

Sartorius Stedim Biotech GmbH, 37070 Göttingen

To whom it may concern

Kevin Wallace Prosser
Phone +49551.308.4732
kevin.wallace.prosser@sartorius.com

December 19th, 2022

Letter of Authorization

Dear Sir or Madam,

We, Sartorius Stedim Biotech GmbH, August-Spindler-Straße 11,
37079 Göttingen, Germany, confirms, that

**TEKNOLEB LABORATORY SRL
DIONISIE LUPU 82
10459 BUCHAREST
ROMANIA**

is authorized distributor of Sartorius Stedim Biotech GmbH to may act and promote the marketing, sales, supply, support, distribution, consultancy and service of Sartorius Stedim Biotech GmbH product group in Republic of Moldova.

They are authorized to participate in public and private tenders and to provide for the fulfilment of the obligations deriving from the supply contract relating to the installation, commissioning, maintenance and technical assistance services on their own behalf and obligations.

This authorization is valid until 31.12.2023.

Best regards
Sartorius Stedim Biotech GmbH
Sales EEMEA


Tonci Jelavic
Regional Sales Manager EEMEA

Digitally signed by Baltag Lilian
Date: 2023.11.10 10:25:32 EET
Reason: MoldSign Signature
Location: Moldova

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




Cem Gür
Account Manager EE

Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius.com

Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB No. 200266

Managing Directors:
Uwe Becker,
Bettina Berendsen

Chairman of the Supervisory
Board:
Dr. Joachim Kreuzburg

S.C. TEKNOLEB LABORATORY S.R.L.
INTRARE Nr. 56
IESIRE
Ziua 09 Luna 11 Anul 2023

We, TEKNOLEB LABORATORY SRL, Sartorius authorized dealer in Romania and Republic of Moldova, based in Bucharest, 82 Dionisie Lupu, District 1, Romania, assign DIAGNOMED D.S.SRL, based in strada Piata 10, Republic of Moldova, as **authorized representative** in correspondence with the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Bucharest, Romania Date: 09.11.2023

Signed: LUCIARA CIOCARAN



Digitally signed by Baltag Lilian
Date: 2023.11.10 10:32:10 EET
Reason: MoldSign Signature
Location: Moldova



Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: DIAGNOMED D.S SRL, cu sediul social str. Piața Veche, 10, of.13,
mun. Chișinău, Republica Moldova,
tel. 079520116, e-mail : libaltag@gmail.com,

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate
pentru notificarea dispozitivelor medicale prezentate, conform Listei dispozitive
Sartorius Stedim Biotech GmbH.

Sunt autentice și corespund realității.

**Baltag Lilian,
Administrator**

Digitally signed by Baltag Lilian
Date: 2023.11.10 10:31:21 EET
Reason: MoldSign Signature
Location: Moldova



Semnătura _____

Data 06.11.2023

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul SRL DIAGNOMED D.S., cu sediul sediul social Piața Veche, 10, of.13,
mun. Chișinău, Republica Moldova,
tel. 079520116, e-mail: libaltag@gmail.com
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe
piață a dispozitivelor medicale, conform Listei dispozitive Sartorius Stedim Biotech
GmbH.

Se anexează următoarele acte:
Declarația pe propria răspundere 1 ex;
Formular de notificare 2 ex;
Lista dispozitive și consumabile 1ex .
Act reprezentant autorizat (1) 1ex
Act reprezentant autorizat (2) 1ex
Certificate de conformitate 1 ex

Digitally signed by Baltag Lilian
Date: 2023.11.10 10:33:09 EET
Reason: MoldSign Signature
Location: Moldova



Data 06.11.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul SRL DIAGNOMED D.S, cu sediul sediul social Piața Veche, 10, of.13,
mun. Chișinău, Republica Moldova,
tel. 079520116, e-mail: libaltag@gmail.com
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a dispozitivelor medicale, conform Listei dispozitive Sartorius Stedim Biotech
GmbH.

