maschinen / Machines
2006/42/EC	EN ISO 12100:2010, EN 61010-1:2010
	Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen: <i>The person authorised to compile the technical file:</i> Sartorius Lab Instruments GmbH & Co. KG International Certification Management 37070 Goettingen. Germany
	Jahreszahl der CE-Kennzeichenvergabe / Year of the CE mark assignment: 18
	Sartorius Lab Instruments GmbH & Co. KG Goettingen, 2018-02-16
	iv. P.B. Me i.V. M.A
	Dr. Reinhard Baumfalk Dr. Dieter Klausgrete Vice President R&D Head of International Certification Management
	Diese Erklärung bescheinigt die Übereinstimmung mit den genannten EG- und EU-Richtlinien, ist jedoch keine Zusicherung von Eigenschaften. Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit. Die Sicherheitshinweise der zugehörigen Produktdokumentation sind zu beachten.
	This declaration certifies conformity with the above mentioned EC and EU Directives, but does not guarantee product attributes. Unauthorised product modifications make this declaration invalid. The safety information in the associated product documentation must be observed.
	Doc 2264243-00 SU17CE003-00 de en 1 / 1 PME 2264241 OP-113 foi 2015 10 12

0	TM		· <b>y</b>
	INTERNATIONAL ELECTR IEC Certification Scheme for rules and details of the IEC	OTECHNICAL COMMISSIC for Explosive Atmospheres	DN
Certificate No.:	IECEx DEK 17.0056X	Issue No: 0	Certificate history:
Status:	Current		Issue INO. 0 (2018-02-07)
Date of Issue:	2018-02-07	Page 1 of 4	
Applicant:	Sartorius Lab Instruments GmbH & Co. KG Otto-Brenner-Strasse 20, 37079 Göttingen Germany		
Equipment:	Fully Automatic Filter Integrity Testing Device, FT and Model 26787—FT—P, Accessory Kit I EV	Type Sartocheck 5 (SC5), Model 26787- External Venting SC5, Model 26787—AK-	-
Optional accessory:	Environmental Temperature Sensor for SC5 F	Plus, Model 26787ES	
Type of Protection:	Ex nA [ia], Ex ia		
Marking:	Ex nA [ia Ga] IIB T4 Gc (Sartocheck 5) Ex ia IIB T4 Ga (Accessory Kit Exte	rna <b>l</b> Venting)	
Approved for issue on Certification Body:	behalf of the IECEx	R. Schuller	
Position:		Certification manager	
Signature:		Rlath	
(for printed version)		Ja	
Date:		2018-02-07	
1. This certificate and 2. This certificate is no 3. The Status and aut	schedule may only be reproduced in full. ot transferable and remains the property of the is henticity of this certificate may be verified by visit	suing body. ting the Official IECEx Website.	
Certificate issued by:	DEKRA Certification B.V. Meander 1051, 6825 MJ Amhem The Netherlands	DEKRA	

	T.V	IECEx Certificate
		of Conformity
Certificate No:	IECEx DEK 17.0056X	Issue No: 0
Date of Issue:	2018-02-07	Page 2 of 4
Manufacturer:	Sartorius Lab Instruments GmbH Otto-Brenner-Strasse 20, 37079 Germany	& Co. KG Göttingen
Additional Manufacturing loc	cation(s):	

This certificate is issued as verification that a sample(s), representative of production, was assessed and tested and found to comply with the IEC Standard list below and that the manufacturer's quality system, relating to the Ex products covered by this certificate, was assessed and found to comply with the IECEx Quality system requirements. This certificate is granted subject to the conditions as set out in IECEx Scheme Rules, IECEx 02 and Operational Documents as amended.

#### STANDARDS:

The electrical apparatus and any acceptable variations to it specified in the schedule of this certificate and the identified documents, was found to comply with the following standards:

IEC 60079-0 : 2011	Explosive atmospheres - Part 0: General requirements
Edition:6.0	
<b>IEC 60079-11 : 2011</b> Edition:6 <b>.</b> 0	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
<b>IEC 60079-15 : 2010</b> Edition:4	Explosive atmospheres - Part 15: Equipment protection by type of protection "n'

This Certificate does not indicate compliance with electrical safety and performance requirements other than those expressly included in the

Standards listed above.

