



Abbott Products Romania S.R.L.
Green Court Bucharest
Gara Herastrau 4C
Corp B, etaj 2, sector 2
Bucuresti, Romania

C.U.I. RO 15910608
R.C.: J40/15462/18.11.2003
Capital Social: 595002 lei
Banca: Citibank
IBAN: RO22CITI000000724585043

Te: +40-21-529 30 00
Fa: +40-21-529 30 01

AUTORIZARE

Catre: **IMSP AMT Buiucani**
LP: **21013977**

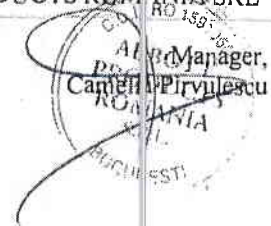
Noi, **ABBOTT PRODUCTS ROMANIA SRL**, reprezentant autorizat in Romania (Strada Gara Herastrau, numarul 4C, sector 2, Bucuresti, inreg. la MEC sub nr. 1069/22) al companiei Abbott Laboratories, producator de instrumente de biochimie Architect C8000, precum si de reactivi, controale, calibratori si consumabile pentru acestea, avand capacitatile de productie in SUA, Abbott Park 60064, Illinois, Santa Clara California, Germania – Wiesbaden, Marea Britanie - Dartford, autorizam prin prezenta pe furnizorul **Global Biomarketing Group – Moldova SRL**, sa oferteze in licitatie si sa livreze produsele mai sus mentionate, la **IMSP AMT Buiucani**. Prin prezenta, garantam calitatea si performantele produselor oferite si autorizam pe **Global Biomarketing Group – Moldova SRL** sa asigure, pentru produsele respective, indeplinirea obligatiilor care decurg din contractul de furnizare.

Aceasta autorizare s-a eliberat pentru a servi la licitatia LP nr. 21013977, din 21 Noiembrie 2019, avand ca si autoritate contractanta - **IMSP AMT Buiucani**

Data completarii:
15 Noiembrie 2019

Producator:

ABBOTT PRODUCTS ROMANIA SRL



ВЕКТОР

БЕСТ

ОГРН 1025404347550
ИНН 5433104584/ КПП 543301001
р/с 40702810244020101090
в Сибирском банке ПАО Сбербанк,
БИК 045004641
корр. сч. 30101810500000000641
ОКВЭД 21.20.2, 72.11 / ОКПО 23548172

от 18.11.2019 № Кс-151

АО "Вектор-Бест"
630 17, г Новосибирск, а/я 492
тел: (383) 227-73-60, 332-36-34
тел./факс: 332-67-49, 332-67-52
e-mail: vbmarket@vector-best.ru
internet: http://www.vector-best.ru

«GBG-MLD» SRL
Республики Молдова, г. Кишинев,
ул. Тигина, 65, оф. 607
Чайковскому Т.К.

Авторизация от производителя

Акционерное общество «Вектор-Бест» (Российская Федерация, 630559, Новосибирская область, рабочий поселок, Кольцово, Научно-производственная зона, корпус 36, к. 211) официально удостоверяет, что «GBG-MLD» SRL (Республика Молдова, г. Кишинев, ул. Тигина, 65, оф. 607) имеет право участвовать от имени АО «Вектор-Бест» в тендерах, проводимых медицинскими учреждениями Республики Молдова и осуществлять рекламно-информационное сопровождение.

Срок действия авторизации по 31 декабря 2020 года включительно.

Коммерческий директор АО «Вектор-Бест»  Гусев Ю.М.



EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

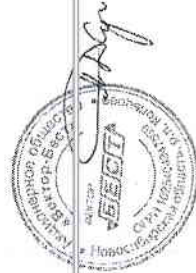
AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

Bioron GmbH
Address: Rheinhorststr. 18, D-67071 Ludwigshafen, Germany, tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2017/10/16

Murat Knusainov
General Director AO Vector-Best



Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the quantitative and qualitative determination of IgG to measles virus in blood serum (plasma)	D-1356
3.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to nuclear antigen of Epstein-Barr virus in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to early antigens of Epstein-Barr virus in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	VectoMumps-IgM	Enzyme immunoassay kit for the detection of IgM to mumps virus in blood serum (plasma)	D-2604
11.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
12.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
13.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
14.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
15.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
16.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosis antigens in blood serum (plasma)	D-3356
17.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoideis antigens in blood serum (plasma)	D-3452
18.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the determination of IgA to tissue transglutaminase in blood serum (plasma)	D-3758
19.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
20.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 1 concentration in blood serum	D-3762
21.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 2 concentration in blood serum	D-3764



22.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to Hantavirus in blood serum (plasma)	D-4902
23.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to Hantavirus in blood serum (plasma)	D-4904
24.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile Virus in blood serum (plasma)	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile Virus in blood serum (plasma)	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile Virus in blood serum (plasma)	D-5154

Certificate

mdc medical device certification GmbH
certifies that

VECTOR



AO Vector-Best
Research and Production area
building 36, Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

with the locations listed in the attachment
for the scope

Design and development, production and distribution of
medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)
has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from 2018-07-13
Valid until 2020-07-03
Registration no. D1213100017
Report no. P18-00489-117896
Stuttgart 2018-07-13



mdc medical device certification GmbH
Kriegestraße 8
D-70191 Stuttgart, Germany
Phone: +49 (0) 71 49 07 37 1
Fax: +49 (0) 71 49 07 37 1
Internet: <http://www.mdc.de>



Attachment of the certificate

No. D1213100017

date 2018-07-13

Page 1 of 1

Location	Scope
AO Vector-Best Arbuzova str. 1/1, 630117 Novosibirsk, Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region, Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best, Pasechnaya str. 3, 630117 Novosibirsk, Russian Federation	design and development, production of medical devices for in vitro diagnostics



mdc medical device certification GmbH
Kriegestraße 8
D-70191 Stuttgart, Germany
Phone: +49 (0) 71 49 07 37 1
Fax: +49 (0) 71 49 07 37 1
Internet: <http://www.mdc.de>

Head of Certification Body





Dia.Pro
Diagnostic
BioProbes

Letter of Authorization

We, "Dia.Pro Diagnostic Bioprobes S.r.l." located at Via G. Carducci, Nr. 27 – Sesto San Giovanni (Milan) 20099, Italy, authorize

GLOBAL BIOMARKETING GROUP – MOLDOVA SRL
Str. Tighina 65, Oficiu 607
MD-2001 CHISINAU
REP. MOLDOVA

as our exclusive distributor for the territory of the Republic of Moldova, to participate in various tenders with **Dia.Pro** ELISA products.

