ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Производитель
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Место производства медицинского изделия
196240, Санкт-Петербург, ул. Кубинская, д.73, корп. 1, литер А

Номер регистрационного досье **№ РД-6506/50043 от 04.03.2015**

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции для медицинского изделия **94 4330**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 16 марта 2015 года № 1 допущено к обращению на территории Российской Федерации.

Digitally signed by Ceaicovschi Tudor
Date: 2022.02.21 11:12:11 EET
Reason: MoldSign Signature
Location: Moldova

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0011726

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

Лист 1

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007:

1. Дозатор пипеточный ДПОФ-1 -1.
2. Дозатор пипеточный ДПОФ-1-5.
3. Дозатор пипеточный ДПОФ-1-10.
4. Дозатор пипеточный ДПОФ-1-20.
5. Дозатор пипеточный ДПОФ-1 -25.
6. Дозатор пипеточный ДПОФ-1-50.
7. Дозатор пипеточный ДПОФ-1-100.
8. Дозатор пипеточный ДПОФ-1-200.
9. Дозатор пипеточный ДПОФ-1-250.
10. Дозатор пипеточный ДПОФ-1-500.
11. Дозатор пипеточный ДПОФ-1-1000.
12. Дозатор пипеточный ДПОП-1-1-10.
13. Дозатор пипеточный ДПОП-1-2-20.
14. Дозатор пипеточный ДПОП-1-5-50.
15. Дозатор пипеточный ДПОП-1-10-100.
16. Дозатор пипеточный ДПОП-1-20-200.
17. Дозатор пипеточный ДПОП-1-100-1000.
18. Дозатор пипеточный ДПОП-1-1000-10 000.
19. Дозатор пипеточный ДПМП-8-1-10.
20. Дозатор пипеточный ДПМП-8-5-50.
21. Дозатор пипеточный ДПМП-8-30-300.
22. Дозатор пипеточный ДПМП-8-50-300.
23. Дозатор пипеточный ДПМП-12-1-10.
24. Дозатор пипеточный ДПМП-12-5-50.
25. Дозатор пипеточный ДПМП-12-30-300.
26. Дозатор пипеточный ДПМП-12-50-300.
27. Дозатор пипеточный ДПМП-16-5-50.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0010176

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*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	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

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

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 EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed 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. Commercializzazione di articoli da laboratorio

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. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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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.
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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	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

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EU Declaration of Conformity

Unit type	Rockers, shakers, rotators, vortexes
Models	**MR-1, MR-12;** **3D, Multi Bio 3D, PSU-10i, PSU-20i, MPS-1, PSU-2T;** **Bio RS-24, Multi Bio RS-24, Multi RS-60;** **V-1 plus, V-32, MSV-3500**
Serial number	14 digits styled XXXXXXYYMMZZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.
Manufacturer	SIA BIOSAN Latvia, LV-1067, Riga, Ratsupites str. 7/2

The objects of the declaration described above is in conformity with the following relevant Union harmonization legislations:

LVD 2014/35/EU	**LVS EN 61010-1:2011** Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. **LVS EN 61010-2-051:2015** Particular requirements for laboratory equipment for mixing and stirring.
EMC 2014/30/EU	**LVS EN 61326-1:2013** Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
RoHS3 2015/863/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
WEEE 2012/19/EU	Directive on waste electrical and electronic equipment.

I declare that the Declaration of Conformity is issued under sole responsibility of the manufacturer and belongs to the above-mentioned objects of the declaration.

Svetlana Bankovska
Managing director

Signature

07.02.2020.

Date

EU Declaration of Conformity

Unit type	Minicentrifuges-vortexes
Models	**FV-2400, FVL-2400N, MSC-3000, MSC-6000, CVP-2**
Serial number	14 digits styled XXXXXXYYMMZZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.
Manufacturer	SIA BIOSAN Latvia, LV-1067, Riga, Ratsupites str. 7/2

The objects of the declaration described above is in conformity with the following relevant Union harmonization legislations:

LVD 2014/35/EU	**LVS EN 61010-1:2011** Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. **LVS EN 61010-2-020:2016** Particular requirements for laboratory centrifuges.
EMC 2014/30/EU	**LVS EN 61326-1:2013** Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
RoHS3 2015/863/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
WEEE 2012/19/EU	Directive on waste electrical and electronic equipment.

I declare that the Declaration of Conformity is issued under sole responsibility of the manufacturer and belongs to the above-mentioned objects of the declaration.

Svetlana Bankovska
Managing director

Signature

07.02.2020.

Date

BUREAU VERITAS
Certification

LATAK -S2-424

Certification

Awarded to

SIA "Biosan"

Rātsupītes iela 7, korp.2, Rīga, LV-1067, LATVIA

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below

STANDARD

ISO 9001:2015

SCOPE OF CERTIFICATION

DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF LABORATORY EQUIPMENT.