#### TEST & ASSESSMENT REPORTS:

A sample(s) of the equipment listed has successfully met the examination and test requirements as recorded in

Test Report: NL/DEK/ExTR17.0049/00

Quality Assessment Report:

GB/FME/QAR13.0020/02



# IECEx Certificate of Conformity

Certificate No:

ECEx DEK 17.0056X

ssue No: 0

Page 3 of 4

Date of Issue:

2018-02-07

Schedule

#### EQUIPMENT:

Equipment and systems covered by this certificate are as follows:

#### Description:

Fully Automatic Filter Intergrity Testing Device, Sartocheck 5 (SC5), Model 26787---FT and Model 26787---FT ---P, serves for testing filters. The two models differ in software only.

The Sartocheck 5 is located in an area, requiring equipment protection level Gc. The Sartocheck 5 contains an air-tank, several air-valves, electronics and a touch screen, and the enclosure provides a degree of protection of at least IP4X, when tested in accordance with IEC 60079-0: 2011.

The Environmental Temperature Sensor for SC5 Plus, Model 26787---ES---. only contains a PT1000 temperature sensor and is considered a "simple apparatus". When it is connected to the "Ext. Press Sensor" connector (pin 1, 2), it conforms to the requirements: Ex ia IIB T4 Ga.

Ambient temperature range: 0 to 40 °C.

#### SPECIFIC CONDITIONS OF USE: YES as shown below:

The Sartocheck 5 (SC5), when applied in an area requiring the use of EPL Gc equipment, shall be installed in such a way that:

- it is protected against the entry of solid foreign objects or water capable of impairing the safety of the apparatus
- the pollution degree 2 of the internal electronics is guaranteed
- the risk of mechanical danger is low

Static charging of the plastic parts of the enclosure of the Sartocheck 5 shall be avoided.

For the Accessory Kit External Venting, when installed in an area requiring EPL Ga: Because the enclosure is made of aluminium it shall be installed such, that, even in the event of rare incidents, ignition sources due to impact and friction sparks are excluded.



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KRA D DE EXPA	KRA DE	(1)	EU-Ty	pe Examination	
VC	5	(2)	Equipment o potentially e 2014/34/EU	or protective systems intended for use in xplosive atmospheres - Directive	
5	2	(3)	EU-Type Exam	ination Certificate Number: DEKRA 17ATEX0084 X Issue Number: 0	
	D	(4)	Product:	Fully Automatic Filter Integrity Testing Device, Type Sartocheck 5 (SC5), Model 26787FT and Model 26787FTP, Accessory Kit External Venting SC5, Model 26787AKEV	
L		(5)	Manufacturer:	Sartorius Lab Instruments GmbH & Co. KG	
NRA > DE	D D D KRA	(6)	Address:	Otto-Brenner-Strasse 20, 37079 Göttingen, Germany	
EKRA D D SEKRJ	EKEA	(7)	This product an therein referred	nd any acceptable variation thereto is specified in the schedule to this certificate and the documents I to.	
DEKR DEKR DEK	dekr dekr RA D	(8)	DEKRA Certific European Parli comply with the intended for us	cation B.V., Notified Body number 0344 in accordance with Article 17 of Directive 2014/34/EU of the ament and of the Council, dated 26 February 2014, certifies that this product has been found to a Essential Health and Safety Requirements relating to the design and construction of products e in potentially explosive atmospheres given in Annex II to the Directive.	
84 <i>9</i> 9 06	KRA		The examination	on and test results are recorded in confidential test report number NL/DEK/ExTR17.0049/00.	
ea J D D	D DE	(9)	Compliance with	th the Essential Health and Safety Requirements has been assured by compliance with:	
KRA D D	Þ ÞÍ IEKRI		EN 60079-0 : 2012 + A11: 2013 // EN 60079-11 : 2012 // EN 60079-15 : 2010		
EKRA	DEKR		except in respe	ct of those requirements listed at item 18 of the Schedule.	
EKRI	DEK	(10)	If the sign "X" is of Use specifie	s placed after the certificate number, it indicates that the product is subject to the Specific Conditions d in the schedule to this certificate.	
DEKR RA D DEK	n der Ra I	(11)	This EU-Type I requirements of by this certifica	Examination /Certificate relates only to the design and construction of the specified product. Further If the Directive apply to the manufacturing process and supply of this product. These are not covered te.	
cea > dei	CRA DD	(12)	The marking of	the product shall include the following:	
D DE EKRA D D DEKR DEKR	KRA DEKRA A D DEKR		(Ex)	II 3(1) G Ex nA [ia Ga] IIB T4 Gc (Sartocheck 5) II 1 G Ex ia IIB T4 Ga (Accessory Kit External Venting)	
A D	(RA )		Date of certifica	ation: 7 February 2018	
RA J D DE	KRA		DEKRA Certific	cation B.V.	
DD XRA DC EKRA	EKRA D D DEKRA DEKR DEKR		B	Lille	
DEKR DEKR DEKR	a D dek za D def		R. Schuller Certification Ma	anager Page 1/3	
DER KRA	RA 1 D DI				
> de ekra	20	PHOL BVA	1011S •	Integral publication of this certificate and adjoining reports is allowed. This Certificate may only be reproduced in its entirety and without any change.	
	LICEA N D NEKRI NA D	DEKRA T +31 8	A Certification B.V 38 96 83000 F +3	. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands 31 88 96 83100 www.dekra-certification.com Registered Arnhem 09085396	
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# DEKRA