We, Dia.Pro Diagnostic Bioprobes S.r.l shall supply our distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL with all products in strict compliance with the existing "Distribution Agreement" rev.0117 valid until 31-Dec-2020, with possibility of renewal upon agreement between both parties for an additional period.

Dia.Pro Diagnostic Bioprobes S.r.l will grant the supply of all awarded tenders until their natural expiry, of which a documental proof has to be provided to Dia.Pro by the distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL.

Sincerely yours,

Date: **Milan, 31-January-2018**

Dia.Pro Diagnostic Bioprobes S.r.l.

DIA.PRO.

DIAGNOSTIC BIOPROBES S.r.l.

Dr.ssa Fiorenza Scozzesi

Legal Representative



LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número
 grants the certificate no.

2013 11 0039 EN

según la norma
 in accordance with the standard

UNE-EN ISO 13485:2018

(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios
Medical devices – Quality management systems – Requirements for regulatory purposes

a la empresa / to the company

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ Headquarters and manufacturing facility
 Via G. Carducci, 27-20099- Sesto San Giovanni-Milano-Italy

Para las siguientes actividades / For the following activities:

Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.

Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico in vitro.

Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.

Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.

Modificaciones de alcance: Ver Anexo I / see Annex I

Fecha de validez/ Date of validity: Desde/ From: 8-03-2019 Hasta/To: 17-12-2021

Certificación inicial/ Initial certification date: 27-11-2013

Renovación / Renewal of certification date: 8-03-2019

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de
 medicamentos y
 productos sanitarios

Fdo. M^a Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://sede.aemps.gob.es>

CORREC ELECTRÓNICO

an0318@sempsa.es

Página 1 de 2

CI CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

Tel.: (+34) 902.101.122 / (+34) 91.822.52.85

Fax: (+34) 91.822.52.85

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

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Página 2 de 2

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Fax: (+34) 91.822.52.85



ANEXO I / ANNEX I

CERTIFICADO UNE-EN ISO 13485:2018/ UNE-EN ISO 13485:2018 CERTIFICATE

Modificaciones del alcance / Scope modifications:

Fecha/Date	Descripción de la modificación/ Modification description
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico <i>Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques). Change in the level of detail of the technological scope description.</i>
8-03-2019	Ampliación del ámbito tecnológico para incluir: Inmunquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro". <i>Extension of technological scope: Immunochemistry and Microbiology Instruments and software for "in vitro" diagnostic</i> <i>Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic</i>

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de
 medicamentos y
 productos sanitarios

Fdo. M^a Jesús Lamas Díaz

Localizador: LPD TJL5ZDF



CI CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

Tel.: (+34) 902.101.122 / (+34) 91.822.52.85

Fax: (+34) 91.822.52.85



Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	Chlamydia Trachomatis IgA CODE: CTA.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

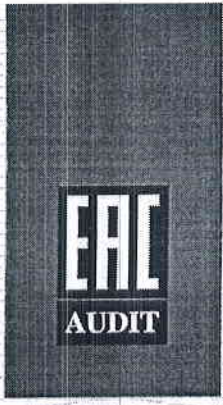
MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	Chlamydia Trachomatis IgG CODE: CTG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
 PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
 DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"> FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



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@eacaudit.ru



№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссе́йная, д.17А

(юридический адрес лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссе́йная, д.17А

(фактический адрес лица)

ИНН: 3234007127

ОГРН: 1023202138332

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации:

(подпись)

В. И. Иогодин



(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



GOST R CERTIFICATION SYSTEM
FEDERAL AGENCY FOR TECHNIQUE REGULATION AND
METROLOGY

VOLUNTARY CERTIFICATION SYSTEM
"SMK-STANDARD"

Reg. No. POCC RU.31060.04ЖЖЮ0

Certification authority:

REG No. SMK STANDART.RU.0005

INTERNATIONAL CERTIFICATION CENTER Limited Liability Company

Address: 138, Naberezhnaya Obvodnogo Canala, block 1, office 421, St. Petersburg, 190020

phone: +7 (812) 438-76-71 standart@iso-smk.ru

Check the authenticity of the certificate in the register on the website <http://www.iso-smk.ru>

CERTIFICATE OF CONFORMITY

No. ST.RU.0001.M0013380

This Certificate of Conformity is issued to

Agat-Med, Ltd.

Address: 6, Glavnaya st., Moscow, 105173, Russia

TRN 7719187311 OGRN 1037739078970

Date of issue: 26.01.2018

Period of validity: 26.01.2021

This certificate certifies that:

Medical devices. Quality management system. System requirements for regulatory purposes in relation to the works in accordance with Annex 1 to this certificate

(the attachment is an integral part of the certificate)

CORRESPONDS TO THE REQUIREMENTS OF GOST ISO 13485-2011 (EN ISO 13485:2003)

Manager of "Expert" authority

V.V. Koptsev



O.V. Gundareva

THIS CERTIFICATE BINDS THE ORGANIZATION TO MAINTAIN THE WORKS PERFORMED ACCORDING TO THE STANDARD MENTIONED ABOVE TO BE CONTROLLED BY THE INSTITUTIONAL BODY OF VOLUNTARY CERTIFICATION SYSTEM "SMK STANDARD" AND IS CONFIRMED DURING THE ANNUAL INSPECTION CONTROL



CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT
United Kingdom

UL LLC® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2003 / Cor 1:2009
EN ISO 13485:2012

The manufacture of In vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

File Number A12241
Certificate No. 11640248.PDWS

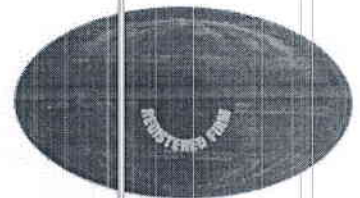
Effective Date May 23, 2017
Expiry Date February 28, 2019

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC



4426



This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



00-MB-50043 Issue 11.0

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Curbush Park Industrial Estate,
Daneshill, Lower Earley, Berkshire RG6 4UT, UK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro
Diagnostic Medical Devices

Scope of Certificate:

The design and manufacture of in vitro diagnostic reagents for
identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

Cycle Start Date 23 May 2017
Effective Date 23 May 2017
Expiry Date 22 May 2022

File Number A12241
Certificate No. 354.170425

Authorised by

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing modal numbers.

Notified Body

0843

UL International (UK) Limited
Womersley House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

IND 04 S3 F0 00-NE-F0051 Issue: 6.0



EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Curbush Park Industrial Estate,
Daneshill, Lower Earley, Berkshire RG6 4UT, UK

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
Anti-A Monoclonal	600005/600010/600000	Annex II List A
Anti-B Monoclonal	610005/610010/610000	Annex II List A
Anti-A, B Monoclonal	620005/620010/620000	Annex II List A
Anti-C Monoclonal	690005	Annex II List A
Anti-E Monoclonal	691005	Annex II List A
Anti-c Monoclonal	692005	Annex II List A
Anti-e Monoclonal	693005	Annex II List A
Anti-K Monoclonal	760005/760010	Annex II List A
Anti-D Clone 2 Monoclonal	710010/710000	Annex II List A
Anti-D Clone 1 Monoclonal	730010/730000	Annex II List A
Anti-D Duoclonal Monoclonal	740010/740000	Annex II List A
Anti-Ika Polyclonal	323002/323000	Annex II List B
Anti-Ikb Polyclonal	324002/324000	Annex II List B
Anti-Fyb Polyclonal	317002/317000	Annex II List B
AHG Elite Clear	415010/415100/415000	Annex II List B
AHG Elite Green	435010/435100/435000	Annex II List B
Anti-Fya Monoclonal	774000/774002	Annex II List B
Anti-C+D+E Monoclonal	700005/700010/700000	Annex II List A
Anti-Human IgG Clear	401010/401000	Annex II List B
Anti-Human IgG Green	402010/402000	Annex II List B
Monoclonal Rh Control	640010	Annex II List A
Monoclonal D Negative Control	650010	Annex II List A

File Number A12241
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Guildford, Surrey, GU3 1LR, United Kingdom

IND 04 S3 F0 00-NE-F0051 Issue: 6.0



CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

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.
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. 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.
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.

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Modifica
Modified Date

2019-11-06

Data di Scadenza
Expiration Date

2020-10-29

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



CERTIFICATO N° 505DM06

CERTIFICATE N° 505DM06

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.
Commercializzazione di dispositivi medici e diagnostici in vitro.

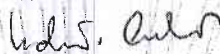
*Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural
orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories.
Marketing of medical and diagnostic devices in vitro.*

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.

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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 Modifica
Modified Date
2019-11-06

Data di Scadenza
Expiration Date
2020-10-29



55011° 023A

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

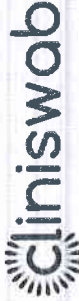
CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che i Dispositivi Medici di seguito descritti:
That Medical Devices described as follows:



TAMPONI PER LA RACCOLTA E LA CONSERVAZIONE DI CAMPIONI BIOLOGICI,
ANCHE IN AMBITO CHIRURGICO, CON O SENZA TERRENO DI TRASPORTO
MEDICAL SWABS AND APPLICATORS FOR BIOLOGICAL SAMPLE COLLECTION
AND PRESERVATION, ALSO FOR SURGERY USE, WITH OR WITHOUT
TRANSPORT MEDIUM

PRODOTTI STERILI - STERILE PRODUCTS

(i cui codici di dettaglio sono riportati nell'allegato 1)
 (which detailed codes are reported in Annex 1)

- Sono conformi ai requisiti essenziali di cui all'allegato I della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE recepite con D.lgs n° 46 del 24/02/1997 emendato con D.lgs n° 37 del 25/01/2010 e s.m.i. They are conform to the essential requirements of Annex I of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC, put into force by D.Lgs n° 46 dated 24/02/1997 and as amended by D.lgs n° 37 dated 25/01/2010.
- Sono classificati di Classe IIa sterile in base all'Allegato IX - regola 6 - p.to 2.2. della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE. They are classified as Class IIa sterile according to Annex IX - Rule 6 - p.t. 2.2. of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC.
- Sono soggetti a marcatura CE rilasciata dall'Organismo Notificato n° 0426 Italcert Srl. They are subject to CE mark issued by the Notified Body n° 0426 Italcert Srl.

They are manufactured with a production quality system in accordance with Annex V of Directive 93/42/EC

Tale dichiarazione è supportata dalla certificazione del Sistema Qualità Nuova Aptaca secondo gli standard UNI EN ISO 9001 e UNI EN ISO 13485

This statement is supported by the New Aptaca Quality System Certification according to UNI EN ISO 9001 and UNI EN ISO 13485

Rilasciato / Released
 Canelli, 08.06.2017

Dujito BUONO
 Quality Assurance Manager


ALLEGATO 1 alla Dichiarazione di Conformità Tamponi sterili Annex 1 to Declaration of Conformity Sterile Swabs

