



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@cacaudit.ru



№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



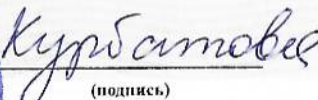
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.

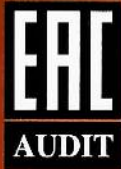




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



РАЗРЕШЕНИЕ
на применение знака соответствия
системы добровольной сертификации ГОСТ Р
«EAC AUDIT»
Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ
СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключаяющей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа
по сертификации:

(подпись)

В. И. Погдин

Председатель
экспертной комиссии:

М.П.



(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



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«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.СМ.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



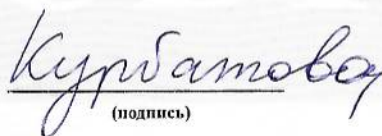
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«ЕАС AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04ЕАС1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028

ИНН 7717616798 ОГРН 1087746489060

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04ЕАС1.СМ.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «ЕАС AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



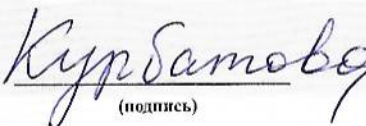
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "ЕАС AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2020-10-30

Data di Scadenza
Expiration Date
2023-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO N° 505DM07

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concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi
del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in
Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
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invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile).
Marketing of medical and diagnostic devices in vitro.*

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2011-10-30

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2020-10-30

Data di Scadenza
Expiration Date
2023-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

For and on behalf of NQA, USA

Certificate Number: 16880
EAC Code: 34
Certified Since: March 22, 2012
Valid Until: March 19, 2024
Reissued: March 20, 2021
Cycle Issued: March 20, 2021





CERTIFICATE



This is to certify that



VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:

Sales and supply of branded and private label chemicals, consumables, laboratory equipment, furniture, and medical devices from global leading developers and manufacturers of those products to customers in biopharma, healthcare, advanced technology and applied materials, education and government; manufacture of private label products, primarily laboratory and production chemicals including custom manufacturing solutions used in biopharmaceutical and industrial applications and production processes; provide value-added service offerings such as client outsourced activities: including sourcing and procurement, logistics, chemical and equipment tracking, lab and production services, scientific services and sample management; technical services in-house and at customer sites including installation, maintenance, qualification, calibration and repair of laboratory equipment

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no. 530840 QM15
Valid from 2021-08-04
Valid until 2024-06-28
Date of certification 2021-08-04



DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530842 VWR International GmbH Graumanngasse 7 1150 Wien Austria	Sales and supply; Lab and Production Services
530843 VWR International GmbH Zimbagasse 5 1210 Wien Austria	Distribution; Technical Services
530841 VWR International bv Researchpark Haasrode 2020 Geldenaaksebaan 464 3001 Leuven Belgium	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531223 VWR International GmbH Rue de Rive 18 1260 Nyon Switzerland	Sales and supply
531224 VWR International GmbH Grabenstraße 1 8952 Schlieren Switzerland	Sales and supply; Distribution; Lab and Production Services; Technical services
531221 VWR International GmbH Lerzenstraße 16 / 18 8953 Dietikon Switzerland	Sales and supply

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



Annex to certificate Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530844 VWR International s.r.o. Praská 442 281 67 Stribrná Skalice Czech Republic	Sales and supply; Distribution; Kitting Services; Technical services
530847 VWR International s.r.o. Pivovarská 30 75661 Rožnov prod Radhoštěm Czech Republic	Sales and supply
530868 VWR International GmbH Großenhainer Straße 99 01127 Dresden Germany	Sales and supply
530869 VWR International GmbH Wöhlerstraße 42 30163 Hannover Germany	Sales and supply
530867 VWR International GmbH Hilpertstraße 20A 64295 Darmstadt Germany	Sales and supply; Lab and Production Services; Technical services
539946 VWR International GmbH Heinrich-Blanc-Straße 40 76646 Bruchsal Germany	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530865 VWR International GmbH John-Deere-Straße 5 76646 Bruchsal Germany	Sales and supply; Distribution
530866 VWR International GmbH Vichystraße 2 76646 Bruchsal Germany	Distribution
530870 VWR International GmbH Fraunhoferstr.11 85737 Ismaning Germany	Sales and supply
530871 VWR International GmbH James-Franck-Ring 9 89081 Ulm Germany	Sales and supply
530859 VWR International A/S Tobaksvej 21 2860 Søborg Denmark	Sales and supply; Distribution; Lab and Production Services; Technical services
531213 VWR International Eurolab, S.L. C/ De la Tecnología, 5-17A7 - Llinars Park 08450 Llinars Del Vallès Barcelona Spain	Sales and supply; Distribution; Lab and Production Services; Technical services