#### (13) SCHEDULE

#### (14) to EU-Type Examination Certificate DEKRA 17ATEX0084 X

Issue No. 0

#### (15) Description

Fully Automatic Filter Intergrity Testing Device, Sartocheck 5 (SC5), Model 26787---FT and Model 26787---FT---P, serves for testing filters. The two models differ in software only.

The Sartocheck 5 is located in an area, requiring equipment protection level Gc. The Sartocheck 5 contains an air-tank, several air-valves, electronics and a touch screen, and the enclosure provides a degree of protection of at least IP4X, when tested in accordance with EN 60079-0: 2011.

The Environmental Temperature Sensor for SC5 Plus, Model 26787---ES---. only contains a PT1000 temperature sensor and is considered a "simple apparatus". When it is connected to the "Ext. Press Sensor" connector (pin 1, 2), it conforms to the requirements: Ex ia IIB T4 Ga.

Ambient temperature range: 0 to 40 °C.

Electrical data

Supply: 100 Vac to 240 Vac.

All non intrinsically safe signals: Um = 264 Vac.

"Ext. Valves" connector: Valve circuits (combined circuits) in type of protection intrinsic safety Ex ia IIB, with the following maximum values:  $U_0 = 28,1 \text{ V}$ ;  $I_0 = 123 \text{ mA}$ ;  $P_0 = 860 \text{ mW}$ ;  $C_0 = 600 \text{ nF}$ ;  $L_0 = 5 \text{ mH}$ ;.

"Ext. Press Sensor" connector (pin 1, 2): Pressure Sensor circuits (combined circuits): in type of protection intrinsic safety Ex ia IIB, with the following maximum values:  $U_0 = 18,4 \text{ V}$ ;  $I_0 = 86 \text{ mA}$ ;  $P_0 = 605 \text{ mW}$ ;  $C_0 = 1,69 \mu\text{F}$ ;  $L_0 = 8 \text{ mH}$ ; (non linear characteristic) "Ext. Press Sensor" connector (pin 4, 5, 6, 8, 11, 12): temperature sensor and pressur sensor data (combined circuits): in type of protection intrinsic safety Ex ia IIB, with the following maximum values:  $U_0 = 5,6 \text{ V}$ ;  $I_0 = 47 \text{ mA}$ ;  $P_0 = 181 \text{ mW}$ ;  $C_0 = 900 \mu\text{F}$ ;  $L_0 = 4 \text{ mH}$ ;

"Env, Temp. Sensor" connector: Environmental temperature sensor (combined circuits): in type of protection intrinsic safety Ex ia IIB, with the following maximum values:  $U_0 = 5,6 \text{ V}$ ;  $I_0 = 39 \text{ mA}$ ;  $P_0 = 144 \text{ mW}$ ;  $C_0 = 900 \text{ }\mu\text{F}$ ;  $L_0 = 5 \text{ mH}$ ;

"Extender Box" connector: Ethernet circuit (combined circuits): in type of protection intrinsic safety Ex ia IIB, only for connection to a certified intrinsically safe circuit, with the following maximum values:  $U_I = 30 \text{ V}$ ;  $I_I = any$ ;  $P_I = any$ ;  $C_I = 660 \text{ nF}$ ;  $L_I = 1 \text{ mH}$ .  $U_0 = 4,0V$ ;  $I_0 = 80 \text{ mA}$ ;  $P_0 = 320 \text{ mW}$ .

#### Installation instructions

The instructions provided with the product shall be followed in detail to assure safe operation.

#### (16) Report Number

No. NL/DEK/ExTR17.0049/00.