REF	DESCRIZIONE	DESCRIZIONE
301/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES clear, with label, sterile individually wrapped
301/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES clear, with label, sterile individually wrapped
301/SG/XL	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES MAGGIORATO (6ml) senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES clear, with label, sterile individually wrapped
303/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES with Charcoal, with label, sterile individually wrapped
303/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES with Charcoal, with label, sterile individually wrapped
303/SG/XL	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES MAGGIORATO (6ml) con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES with Charcoal, with label, sterile individually wrapped
305/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART clear, with label, sterile individually wrapped
305/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART clear, with label, sterile individually wrapped
307/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART with Charcoal, with label, sterile individually wrapped
307/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART with Charcoal, with label, sterile individually wrapped
309/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto CARY BLAIR senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
309/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto CARY BLAIR senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
CLINISWAB [®]	CLINISWAB [®]	CLINISWAB [®]
311/SG	Tampone tipo Plastica e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno VIRUS, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Virus medium, with label, sterile individually wrapped
313/SG	Tampone tipo Alluminio e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno VIRUS, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Virus medium, with label, sterile individually wrapped
321/SG	Tampone tipo Plastica e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno CLAMIDIA, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Chlamydia medium, with label, sterile individually wrapped
323/SG	Tampone tipo Alluminio e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno CLAMIDIA, sterile confezione singola	Swabs aluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Chlamydia medium, with label, sterile individually wrapped
CLINISWAB [®] LS	CLINISWAB [®] LS	CLINISWAB [®] LS
430/SG/STIF	Tampone tipo STANDARD FOAM, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/TFIF	Tampone tipo FINE FOAM, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/STIF	Tampone tipo STANDARD FOAM, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/TFIF	Tampone tipo FINE FOAM, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped

REF	DESCRIZIONE	DESCRIPTION
440/SG/STIF	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/STIF	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/STIF	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/STIF	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/STIF	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/STIF	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
CLINISWAB [®]		
Tamponi Poliesteri Con Terreno Trasporto Liquido / Polyester Liquid Transport Swabs		
430/SG/STID	Tampone tipo STANDARD POLIESTERE, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/STID	Tampone tipo FINE POLIESTERE, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/STID	Tampone tipo STANDARD POLIESTERE, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/STID	Tampone tipo FINE POLIESTERE, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/STID	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/STID	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/STID	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/STID	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/STID	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/STID	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
CLINISWAB [®]		
Tamponi Viscosa Con Terreno Trasporto Liquido / Viscous Liquid Transport Swabs		
430/SG/STIR	Tampone tipo STANDARD VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/STIR	Tampone tipo FINE VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/STIR	Tampone tipo STANDARD VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/STIR	Tampone tipo FINE VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/STIR	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/STIR	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/STIR	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/STIR	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/STIR	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/STIR	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
CLINISWAB [®]		
Tamponi Alluminio Con Terreno Trasporto Liquido / Aluminum Liquid Transport Swabs		
430/SG/SGAL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped

REF	DESCRIZIONE	DESCRIPTION
435/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
CLINISWAB [®]		
Tamponi Secchi In Provetta / Dry Swabs In Test Tubes		
2150/SG	Tampone Legno, puntale in Cotone, in provetta PP Ø12x150, con etichetta, sterile	Swabs Wooden stick and Cotton tip, in PP test tubes Ø12x150 mm, with label, sterile
2150/SG/CS	Tampone Legno, puntale in Cotone, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Wooden stick and Cotton tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2160/SG	Tampone Plastica, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2160/SG/CS	Tampone Plastica, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2170/SG	Tampone Alluminio, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile	Swabs Aluminum stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile
2170/SG/CS	Tampone Alluminio, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Aluminum stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2190/SG	Tampone asta Plastica, puntale in FOAM standard, in provetta Ø12x150, con etichetta, sterile	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2190/SG/CS	Tampone asta Plastica, puntale in FOAM standard, in provetta Ø12x150, con etichetta, sterile confezione singola	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2191/SG	Tampone asta Plastica, puntale in FOAM fine/pediatrico, in provetta Ø12x150, con etichetta, sterile	Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2191/SG/CS	Tampone asta Plastica, puntale in FOAM fine/pediatrico, in provetta Ø12x150, con etichetta, sterile confezione singola	Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
CLINISWAB [®]		
TAMPONI SECCHI IN BLISTER / Dry Swabs In Blister		
5100/SG/CS	Tampone Legno, puntale in Cotone, sterile confezione singola	Swabs Wooden stick and Cotton tip, sterile individually wrapped
5100/SG/2	Tampone Legno, puntale in Cotone, sterile confezione da 2 pezzi	Swabs Wooden stick and Cotton tip, sterile in peel-pack of 2 pieces
5100/SG/10	Tampone Legno, puntale in Cotone, sterile confezione da 10 pezzi	Swabs Wooden stick and Cotton tip, sterile in peel-pack of 10 pieces
6100/SG/CS	Tampone Plastica, puntale in Viscosa, sterile confezione singola	Swabs Plastic stick and Rayon tip, sterile individually wrapped
7100/SG/CS	Tampone Alluminio, puntale in Viscosa, sterile confezione singola	Swabs Aluminum stick and Rayon tip, sterile individually wrapped
6200/SG/CS	Tampone Plastica, puntale in FOAM standard, sterile confezione singola	Swabs Plastic stick and Standard Foam tip, sterile individually wrapped
6300/SG/CS	Tampone Plastica, puntale in FOAM pediatrico, sterile confezione singola	Swabs Plastic stick and Fine Foam tip, sterile individually wrapped
CLINISWAB [®]		
Tamponi Stantuffo Con Terreno Di Trasporto Agar Gel / Sliding Transport Agar Gel Swabs		
2015/G	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES Ø12x150 mm in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile
2015/G/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile individually wrapped
2035/G	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES with Charcoal, with label, sterile individually wrapped
2035/G/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Charcoal, with label, sterile individually wrapped
2055/G	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile
2055/G/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile individually wrapped
2075/G	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART con carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART with Charcoal, with label, sterile



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207/SG/GCS	Tampone "stantufo" Plastica puntale in Viscosa, con terrano STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Charcoal, with label, sterile individually wrapped
209/SG	Tampone "stantufo" Plastica puntale in Viscosa, con terrano CARY BLAIR in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile
209/SG/GCS	Tampone "stantufo" Plastica puntale in Viscosa, con terrano CARY BLAIR in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped

CERTIFIED COMPANY UNI ISO 9001:2008 & UNI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
 The undersigned Nuova Aptaca s.r.l.