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530860 VWR International Oy Valimotie 9 00380 Helsinki Finland	Sales and supply; Distribution; Lab and Production Services; Technical services
530863 VWR International S.A.S. Europarc 26 Avenue Leonard de Vinci 33608 Pessac Cedex France	Sales and supply
530861 VWR International S.A.S Chemin de la Croix Saint-Marc Z.I. de Vaugereau 45250 Briare-le-Canal France	Distribution; Manufacture
530862 VWR International S.A.S Immeuble Estréo, 1-3 Rue d'Aurion 93110 Rosny-sous-Bois France	Sales and supply; Lab and Production Services; Technical services
531226 VWR International Ltd VWR House Warren Court Feldspar Close Enderby LE19 4SD Leicester United Kingdom	Sales and supply

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531228 LAB3 Service 1 Dragon Court Crofts End Road St George Bristol BS5 7XX United Kingdom	Lab and Production Services; Technical services
531225 VWR International Ltd. Customer Service Centre Hunter Boulevard Magna Park Lutterworth, Leicestershire LE17 4 XN United Kingdom	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531227 VWR International Ltd. 14 Media Village Liscombe Park Soulbury Leighton Buzzard LU7 0GA United Kingdom	Sales and supply
540366 VWR International Medical Equipment Supplies and Management The Solutions Buckshaw Village, Chorley Chorley PR7 7EL United Kingdom	Sales and supply; Distribution; Technical Services

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location

Scope

531229

**Basan - the cleanroom division of VWR
Units 2 & 3 Newton Court
Basingstoke
RG24 8GF
United Kingdom**

Sales and supply;
Distribution;
Manufacture

546015

**Hichrom Ltd
1-3 The Markham Centre, Station Road,
Theale,
Reading, Berkshire
RG7 4AB
United Kingdom**

Manufacture of UHPLC and HPLC columns
with lot traceability. Procurement and
distributor for UHPLC and HPLC columns
and associated solvents, packing materials
and accessories with lot traceability

531198

**VWR International Kft.
Simon László utca 4
4034 Debrecen
Hungary**

Sales and supply;
Distribution;
Lab and Production Services;
Technical services

531199

**VWR International Ltd
Orion Business Campus
Northwest Business Park
Ballycoolin, Blanchardstown
Dublin 15
Ireland**

Sales and supply;
Distribution;
Lab and Production Services;
Technical services

531200

**VWR International (Northern Ireland) Ltd
19 Clarendon Street
Derry BT4 87EP
Ireland**

Sales and supply



**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531201 VWR International s.r.l. Via San Giusto 85 20153 Milano Italy	Sales and supply; Lab and Production Services; Technical Services; Manufacture
531203 VWR International B.V. Orlyplein 85 1043 AP Amsterdam Netherlands	Sales and supply; Lab and Production Services; Technical services
531205 VWR International AS Brynsalleen 4 0667 Oslo Norway	Sales and supply; Lab and Production Services; Technical services
531206 VWR International AS Kokstadflaten 35 5152 Bønes (Bergen) Norway	Sales and supply
531207 VWR International AS Leirfossvegen 27 7038 Trondheim Norway	Sales and supply
531211 VWR International Sp. z. o.o. Limbowa 5 80-175 Gdańsk Poland	Sales and supply; Lab and Production Services; Technical services

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**Annex to certificate
Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531212 VWR International Sp. z. o.o. Aleja Niepodległości 606/610 81-879 Sopot Poland	Distribution
531208 VWR International Material De Laboratorio, LDA Centro Empresarial de Alfragide Rua da Industria, n° 6 2610-088 Alfragide Portugal	Sales and supply; Distribution; Lab and Production Services; Technical services
531217 VWR International AB Fagerstagatan 18A 163 94 Stockholm Sweden	Sales and supply; Lab and Production Services; Technical services
531220 VWR International AB Skiffervägen 12 224 78 Lund Sweden	Sales and supply
531218 VWR International AB Varbergsgatan 2 412 65 Göteborg Sweden	Sales and supply
531219 VWR International AB Nordiskt Centrallager Gjuterigatan 3 (Bofors Industriområde) 691 50 Karlskoga Sweden	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Declaration of Conformity

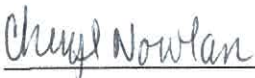
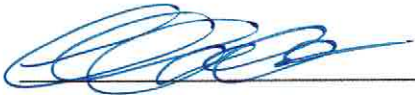
Certificate Identification: SC-09H39
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H39-01	35476	CELL-DYN Emerald Instrument	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France, Parc Euromedécine II, Rue de la Valsière, CEDEX 5, CS 14287 34 099 – Montpellier FRANCE
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: <u></u> Full Name: <u>Cheryl Nowlan</u> Position: <u>Director Quality Assurance</u> Date of Approval: <u>14 JAN 2021</u> Date Issued: <u>JAN 14 2021</u> Supersedes: <u>IRIS V7 (July 1, 2016)</u>	Signature: <u></u> Full Name: <u>Thao Phan</u> Position: <u>Associate Director Regulatory Affairs</u> Date of Approval: <u>14 JAN 2021</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>JAN 14 2021</u>
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Declaration of Conformity