Original cycle start date: 25.05.2004.

Recertification Audit date: 09.04.2019.

Recertification cycle start date: 26.05.2019.

Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on: 25.05.2022.

Certificate Number : LVRIG24119A *Version:* 1 *Revision date:* 11.04.2019.

Certification Manager
Iveta Lazdiņa

Certification body address: Bureau Veritas Latvia SIA, Duntes street 17a, Riga, LV-1005, Latvia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please call +371 67323246

BUREAU VERITAS

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer:

Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d 04.08 TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-08-07
Certificate Registration No.:	SX 60138020 0001
An audit was performed. Report No.:	15092074 004
This Certificate is valid until:	2022-02-27

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-08-07

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail.cert-validity@de.tuv.com http://www.tuv.com/safety

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TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization:
Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:
Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Humidifier Jar (Bubble Humidifier Jar), Wound Drainage System with and without Trocars, Sterile Urine Meters, Needle Free Connectors, Disposable Nasal Speculums, Disposable Ear Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity Kits and Implements, Mercury-free Clinical Thermometers, Digital Thermometers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-08-07

Fuxiu Sheng

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization:
Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:
Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Humidifier Jar (Bubble Humidifier Jar), Wound Drainage System with and without Trocars, Sterile Urine Meters, Needle Free Connectors, Disposable Nasal Speculums, Disposable Ear Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity Kits and Implements, Mercury-free Clinical Thermometers, Digital Thermometers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-08-07

Fuxiu Sheng

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

ha sido evaluado y certificado en cuanto al cumplimiento de los requisitos de

ISO 9001:2015

Para las siguientes actividades

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración, material general de laboratorio, envases y productos para el cuidado personal. Fabricación y comercialización de consumibles de laboratorio. Comercialización y distribución de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, jeringas, material general de laboratorio y envases industriales. Comercialización y distribución de equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso médico especial. Comercialización, distribución, instalación y asistencia técnica de equipos e instrumentación para laboratorio.

Este certificado es válido desde
11 de octubre de 2019 hasta 11 de octubre de 2022.
Edición 4. Organización certificada desde octubre de 2010.
Certificada con SGS desde 11 de octubre de 2016.

Este es un certificado multisede. Ver hoja(s) siguiente(s).

Autorizado por

CERTIFICACIÓN
Nº 05 / C - SC001

Dirección de Certificación

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C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

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DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

ISO 9001:2015

Edición 4

Emplazamientos en los que se realizan total o parcialmente dichas actividades

DELTALAB, S.L.
Pol. Ind. La Llana, Plaza. de la Verneda, 1 - 08191 Rubi (Barcelona)

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso medico especial.

KEYLAB, S.L.U.
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí (Barcelona)

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso médico especial.

CERTIFICACIÓN Nº 05 / C - SC001

NIRCO, S.L.
Pol. Ind. Expansión, Puerto de Navafría, 12 – 28935 Móstoles (Madrid)
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí (Barcelona)

Fabricación y comercialización de consumibles para laboratorio
Comercialización y distribución de reactivos para diagnóstico
Comercialización, distribución, instalación y asistencia técnica de equipos e instrumentación para laboratorio.

ENVASES FARMACÉUTICOS, S.A.
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis, material general de laboratorio, envases y productos para el cuidado personal.
Comercialización y distribución de material general de laboratorio, productos y equipos para el cuidado personal, jeringas y productos cosméticos.

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

ha sido evaluado como parte del sistema de gestión de DELTALAB GROUP
organización certificada en cuanto al cumplimiento de los requisitos de

ISO 9001:2015

Para las siguientes actividades

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso medico especial.

en/desde los siguientes emplazamientos

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubi (Barcelona)

Válido desde
11 de octubre de 2019 hasta 11 de octubre de 2022.
Edición 1.

El presente documento es parte del certificado nº ES16/20725.
La vigencia de este documento queda supeditada a la de este certificado.

Autorizado por

Dirección de Certificación

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115□f 34 91 313 8102 □www.sgs.com

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Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza De La Verneda 1,
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and sale of sterile and nonsterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.
Distribution of non-active medical devices and in vitro diagnostic medical devices.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.
Distribución de productos sanitarios no activos y productos sanitarios para diagnóstico in vitro.

This certificate is valid from 11 October 2019 until 11 October 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 September 2022
Issue 9. Certified since 12 October 2010

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
59878-2009-AQ-MCW-FINAS

Initial certification date:
20 December 2000

Valid:
01 September 2021 – 31 August 2024

This is to certify that the management system of

THERMO FISHER SCIENTIFIC

Kubinskaya 73, liter A, build.1, Saint-Petersburg, Russian Federation, 196240

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

MANUFACTURING OF LIQUID HANDLING PRODUCTS AND SPECIAL DIAGNOSTIC PLASTICS.