DICHIARA
 DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
 That in vitro diagnostic medical devices described as follows:

PIASTRE DI PETRI, PIASTRE PER MICROMETODI PETRI DISHES, MICROTITER PLATES

(i cui codici di dettaglio sono riportati nell'allegato 1)
 (which detailed codes are reported in Annex 1)

- > Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.
 Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- > I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.
 The devices as per Annex 1 do not fall under list A or B of annex II of the Directive 98/79/CE.
- > Classificazione EDMA: 14909090 - Other Other Microbiology
 EDIMA code: 14909090 - Other Other microbiology
- > La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.
 The present Declaration was drafted in accordance with annex III to Directive 98/79/CE.

Rilasciato / Released
 Conelli, 01.11.2014


 Duilio PIROVANO
 Responsabile Accreditamento Qualità

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
101	Piastrine di Petri Ø90mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø90mm, PS, without triple vents, ASEPTIC
101/5	Piastrine di Petri Ø90mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø90mm, PS, without triple vents, ASEPTIC
101/AN	Piastrine di Petri Ø90mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø90mm, PS, without triple vents, ASEPTIC
101/B	Piastrine di Petri Ø90mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø90mm, PS, without triple vents, ASEPTIC
101/CS	Piastrine di Petri Ø90, PS, senza ventilazione, sterili	Petri dishes Ø90, PS, without triple vents, sterile
101/SG	Piastrine di Petri Ø90, PS, senza ventilazione, sterili	Petri dishes Ø90, PS, without triple vents, sterile
101/SGIAN	Piastrine di Petri Ø90, PS, senza ventilazione, sterili	Petri dishes Ø90, PS, without triple vents, sterile
101/SGIB	Piastrine di Petri quadre ANTIBIOGRAMMA, 120x120mm., con ventilazione, sterili	Square Petri dishes for ANTIBIOGRAMMA 120x120mm., PS, with triple vents, sterile
1120	Piastrine di Petri Ø100mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø100mm, PS, without triple vents, ASEPTIC
141	Piastrine di Petri Ø100mm, PS, senza ventilazione, ASEPTICHE	Petri dishes Ø100mm, PS, without triple vents, ASEPTIC
141/AN	Piastrine di Petri Ø100, PS, senza ventilazione, sterili	Petri dishes Ø100, PS, without triple vents, sterile
141/CS	Piastrine di Petri Ø100mm, PS, senza ventilazione, sterili	Petri dishes Ø100mm, PS, without triple vents, sterile
141/IN	Piastrine di Petri Ø100mm, PS, senza ventilazione, sterili	Petri dishes Ø100mm, PS, without triple vents, sterile
141/SG	Piastrine di Petri Ø100, PS, senza ventilazione, sterili	Petri dishes Ø100, PS, without triple vents, sterile
141/SGIAN	Piastrine di Petri Ø100, PS, senza ventilazione, sterili	Petri dishes Ø100, PS, without triple vents, sterile
151	Piastrine di Petri Ø100mm, PS, con ventilazione, ASEPTICHE	Petri dishes Ø100mm, PS, with triple vents, ASEPTIC
151/AN	Piastrine di Petri Ø100mm, PS, con ventilazione, ASEPTICHE	Petri dishes Ø100mm, PS, with triple vents, ASEPTIC
151/IN	Piastrine di Petri Ø100mm, PS, con ventilazione, sterili	Petri dishes Ø100mm, PS, with triple vents, sterile
151/SG	Piastrine di Petri Ø100, PS, con ventilazione, sterili	Petri dishes Ø100, PS, with triple vents, sterile
151/SGIAN	Piastrine di Petri Ø100, PS, con ventilazione, sterili	Petri dishes Ø100, PS, with triple vents, sterile
155	Piastrine di Petri tipo CONTACT Ø60, PS, con griglia di conta, con ventilazione, sterili	Petri dishes CONTACT type Ø60, PS, with counting area, with triple vents, sterile
155/N	Piastrine di Petri tipo CONTACT Ø60, PS, con griglia di conta, con ventilazione	Petri dishes CONTACT type Ø60, PS, with counting area, with triple vents
161	Piastrine di Petri Ø60, PS, con ventilazione, sterili	Petri dishes Ø60, PS, with triple vents, sterile
161/N	Piastrine di Petri Ø60, PS, con ventilazione, aseptiche	Petri dishes Ø60, PS, with triple vents, aseptic
181/IN	Piastrine di Petri Ø120, PS, senza ventilazione	Petri dishes Ø120, PS, without triple vents, aseptic
181/SG	Piastrine di Petri Ø120, PS, senza ventilazione, sterili	Petri dishes Ø120, PS, without triple vents, sterile
195	Piastrine di Petri tipo CONTACT Ø90, PS, con griglia di conta, con ventilazione, sterili	Petri dishes CONTACT type Ø90, PS, with counting area, with triple vents, sterile
221	Piastrine di Petri Ø140; PS, con ventilazione, sterili	Petri dishes Ø140, PS, with triple vents, sterile
221/N	Piastrine di Petri Ø140; PS, con ventilazione	Petri dishes Ø140, PS, with triple vents
231	Piastrine di Petri Ø150, PS, con ventilazione, sterili	Petri dishes Ø150, PS, with triple vents, sterile