Se anexează următoarele acte:
Declarația pe propria răspundere 1 ex;
Formular de notificare 2 ex;
Lista dispozitive și consumabile 1ex .
Act reprezentant autorizat (1) 1ex
Act reprezentant autorizat (2) 1ex
Certificate de conformitate 1 ex

Digitally signed by Baltag Lilian
Date: 2023.11.10 10:33:57 EET
Reason: MoldSign Signature
Location: Moldova



Data 06.11.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexă Lista dispozitive Sartorius Stedim Biotech GmbH

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
Dispozitive					
1	26787---FT	Sartocheck 5	Sartorius StedimBiotech GmbH	Sartocheck 5	

Lilian Baltag

Administrator

DIAGNOMED D.S SRL

Gsm: 079520116

Email: libaltag@gmail.com

Digitally signed by Baltag Lilian
Date: 2023.11.10 17:31:34 EET
Reason: MoldSign Signature
Location: Moldova





Original

EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity



sartorius

Hersteller
Manufacturer

Sartorius Lab Instruments GmbH & Co. KG
37070 Goettingen, Germany

Digitally signed by Baltag Lilian
Date: 2023.11.10 10:35:30 EET
Reason: MoldSign Signature
Location: Moldova



erklärt in alleiniger Verantwortung, dass das Betriebsmittel
declares under sole responsibility that the equipment

Geräteart
Device type

Sartocheck® Integritäts-Testgerät / *Sartocheck® Integrity tester* (Sartocheck® 5)

Modell / Model

26787---FT, 26787---FT---P

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:

in the form as delivered fulfils all the relevant provisions of the following European Directives - including any amendments valid at the time this declaration was signed - and meets the applicable requirements of the harmonized European Standards listed below:

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)G Ex nA [ia Ga] IIB T4 Gc

EG-Baumusterprüfbescheinigung Nummer /

EC-Type Examination Certificate number:

DEKRA 17ATEX0084 X

2006/42/EG
2006/42/EC

Maschinen / *Machines*

EN ISO 12100:2010, EN 61010-1:2010

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:

The person authorised to compile the technical file:

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

i.v. P. Baumfalk

Dr. Reinhard Baumfalk
Vice President R&D

i.v. Klausgrete

Dr. Dieter Klausgrete
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

SLI17CE003-00.de,en

1 / 1

PMF: 2264241

OP-113_fo1_2015.10.12



IECEX Certificate of Conformity

INTERNATIONAL ELECTROTECHNICAL COMMISSION IEC Certification Scheme for Explosive Atmospheres

for rules and details of the IECEx Scheme visit www.iecex.com

Certificate No.:	IECEX DEK 17.0056X	Issue No: 0	Certificate history: Issue No. 0 (2018-02-07)
Status:	Current	Page 1 of 4	
Date of Issue:	2018-02-07		
Applicant:	Sartorius Lab Instruments GmbH & Co. KG Otto-Brenner-Strasse 20, 37079 Göttingen Germany		
Equipment:	Fully Automatic Filter Integrity Testing Device, Type Sartochek 5 (SC5), Model 26787— FT and Model 26787—FT—P, Accessory Kit External Venting SC5, Model 26787—AK— EV		
Optional accessory:	<i>Environmental Temperature Sensor for SC5 Plus, Model 26787---ES----</i>		
Type of Protection:	Ex nA [ia], Ex ia		
Marking:	Ex nA [ia Ga] IIB T4 Gc (Sartochek 5) Ex ia IIB T4 Ga (Accessory Kit External Venting)		
Approved for issue on behalf of the IECEx Certification Body:	R. Schuller		
Position:	Certification manager		
Signature: (for printed version)			
Date:	2018-02-07		

1. This certificate and schedule may only be reproduced in full.
2. This certificate is not transferable and remains the property of the issuing body.
3. The Status and authenticity of this certificate may be verified by visiting the Official IECEx Website.