Certificate Identification: SC-09H59
Legal Manufacturer's Name: Abbott Laboratories
Legal Manufacturer's Address: Diagnostics Division
Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H59-01	35476	CELL-DYN Emerald 22 Instrument	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: <u></u>	Signature: <u></u>
Full Name: <u>Kevin Richardson</u>	Full Name: <u>Mirna DiPano</u>
Position: <u>Manager, Supplier Quality</u>	Position: <u>Director of Regulatory Affairs</u>
Date of Approval: <u>10 - July - 2017</u>	Date of Approval: <u>10 - July - 2017</u>
Date Issued: <u>JUL 10 2017</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V1, April 15, 2016</u>	Effective (Date or Lot Number): <u>JUL 10 2017</u>

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan


TRAINER NAME

ABBOTT DIAGNOSTICS



TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim



Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018

Expiry date: 12 October 2021

Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001

Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155324

Original approval(s):
ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001

Certificate Schedule

Certificate identity number: 10155324

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001

HOLTSCHE Medizinprodukte GmbH

In den Faltern 13 . D – 65232 Taunusstein
Germany

Declaration of conformity

This is to confirm that

the swab dispenser **Quickpad®**
containing fleece swabs, saturated with 70% isopropyl alcohol (V/V)

is

manufactured, packaged and sterilized in accordance with the rules of GMP and the
paragraph 13 of the GERMAN MEDICAL LAW.

These swabs are equal to a
Medical Device Class I (UMNDS Code15-252)
and are checked and released

conform to

the German Medical Product Law according to

the
Medical Device Directive 93/42/EEC
of the European Council.

Taunusstein, November 17th, 2021

HOLTSCHE Medizinprodukte GmbH

HOLTSCHE
Medizinprodukte GmbH
In den Faltern 13 · 65232 Taunusstein
Malte Hertzberg
(Certified Biologist)



Zertifikat-Nr./Certificate no:
DE_SN_01_GMP_2016_0003

Aktenzeichen/Reference Number:
L24-5117/90

**BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES
HERSTELLERS MIT GMP**

Teil 1

Ausgestellt nach einer Inspektion gemäß

- Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller
HOLTSCH Medizinprodukte GmbH

Anschrift der Betriebsstätte
**HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Deutschland**

- Sonstiges:

Der Hersteller wurde im Rahmen der nationalen Arzneimittelüberwachung inspiziert in Verbindung mit der Herstellungserlaubnis Nr. DE_SN_01_MIA_2012_0045 gemäß Art. 40 der Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch § 13 Abs. 1 Arzneimittelgesetz.

Aufgrund der aus der letzten Inspektion vom 27. November 2015 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

- den Grundsätzen und Leitlinien der Guten Herstellungspraxis gemäß
- Richtlinie 2003/94/EG

ergeben.

**CERTIFICATE OF GMP COMPLIANCE OF A
MANUFACTURER**

Part 1

Issued following an inspection in accordance with

- Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the following:

The manufacturer
HOLTSCH Medizinprodukte GmbH

Site address
**HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Germany**

- Other:

The manufacturer has been inspected under the national inspection programme in connection with manufacturing authorisation no. DE_SN_01_MIA_2012_0045 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Sec 13 para 1 Arzneimittelgesetz (German Drug Law).

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 27 November 2015, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

- the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC



Dieses Zertifikat bestätigt den Status der Betriebsstätte zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten Inspektion mehr als drei Jahre vergangen sind. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt werden.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.



Teil 2

- Humanarzneimittel

1 HERSTELLUNGSTÄTIGKEITEN

- Die erlaubten Herstellungstätigkeiten umfassen vollständige und teilweise Herstellung (einschließlich verschiedener Prozesse wie Umfüllen, Abpacken oder Kennzeichnen), Chargenfreigabe und -zertifizierung, Lagerung und Vertrieb der genannten Darreichungsformen sofern nicht anders angegeben;

- Die Qualitätskontrolle und/oder Freigabe und/oder Chargenzertifizierung ohne Herstellungsschritte sollten unter den entsprechenden Punkten spezifiziert werden;

- Unter der relevanten Produktart und Darreichungsform sollte auch angegeben werden, wenn der Hersteller Produkte mit speziellen Anforderungen herstellt, z.B. radioaktive Arzneimittel oder Arzneimittel, die Penicilline, Sulfonamide, Zytostatika, Cephalosporine, Stoffe mit hormoneller Wirkung oder andere potenziell gefährliche Wirkstoffe enthalten (anwendbar für alle Bereiche des Teils 1 mit Ausnahme 1.5.2 und 1.6).

1.1 Sterile Produkte

1.1.3 Ausschließlich Chargenfreigabe

1.2 Nichtsterile Produkte

1.2.1 Nichtsterile Produkte

- 1.2.1.17 Andere nichtsterile Produkte
Alkoholtupfer

Part 2

- Human Medicinal Products

1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1 Sterile Products

1.1.3 Batch certification only

1.2 Non-sterile products

1.2.1 Non-sterile products

- 1.2.1.17 Other non-sterile medicinal product
alcoholic pads

13. Januar 2016



Name und Unterschrift des Bearbeiters der zuständigen Behörde

Klaus Hartmann
Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201

13 January 2016

Name and signature of the authorised person of the Competent Authority

Klaus Hartmann
Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201