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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE
Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
231/N	Piastre di Petri Ø150, PS, con ventilazione	Petri dishes Ø150, PS, with triple vents
251	Piastre di Petri 2 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 2 sectors Ø90, PS, with triple vents, aseptic
251/AN	Piastre di Petri 2 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 2 sectors Ø90, PS, with triple vents, aseptic
251/B	Piastre di Petri 2 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 2 sectors Ø90, PS, with triple vents, aseptic
251/SG	Piastre di Petri 2 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 2 sectors Ø90, PS, with triple vents, sterile
251/SG/AN	Piastre di Petri 2 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 2 sectors Ø90, PS, with triple vents, sterile
251/SG/B	Piastre di Petri 2 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 2 sectors Ø90, PS, with triple vents, sterile
261	Piastre di Petri 3 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 3 sectors Ø90, PS, with triple vents, aseptic
261/AN	Piastre di Petri 3 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 3 sectors Ø90, PS, with triple vents, aseptic
261/B	Piastre di Petri 3 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 3 sectors Ø90, PS, with triple vents, aseptic
261/SG	Piastre di Petri 3 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 3 sectors Ø90, PS, with triple vents, sterile
261/SG/AN	Piastre di Petri 3 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 3 sectors Ø90, PS, with triple vents, sterile
261/SG/B	Piastre di Petri 3 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 3 sectors Ø90, PS, with triple vents, sterile
271	Piastre di Petri 4 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 4 sectors Ø90, PS, with triple vents, aseptic
271/AN	Piastre di Petri 4 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 4 sectors Ø90, PS, with triple vents, aseptic
271/B	Piastre di Petri 4 settori Ø90, PS, con ventilazione, asettiche	Petri dishes with 4 sectors Ø90, PS, with triple vents, aseptic
271/SG	Piastre di Petri 4 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 4 sectors Ø90, PS, with triple vents, sterile
271/SG/AN	Piastre di Petri 4 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 4 sectors Ø90, PS, with triple vents, sterile
271/SG/B	Piastre di Petri 4 settori Ø90, PS, con ventilazione, sterili	Petri dishes with 4 sectors Ø90, PS, with triple vents, sterile
31	Piastre di Petri Ø35, PS, con ventilazione, sterili	Petri dishes Ø35, PS, with triple vents, sterile
31/N	Piastre di Petri Ø35, PS, con ventilazione	Petri dishes Ø35, PS, with triple vents
5096/C	Coperchi per Piastre per Micrometodi, 86x128mm, PS.	Lid for 86x128mm micrometri plates, PS.
5096/C/SG	Coperchi per Piastre per Micrometodi, 86x128mm., PS, confezione singola, sterili	Lid for 86x128mm. Micrometri plates, PS, individually wrapped, sterile
5096/P	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a piatto	Micrometri plates, PS, with 96 wells, flat bottom.
5096/P/SG	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a piatto, confezione singola, sterili	Micrometri plates, PS, 96 wells, flat bottom, individually wrapped, sterile
5096/P/SG+COP	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a piatto, confezione singola, sterili, coperchio	Micrometri plates, PS, 96 wells, flat bottom, individually wrapped, sterile, lid
5096/P+COP	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a piatto, coperchio	Micrometri plates, PS, with 96 wells, flat bottom, lid
5096/U	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a piatto, coperchio	Micrometri plates, PS, with 96 wells, "U" shaped wells



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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE
Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
5096/U/25	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U"	Microtiter plates, PS, with 96 wells, "U" shaped wells bottom.
5096/U/25/SG	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U", sterili	Microtiter plates, PS, with 96 wells, "U" shaped wells bottom, sterile
5096/U/5	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U"	Microtiter plates, PS, with 96 wells, "U" shaped wells bottom.
5096/U/SG	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U", confezione singola, sterili	Microtiter plates, PS, 96 wells, "U" shaped wells bottom, individually wrapped, sterile
5096/U/SG+COP	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U", confezione singola, sterili, coperchio	Microtiter plates, PS, 96 wells, "U" shaped wells bottom, individually wrapped, sterile, lid
5096/U+COP	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "U", coperchio	Microtiter plates, PS, with 96 wells, "U" shaped wells bottom, lid
5096/V	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "V"	Microtiter plates, PS, with 96 wells, "V" shaped wells bottom.
5096/V/SG	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "V", confezione singola, sterili	Microtiter plates, PS, 96 wells, "V" shaped wells bottom, individually wrapped, sterile
5096/V/SG+COP	Piastre per Micrometodi, PS, a 96 pozzetti, fondo a "V", confezione singola, sterili, coperchio	Microtiter plates, PS, 96 wells, "V" shaped wells bottom, individually wrapped, sterile, lid
61	Piastre di Petri Ø60, PS, senza ventilazione, sterili	Petri dishes Ø60, PS, without triple vents, sterile
61/N	Piastre di Petri Ø60, PS, senza ventilazione	Petri dishes Ø60, PS, without triple vents
81	Piastre di Petri Ø80, PS, senza ventilazione, sterili	Petri dishes Ø80, PS, without triple vents, sterile
81/N	Piastre di Petri Ø80, PS, senza ventilazione	Petri dishes Ø80, PS, without triple vents
91	Piastre di Petri Ø90mm, PS, con ventilazione, ASETTICHE	Petri dishes Ø90mm, PS, with triple vents, ASEPATIC
91/AN	Piastre di Petri Ø90mm, PS, con ventilazione, ASETTICHE	Petri dishes Ø90mm, PS, with triple vents, ASEPATIC
91/B	Piastre di Petri Ø90mm, PS, con ventilazione, ASETTICHE	Petri dishes Ø90mm, PS, with triple vents, ASEPATIC
91/SAC	Piastre di Petri Ø90, PS, con ventilazione, asettiche, con sacchetto interno	Petri dishes Ø90, PS, with triple vents, aseptic, with inner bags
91/SG	Piastre di Petri Ø90, PS, con ventilazione, sterili	Petri dishes Ø90, PS, with triple vents, sterile
91/SG/AN	Piastre di Petri Ø90, PS, con ventilazione, sterili	Petri dishes Ø90, PS, with triple vents, sterile
91/SG/B	Piastre di Petri Ø90, PS, con ventilazione, sterili	Petri dishes Ø90, PS, with triple vents, sterile
91/SG/SAC	Piastre di Petri Ø90, PS, con ventilazione, sterili, con sacchetto interno	Petri dishes Ø90, PS, with triple vents, sterile, with inner bags

Dalila PIGNONO
 Responsabile Interfunzionale Qualità

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE
CE DECLARATION OF CONFORMITY
DECLARAÇÃO CE CONFORMIDADE

Nuova Aptaca s.r.l.