Certificate issued by:

DEKRA Certification B.V.
Meander 1051,
6825 MJ Arnhem
The Netherlands





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 & Co. KG**
Otto-Brenner-Strasse 20, 37079 Göttingen
Germany

Additional Manufacturing location(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 Edition:6.0	Explosive atmospheres - Part 0: General requirements
IEC 60079-11 : 2011 Edition:6.0	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
IEC 60079-15 : 2010 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: IECEx DEK 17.0056X

Issue No: 0

Date of Issue: 2018-02-07

Page 3 of 4

Schedule

EQUIPMENT:

Equipment and systems covered by this certificate are as follows:

Description:

Fully Automatic Filter Integrity 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.



IECEX Certificate of Conformity

Certificate No: IECEx DEK 17.0056X

Issue No: 0

Date of Issue: 2018-02-07

Page 4 of 4

EQUIPMENT (continued):

Electrical data:

Supply: 100 Vac to 240 Vac.

All non intrinsically safe signals: $U_m = 264 \text{ Vac}$.

"Ext. Valves" connector: Valve circuits (combined circuits)

in type of protection intrinsic safety Ex ia IIB, with the following maximum values:

$U_o = 28,1 \text{ V}$; $I_o = 123 \text{ mA}$; $P_o = 860 \text{ mW}$; $C_o = 600 \text{ nF}$; $L_o = 5 \text{ mH}$; (non linear characteristics)

"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:

$U_o = 18,4 \text{ V}$; $I_o = 86 \text{ mA}$; $P_o = 605 \text{ mW}$; $C_o = 1,69 \mu\text{F}$; $L_o = 8 \text{ mH}$;

"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:

$U_o = 5,6 \text{ V}$; $I_o = 47 \text{ mA}$; $P_o = 181 \text{ mW}$; $C_o = 900 \mu\text{F}$; $L_o = 4 \text{ mH}$;

"Env, Temp. Sensor" connector: environmental temperature sensor (combined circuits):

in type of protection intrinsic safety Ex ia IIB, with the following maximum values:

$U_o = 5,6 \text{ V}$; $I_o = 39 \text{ mA}$; $P_o = 144 \text{ mW}$; $C_o = 900 \mu\text{F}$; $L_o = 5 \text{ mH}$;

"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:

$U_i = 30 \text{ V}$; $I_i = \text{any}$; $P_i = \text{any}$; $C_i = 660 \text{ nF}$; $L_i = 1 \text{ mH}$.

$U_o = 4,0 \text{ V}$; $I_o = 80 \text{ mA}$; $P_o = 320 \text{ mW}$.

CERTIFICATE

(1) EU-Type Examination

(2) Equipment or protective systems intended for use in potentially explosive atmospheres - Directive 2014/34/EU

(3) EU-Type Examination Certificate Number: DEKRA 17ATEX0084 X Issue Number: 0

(4) Product: Fully Automatic Filter Integrity Testing Device,
Type Sartocheck 5 (SC5), Model 26787---FT and
Model 26787---FT---P,
Accessory Kit External Venting SC5, Model 26787---AK---EV

(5) Manufacturer: Sartorius Lab Instruments GmbH & Co. KG

(6) Address: Otto-Brenner-Strasse 20, 37079 Göttingen, Germany

(7) This product and any acceptable variation thereto is specified in the schedule to this certificate and the documents therein referred to.

(8) DEKRA Certification B.V., Notified Body number 0344 in accordance with Article 17 of Directive 2014/34/EU of the European Parliament and of the Council, dated 26 February 2014, certifies that this product has been found to comply with the Essential Health and Safety Requirements relating to the design and construction of products intended for use in potentially explosive atmospheres given in Annex II to the Directive.

The examination and test results are recorded in confidential test report number NL/DEK/ExTR17.0049/00.

(9) Compliance with the Essential Health and Safety Requirements has been assured by compliance with:

EN 60079-0 : 2012 + A11: 2013 EN 60079-11 : 2012 EN 60079-15 : 2010

except in respect of those requirements listed at item 18 of the Schedule.

(10) If the sign "X" is placed after the certificate number, it indicates that the product is subject to the Specific Conditions of Use specified in the schedule to this certificate.