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Form 227A Version 1 (2016-04)

### (13) SCHEDULE

#### (14) to EU-Type Examination Certificate DEKRA 17ATEX0084 X

Issue No. 0

#### (17) Specific conditions of use

The Sartocheck 5 (SC5), when applied in an area requiring the use of EPL Gc equipment, shall be installed in such a way that:

 it is protected against the entry of solid foreign objects or water capable of impairing the safety of the apparatus

DEKRA

- o the pollution degree 2 of the internal electronics is guaranteed
- the risk of mechanical danger is low

Static charging of the plastic parts of the enclosure of the Sartocheck 5 shall be avoided.

For the Accessory Kit External Venting, when installed in an area requiring EPL Ga: Because the enclosure is made of aluminium it shall be installed such, that, even in the event of rare incidents, ignition sources due to impact and friction sparks are excluded.

#### (18) Essential Health and Safety Requirements

Covered by the standards listed at item 9.

#### (19) Test documentation

As listed in Report No. NL/DEK/ExTR17.0049/00.

(20) Certificate history

Issue 0 - 221341800 - initial certificate

Page 3/3

Form 227A Version 1 (2016-04)

CERTIFICATE	OF CONFORMITY



- 1. HAZARDOUS (CLASSIFIED) LOCATION ELECTRICAL EQUIPMENT PER US REQUIREMENTS
- 2. Certificate No:
- 3. Equipment: (Type Reference and Name)
- FM18US0128X

Sartocheck 5 (SC5) Model 26787---FT and 26787---FT---P

- 4. Name of Listing Company:
- 5. Address of Listing Company:

Sartorius Lab Instruments GmbH & Co KG.

Otto-Brenner-Straße 20 Goettingen 37079 Germany

6. The examination and test results are recorded in confidential report number:

PR449720 dated 24th October 2018

7. FM Approvals LLC, certifies that the equipment described has been found to comply with the following Approval standards and other documents:

FM 3810: 2018, ANSI/ISA 60079-0:2013, ANSI/ISA 60079-11:2014, ANSI/ISA 60079-15:2013

- 8. If the sign 'X' is placed after the certificate number, it indicates that the equipment is subject to specific conditions of use specified in the schedule to this certificate.
- 9. This certificate relates to the design, examination and testing of the products specified herein. The FM Approvals surveillance audit program has further determined that the manufacturing processes and quality control procedures in place are satisfactory to manufacture the product as examined, tested and Approved.

Certificate issued by:

9 Marguerdio J./E. Marquedant

VP, Manager, Electrical Systems

24 October 2018 Date

To verify the availability of the Approved product, please refer to www.approvalguide.com

#### THIS CERTIFICATE MAY ONLY BE REPRODUCED IN ITS ENTIRETY AND WITHOUT CHANGE

FM Approvals LLC. 1151 Boston-Providence Turnpike, Norwood, MA 02062 USA T: +1 (1) 781 762 4300 F: +1 (1) 781 762 9375 E-mail: <u>information@fmapprovals.com</u> <u>www.fmapprovals.com</u>

F 347 (Mar 16)

Page 1 of 4

	SCHEDULE <	FM Approvals
		Member of the FM Global Group
	US Certificate Of Conformity No: FM18US0128X	
10.	Equipment Ratings:	
	Sartocheck 5 (SC5) Model 26787FT and 26787FTP	
	Class I, Zone 2, AEx nA, Group IIB Gc hazardous (classified) indoor locations; T-Class = 0°C to +40°C with Intrinsically Safe outputs for connection to Class I, Zone 0, Gro hazardous (classifed) locations in accordance with installation drawing 2058868	T4, Ta = oups_IIB
	Accessory Kit External Venting SC5, Model 26787AKEV and	11.5
	Environmental Temperature Sensor for SC5 Plus, Model 26787ES	410
	Intrinsically Safe for use in Class I, Zone 0, AEx ia IIB T4 Ga hazardous (classified locations, in accordance with installation drawing 2058868. T-Class = T4, Ta = 0°C to +	) indoor 40°C;
11.	The marking of the equipment shall include:	
	Sartocheck 5 (SC5) Model 26787FT and 26787FTP	
	Class I, Zone 2, AEx nA[ia Ga] IIB T4, Gc Ta = 0°C to +40°C,	
	Accessory Kit External Venting SC5, Model 26787AKEV	
	Class I, Zone 0, AEx ia IIB T4, Ga Ta = 0°C to +40°C,	חור
	Class and Division Equivalency Marking also appears on the equipment as permitted per 29.19 of ANSI/ISA 60079-0 and article 501.5 of the National Electrical Code NFPA 70.	sections 29.18 and
12.	Description of Equipment:	COLUMN COMP.
	<b>General</b> - Fully Automatic Filter Integrity Testing Device, Sartocheck 5 (SC5), Model 267 26787FTP, serves for testing filters. The two models differ in software only.	787FT and Model
	The Sartocheck may include the following accessories, located in the area requiring equipr Ga, where the filters under test are located: Accessory Kit External Venting SC5, Model 26787AKEV Environmental Temperature Sensor for SC5 Plus, Model 26787ES	nent protection level
	<b>Construction</b> - The Sartocheck 5 contains an air-tank, several air-valves, electronics and the enclosure provides a degree of protection of at least IP4X.	a touch screen, and
	Ratings –	11.5
	Operation Temperature Ranges: The ambient operating temperature range of the Sartocheck 5 is 0°C to 40°C. Process te 0°C to 40°C.	emperature range is
	<u>Electrical data:</u> The Sartocheck has the following electrical ratings; Supply: 100 Vac to 240 Vac. Um = 264 Vac	
	THIS CERTIFICATE MAY ONLY BE REPRODUCED IN ITS ENTIRETY AND WITHOUT	CHANGE
FM A T: +1	Approvals LLC. 1151 Boston-Providence Turnpike, Norwood, MA 02062 USA I (1) 781 762 4300 F: +1 (1) 781 762 9375 E-mail: <u>information@fmapprovals.com</u> <u>www.fmapprovals.com</u>	
F 34	7 (Mar 16)	Page 2 of 4