DICHIARA / DECLARES / DECLARA

Che il dispositivo medico diagnostico in vitro di seguito descritto:

That in vitro diagnostic medical devices described as follows:

Que os dispositivos medicos de diagnóstico in vitro a seguir discriminados como:

PROVETTE PER ANALISI CON VUOTO PRECALIBRATO
VACUUM TEST TUBES - TUBOS DE EXAME VACUO



DISPOSITIVI STERILI - STERILE DEVICES - DISPOSITIVOS ESTEREIS

(i cui codici di dettaglio sono riportati nell'allegato 1)

(which detailed codes are reported in Annex 1)

(cujas referencias estão descritos no anexo 1)

> Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000 e s.m.i.
 Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
 São fabricados de acordo com os requisitos essenciais da Directiva 98/79/CE anexo I, datada de 27 Outubro 1998 posta em vigor pelo Decreto 332 datado de 08/09/2000

> I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.
 The devices as per Annex 1 do not fall under list A or B of annex II of the Directive 98/79/EC.
 Os dispositivos mencionados no anexo I não se enquadram na lista A e/ou B da Directiva 98/79/CE

> **Classifica EDMA (Versione 2007): 1302808000 Coated tubes (Citrate, Heparin, etc.)**
EDMA code (Version 2007): 1302808000 Coated tubes (Citrate, Heparin, etc.)
Codigo EDMA (Versão 2007): 1302808000 tubos revestidos (Citrate, Heparina, etc.)

> La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.
 The present Declaration was drafted in accordance with annex III (with the exception of point 6) of the Directive 98/79/EC.
 A presente Declaração está redigida de acordo com o anexo III (com exceção do ponto 6) da Directiva 98/79/CE

Rilasciato / Released
Canelli, 25.10.2016

Duilio BUONO
 Quality Assurance Manager

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE
Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
30001	Provette sottovuoto 2.0 ml. in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 2.0 ml. in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30002	Provette sottovuoto 3.0 ml. in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 3.0 ml. in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30003	Provette sottovuoto 4.0 ml. in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 4.0 ml. in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30004	Provette sottovuoto 6.0 ml. in PET Ø13x100 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 6.0 ml. in PET, Ø13x100 mm, without additive, white cap, interior sterile.
30020	Provette sottovuoto 2.0 ml. in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 2.0 ml. in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30021	Provette sottovuoto 4.0 ml. in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml. in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30022	Provette sottovuoto 6.0 ml. in PET Ø13x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 6.0 ml. in PET, Ø13x100 mm, with clot activator, red cap, interior sterile.
30023	Provette sottovuoto 9.0 ml. in PET Ø16x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 9.0 ml. in PET, Ø16x100 mm, with clot activator, red cap, interior sterile.
30011	Provette sottovuoto 3.5 ml. in PET Ø13x75 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 3.5 ml. in PET, Ø13x75 mm, with clot activator + gel, red cap, interior sterile.
30012	Provette sottovuoto 5.0 ml. in PET Ø13x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 5.0 ml. in PET, Ø13x100 mm, with clot activator + gel, red cap, interior sterile.
30013	Provette sottovuoto 8.0 ml. in PET Ø16x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 8.0 ml. in PET, Ø16x100 mm, with clot activator + gel, red cap, interior sterile.
30014	Provette sottovuoto 4.0 ml. in PET Ø13x75 mm, con acceleratore + tappi gel, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml. in PET, Ø13x75 mm, with clot activator + rapid gel, red cap, interior sterile.
30031	Provette sottovuoto 3.5 ml. in PET Ø13x75 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 3.5 ml. in PET, Ø13x75 mm, with clot activator + gel, gold cap, interior sterile.
30032	Provette sottovuoto 5.0 ml. in PET Ø13x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 5.0 ml. in PET, Ø13x100 mm, with clot activator + gel, gold cap, interior sterile.
30033	Provette sottovuoto 8.0 ml. in PET Ø16x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 8.0 ml. in PET, Ø16x100 mm, with clot activator + gel, gold cap, interior sterile.
30200	Provette sottovuoto 2.0 ml. in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml. in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30200/1	Provette sottovuoto 1.0 ml. in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 1.0 ml. in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30201	Provette sottovuoto 3.0 ml. in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml. in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30202	Provette sottovuoto 4.0 ml. in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml. in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30203	Provette sottovuoto 6.0 ml. in PET Ø13x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml. in PET, Ø13x100 mm, with K3 EDTA, lavender cap, interior sterile.
30204	Provette sottovuoto 9.0 ml. in PET Ø16x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml. in PET, Ø16x100 mm, with K3 EDTA, lavender cap, interior sterile.
30100	Provette sottovuoto 2.0 ml. in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml. in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30101	Provette sottovuoto 3.0 ml. in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml. in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30102	Provette sottovuoto 4.0 ml. in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml. in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30103	Provette sottovuoto 6.0 ml. in PET Ø13x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml. in PET, Ø13x100 mm, with K2 EDTA, lavender cap, interior sterile.

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE
Annex 1 to Declaration of Conformity 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
30104	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with K2 EDTA, lavender cap, interior sterile.
30300	Provette sottovuoto 1,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8% per VES, tappo nero, sterile interno.	Vacuum test tubes 1.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.2% for ESR, black cap, interior sterile.
30500	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.2%, light blue cap, interior sterile.
30501	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.2%, light blue cap, interior sterile.
30500/38	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.8%, light blue cap, interior sterile.
30501/38	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.8%, light blue cap, interior sterile.
30503	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.2%, light blue cap, interior sterile.
30503/38	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.8%, light blue cap, interior sterile.
30600	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Floruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30601	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Sodio Floruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30800	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30801	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30802	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with Lithium Heparin, green cap, interior sterile.
30900	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
30901	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
35100	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
35150	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
35200	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
35250	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
36005	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con K2 EDTA + Gel, tappo lavanda, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with K2 EDTA + Gel, lavender cap, interior sterile.