(11) This EU-Type Examination Certificate relates only to the design and construction of the specified product. Further requirements of the Directive apply to the manufacturing process and supply of this product. These are not covered by this certificate.

(12) The marking of the product shall include the following:



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)

Date of certification: 7 February 2018

DEKRA Certification B.V.



R. Schuller
Certification Manager

Page 1/3



Integral publication of this certificate and adjoining reports is allowed. This Certificate may only be reproduced in its entirety and without any change.

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Registered Arnhem 09085396



(13) **SCHEDULE**

(14) **to EU-Type Examination Certificate DEKRA 17ATEX0084 X** Issue No. 0

(15) **Description**

Fully Automatic Filter Integrity 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: $U_m = 264$ Vac.

"Ext. Valves" connector: Valve circuits (combined circuits)
in type of protection intrinsic safety Ex ia IIB, with the following maximum values:
 $U_o = 28,1$ V; $I_o = 123$ mA; $P_o = 860$ mW; $C_o = 600$ nF; $L_o = 5$ 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:
 $U_o = 18,4$ V; $I_o = 86$ mA; $P_o = 605$ mW; $C_o = 1,69$ μ F; $L_o = 8$ 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:
 $U_o = 5,6$ V; $I_o = 47$ mA; $P_o = 181$ mW; $C_o = 900$ μ F; $L_o = 4$ mH;

"Env, Temp. Sensor" connector: Environmental temperature sensor (combined circuits):
in type of protection intrinsic safety Ex ia IIB, with the following maximum values:
 $U_o = 5,6$ V; $I_o = 39$ mA; $P_o = 144$ mW; $C_o = 900$ μ F; $L_o = 5$ 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:
 $U_1 = 30$ V; $I_1 = \text{any}$; $P_1 = \text{any}$; $C_1 = 660$ nF; $L_1 = 1$ mH.
 $U_o = 4,0$ V; $I_o = 80$ mA; $P_o = 320$ 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.



(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
- 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

CERTIFICATE OF CONFORMITY



1. **HAZARDOUS (CLASSIFIED) LOCATION ELECTRICAL EQUIPMENT PER US REQUIREMENTS**
2. **Certificate No:** FM18US0128X
3. **Equipment:** Sartocheck 5
(Type Reference and Name) (SC5) Model 26787---FT and 26787---FT---P
4. **Name of Listing Company:** Sartorius Lab Instruments GmbH & Co KG.
5. **Address of Listing Company:** 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:

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: information@fmapprovals.com www.fmapprovals.com

F 347 (Mar 16)

Page 1 of 4

SCHEDULE



US Certificate Of Conformity No: FM18US0128X

10. Equipment Ratings:

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

Class I, Zone 2, AEx nA, Group IIB Gc hazardous (classified) indoor locations; T-Class = T4, Ta = 0°C to +40°C with Intrinsically Safe outputs for connection to Class I, Zone 0, Groups IIB hazardous (classified) locations in accordance with installation drawing 2058868

Accessory Kit External Venting SC5, Model 26787---AK---EV and

Environmental Temperature Sensor for SC5 Plus, Model 26787---ES---.

Intrinsically Safe for use in Class I, Zone 0, AEx ia IIB T4 Ga hazardous (classified) indoor locations, in accordance with installation drawing 2058868. T-Class = T4, Ta = 0°C to +40°C;

11. The marking of the equipment shall include:

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

Class I, Zone 2, AEx nA[ia Ga] IIB T4, Gc Ta = 0°C to +40°C,

Accessory Kit External Venting SC5, Model 26787---AK---EV

Class I, Zone 0, AEx ia IIB T4, Ga Ta = 0°C to +40°C,

Class and Division Equivalency Marking also appears on the equipment as permitted per sections 29.18 and 29.19 of ANSI/ISA 60079-0 and article 501.5 of the National Electrical Code NFPA 70.