Place and date:
Espoo, 18 June 2021

For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
01 сентября 2021 – 31 августа 2024

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:

ISO 9001:2015

Настоящий сертификат действителен для следующей области:

ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Espoo, 18 июня 2021

От выпускающего офиса:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4265/5/D

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
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CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
“ЭКСПЕРТ”

РЕГИСТРАЦИОННЫЙ № РОСС RU.3693.04ЭБП0
В ГОСУДАРСТВЕННОМ РЕЕСТРЕ

Орган по сертификации “ЭКСПЕРТ-СЕРТ”
ООО “Экспертное Бюро “Прогресс”
125167, РФ, г. Москва, ул. Планетная, д. 11
ОГРН 1107746079143

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ СДС.Э.СМК 004207-19

Выдан
ООО НПФ “Литех”

107023,РФ, г.Москва, ул. Малая Семеновская, д. 3А, стр. 2

ИНН 7704076658

Настоящий Сертификат удостоверяет, что

система менеджмента качества применительно к разработке, производству и реализации медицинских изделий

Соответствует требованиям
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Сертификат выдан на основании Решения экспертной комиссии
Протокол № 15 от 19 апреля 2019 г.

Дата выдачи:
19 апреля 2019 г.

Срок действия: до
19 апреля 2022 г.

А.Н. Тимошенко
Руководитель Органа по сертификации

М.П.

М.А.Алферьев
Председатель экспертной комиссии

Настоящий сертификат обязывает организацию держателя поддерживать объект сертификации в состоянии соответствующем требованиям вышеуказанных нормативных документов, что будет находиться под контролем Органа по сертификации “ЭКСПЕРТ-СЕРТ” и подтверждаться при прохождении инспекционного контроля.

№ 004207

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Thermo Fisher Scientific Baltics UAB
V. A.Graiciuno 8
Vilnius
LT-02241
Lithuania

Holds Certificate No: **FM 642793**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacturing and sales of life science research products, including proteins, nucleic acids, nucleotides, antibodies, bio-sample preparation, cell separation reagents and associated kits, liquid chromatography (LC) silica, columns and supply of accessories for research or further manufacturing of therapeutics or in vitro diagnostics.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2016-03-25
Latest Revision Date: 2021-11-17

Effective Date: 2021-05-23
Expiry Date: 2024-05-22

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.

Certificate No: **FM 642793**

Location	Registered Activities
Thermo Fisher Scientific Baltics V. A.Graiciuno 8 Vilnius LT-02241 Lithuania	Design, development, manufacturing and sales of life science research products, including proteins, nucleic acids, nucleotides, antibodies, bio-sample preparation, cell separation reagents and associated kits, liquid chromatography (LC) silica, columns and supply of accessories for research or further manufacturing of therapeutics or in vitro diagnostics.
Thermo Fisher Scientific Baltics Molėtų pl. 5 Vilnius LT-08409 Lithuania	Manufacturing of nucleotides for research, in vitro diagnostics and further manufacturing.

Original Registration Date: 2016-03-25
Latest Revision Date: 2021-11-17

Effective Date: 2021-05-23
Expiry Date: 2024-05-22

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Thermo Fisher Scientific Baltics
V.A.Graiciuno 8
Vilnius
LT-02241
Lithuania

Holds Certificate Number: **MD 642790**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, and manufacturing of reagents, proteins, nucleic acids, nucleotides, antibodies, associated kits, and materials intended for ex-vivo separation of human cells for in vitro diagnostics, for further manufacturing and applied market applications, including processes under aseptic condition.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-02-15
Latest Revision Date: 2021-11-17

Effective Date: 2021-05-23
Expiry Date: 2024-05-22

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A Member of the BSI Group of Companies.

Certificate No: **MD 642790**

Location	Registered Activities
Thermo Fisher Scientific Baltics V. A.Graiciuno 8 Vilnius LT-02241 Lithuania	Design, development, and manufacturing of reagents, proteins, nucleic acids, nucleotides, antibodies, associated kits, and materials intended for ex-vivo separation of human cells for in vitro diagnostics, for further manufacturing and applied market applications, including processes under aseptic condition.
Thermo Fisher Scientific Baltics Molėtų pl. 5 Vilnius LT-08409 Lithuania	Manufacturing of nucleotides for in vitro diagnostics and further manufacturing.

Original Registration Date: 2016-02-15
Latest Revision Date: 2021-11-17

Effective Date: 2021-05-23
Expiry Date: 2024-05-22

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