## 🗄 sartorius FCC Supplier's Declaration of Conformity **Device type** Sartocheck<sup>®</sup> Integrity tester / Accessory Kit External Venting SC5 26787---FT, 26787---FT---P / 26787---AK---EV Model Party issuing Supplier's Declaration of Conformity / **Responsible Party – U.S. Contact Information** Sartorius Corporation 5 Orville Dr Suite 200 11716 Bohemia, NY USA Telephone: +1.631.254.4249 FCC Compliance Statement This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

#### Information to the user

Note: This equipment has been tested and found to comply with the limits for a **class B** digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Connections between the device and peripherals must be made using shielded cables in order to maintain compliance with FCC radio frequency emission limits.

Any modifications made to this device that are not approved by Sartorius may void the authority granted to the user by the FCC to operate this equipment.

Doc: 2417169-00 SLI18FCC046-00.en 1 / 1 PMF: 2264241 OP-113 fo1 2015.10.12

Made II	n Germany					Zeugnisnr.
ABNAHMEPRÜFZEUGNIS NSPECTION CERTIFICATE ACCORDING TO SERTIFICAT DE RECEPTION	EN 10204 3.1			Deutsche Edelstahlwerke		355562 / UT Seite Page / Page 5 / 5
eesteller ustomer International Metal Service tient		Bestell Nr. Order-No. Commande No.	1049534722			
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21	warmgewalzter Stab, Draht, rund, geschält aus korrossionsbest. Stahl Stahlbauwerken, Metall-/Beton- Verbundbauwerken, Hochbauten und Ingenieurbauwerken					
0432-CPR-00150-01/02 <u>Ine Leistungserklarung (LE) ist zu tinden</u>	Leistungserklärung (LE) 1.4404 1X www.dew-stahl.com/1.4404 1X					
		]				
Das Zeugnis wurde maschinell erstellt und ist This certificate was generated by a data syste Ce certificat a élé étabil sur systéme informati	gemäß EN 10204 ohne Unterschrift rechtsverbindlich. em, acc. to EN 10204, it is valid without signature. ique et est valable selon EN 10204 sans signature.		Tel: 0271/80 Fax: 0271/80 Email: verena	08-2642 08-2521 a.frisch@dew-stahl.com	Datum: Frisch (Abnahr Inspecto	23.04.2021 nebeauftragter/ br)

#### **Certificate Cartridges**



# SVILCIEVS

## **Quality Assurance Certificate**

	Sartopore® Platinum	This document certifies that the designated product was manufactured by Sattorius in conformance with
Order no.	5492507H1	established quality standards.
Use before	10 / 2028	This product is developed, produced and distributed
Pore size	0.45 + 0.2 μm	according to a Quality Management System that is certified for compliance with DIN/ISO 9001
Lot no.	2341003713	
		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  $\ge 1 \times 10^7$  CFU/cm<sup>2</sup> of *Brevun-dimonas 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

Phone +49.551.308.0 Fax +49.551.308.3289

www.sartorius.com