12. **Description of Equipment:**

General - Fully Automatic Filter Integrity 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 may include the following accessories, located in the area requiring equipment protection level Ga, where the filters under test are located:

Accessory Kit External Venting SC5, Model 26787---AK---EV

Environmental Temperature Sensor for SC5 Plus, Model 26787---ES---.

Construction - 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.

Ratings –

Operation Temperature Ranges:

The ambient operating temperature range of the Sartocheck 5 is 0°C to 40°C. Process temperature range is 0°C to 40°C.

Electrical data:

The Sartocheck has the following electrical ratings;

Supply: 100 Vac to 240 Vac. Um = 264 Vac

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FM Approvals LLC. 1151 Boston-Providence Turnpike, Norwood, MA 02062 USA

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F 347 (Mar 16)

Page 2 of 4

SCHEDULE



US Certificate Of Conformity No: FM18US0128X

All other protection techniques, the electronic connection has the following values:
 “Ext. Valves” connector: valve circuits (combined circuits)

in type of protection intrinsic safety Ex ia IIB, with the following maximum values:
 $U_o = 28.1 \text{ V}$; $I_o = 123 \text{ mA}$; $P_o = 860 \text{ mW}$; $C_o = 600 \text{ nF}$; $L_o = 5 \text{ mH}$;

“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:
 $U_o = 18,4 \text{ V}$; $I_o = 86 \text{ mA}$; $P_o = 605 \text{ mW}$; $C_o = 1,69 \text{ }\mu\text{F}$; $L_o = 8 \text{ mH}$; (non linear characteristic).

“Ext. Press Sensor” connector (pin 4, 5, 6, 8, 11, 12): temperature sensor and pressure sensor data
 (combined circuits):
 in type of protection intrinsic safety Ex ia IIB, with the following maximum values:
 $U_o = 5.6 \text{ V}$; $I_o = 47 \text{ mA}$; $P_o = 181 \text{ mW}$; $C_o = 900 \text{ }\mu\text{F}$; $L_o = 4 \text{ mH}$;

“Env Temp. Sensor” connector: Environmental temperature sensor (combined circuits):
 in type of protection intrinsic safety Ex ia IIB, with the following maximum values:
 $U_o = 5.6 \text{ V}$; $I_o = 39 \text{ mA}$; $P_o = 144 \text{ mW}$; $C_o = 900 \text{ }\mu\text{F}$; $L_o = 5 \text{ mH}$;

“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 or
 a circuit, with the following maximum values:
 $U_i = 30 \text{ V}$; $I_i = \text{any}$; $P_i = \text{any W}$; $C_i = 660 \text{ nF}$; $L_i = 1 \text{ mH}$.
 $U_o = 4.0\text{V}$; $I_o = 80 \text{ mA}$; $P_o = 320 \text{ mW}$

13. Specific Conditions of Use:

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

1. The Sartocheck 5 may only be installed in locations providing adequate level of protection against the entry of solid foreign objects or water capable of impairing safety. Equivalent to IP54 protection.
2. The Sartocheck 5 shall be installed in such a way that the risk of mechanical danger is low.

Accessory Kit External Venting SC5, Model 26787---AK---EV Environmental Temperature Sensor for SC5 Plus, Model 26787---ES---.

1. Part of the enclosure is constructed from plastic. To prevent the risk of electrostatic sparking the plastic surface should only be cleaned only with a damp cloth.

14. Test and Assessment Procedure and Conditions:

This Certificate has been issued in accordance with FM Approvals US Certification Requirements.

15. Schedule Drawings

A copy of the technical documentation has been kept by FM Approvals.

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F 347 (Mar 16)

Page 3 of 4

SCHEDULE



US Certificate Of Conformity No: FM18US0128X

16. Certificate History

Details of the supplements to this certificate are described below:

Date	Description
24 th October 2018	Original Issue.

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F 347 (Mar 16)

Page 4 of 4

FCC Supplier's Declaration of Conformity



Device type Sartochek® Integrity tester / Accessory Kit External Venting SC5

Model 26787---FT, 26787---FT---P / 26787---AK---EV

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.