Progettazione e produzione di
apparecchi e strumenti
Fornitura di componenti per
apparecchi e strumenti
e servizi di collaudi per
apparecchi e strumenti



Progettazione e produzione di
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apparecchi e strumenti
e servizi di collaudi per
apparecchi e strumenti



**DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY**

conforme all'Allegato V e VII della Direttiva 93/42/CEE *Dispositivi Medici* e ss.mm.ii.
according to Annex V e VII of the Directive 93/42/EC *Medical Devices* as amended

MEUS S.r.l. - diagnostici per analisi
- *disposable labware*

Via Leonardo da Vinci, 24B
35028 Piove Di Sacco (PD) - Italia

telefono **+ +39-049-9719544** fax **+ +39-049-9719542** e-mail **meus@tecnomeus.it**
address

identificazione dei prodotti / *product identification*
TAMPONI STERILI - SWABS, STERILE

- 23007 Tamponi asta in plastica sterili confezione singola - STERILE PLASTIC SWABS IND WRAPPED
- 23021 Tamponi asta in alluminio sterili in confezione singola - STERILE SWABS ALUMINIUM STICK IND WRAPPED
- 230117 UNI-TER tamponi asta in plastica con terreno di trasporto Stuart sterili confezione singola 12X140 mm
- 230197 UNI-TER tamponi asta in plastica con terreno di trasporto Stuart stick 12X140 mm
- 230140 mm - UNI-TER SWABS STUART CLR PLASTIC STICK 12X140 MM
- 230397 UNI-TER tamponi asta in plastica con terreno di trasporto Amies sterili confezione singola UNI-TER 12X140 mm - SWABS MODIFIED AMIES CLR PLASTIC STICK 12X140 MM
- 230417 UNI-TER SWABS AMIES CHARCOAL PLASTIC STICK 12X140 MM
- 230917 UNI-TER Tamponi asta in plastica con terreno di trasporto Carry-Blair sterili confezione singola 12X140 mm - UNI-TER SWABS AMIES CHARCOAL PLASTIC STICK 12X140 MM
- 230507 UNI-TER Tamponi asta in alluminio con terreno di trasporto Stuart sterili confezione singola 12X140 mm - UNI-TER SWABS STUART CLR ALUMINIUM STICK 12X140 MM
- 230607 UNI-TER Tamponi asta in alluminio con terreno di trasporto Stuart sterili confezione singola 12X140 mm - UNI-TER SWABS STUART CHARCOAL ALUMINIUM STICK 12X140 MM
- 230707 UNI-TER Tamponi asta in alluminio con terreno di trasporto Amies sterili confezione singola 12X140 mm - UNI-TER SWABS MODIFIED AMIES CLR ALUMINIUM STICK 12X140 MM
- 230807 UNI-TER Tamponi asta in alluminio con terreno di trasporto Amies + carbone sterili confezione singola 12X140 mm - UNI-TER SWABS AMIES CHARCOAL ALUMINIUM STICK 12X140 MM
- 23117 Tamponi asta in plastica in provette 12x140 mm sterili - STERILE SWABS PLASTIC STICK IN TEST TUBES 12X140 MM LABELLED
- 23142 Tamponi asta in alluminio in provette 12x140 mm sterili - STERILE SWABS METAL STICK IN TEST TUBE 12X140 MM
- 23125 Tamponi asta in plastica in provette 12x140 mm sterili confezione singola - STERILE SWABS IN TEST TUBES 12X140 MM LABELLED IND WRAPPED
- 23121 Tamponi asta in alluminio in provette 12x140 mm sterili confezione singola - STERILE SWABS ALU IN TEST TUBE 12X140 MM IND WRAPPED LAB
- 180901 Tamponi asta in plastica in provette 16x150 mm sterili - STERILE PLASTIC SWABS IN TEST TUBES 16X150 MM

180982 Tamponi asta in plastica sterili in provetta 16x150 mm etichettata - STERILE SWABS IN PLASTIC IN TUBES 16X150 MM WITH LABEL

180863 Tamponi asta in plastica sterili in provetta 16x150 mm confezione singola - STERILE SWABS IN TEST TUBES 16X150 MM INDIV WRAPPED

180844 Tamponi asta in plastica sterili in provetta 16x150 mm confezione singola etichettata - STERILE SWABS IN TEST TUBES 16X150 MM INDIV WRAPPED + LAB

classificazione dei prodotti **Classe I - sterile come da Direttiva Europea 93/42/CEE e ss.mm.ii.**
Class I - sterile mentioned in Directive 93/42/EC as amended

Si dichiara

sotto la propria responsabilità che i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 93/42/CEE e ss.mm.ii. "*Dispositivi Medici*"

Tutta la documentazione tecnica richiesta dall'Allegato VII della succitata Direttiva, e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 93/42/CEE as amended on *Medical Devices*.

All the supporting documents, as required by Annex VII of the 93/42/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Piove di Sacco (PD), 02/01/2014

firma
signature

Assicuratore Qualità / Quality Manager

Giovanni Chiarin

Giovanni Chiarin



DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato V e VII della Direttiva 93/42/CEE Dispositivi Medici e ss.mm.ii.
according to Annex V e VII of the Directive 93/42/EC Medical Devices as amended

MEUS S.r.l. - diagnostici per analisi

-- disposabili labware

Via Leonardo da Vinci, 24B

35028 Piove Di Sacco (PD) - Italia

fabbricante / manufacturer: **meus@tecnomeus.it**
indirizzo / address: **meus@tecnomeus.it**
telefono / phone: **meus@tecnomeus.it**
fax: **meus@tecnomeus.it**
fax elettronica / e-mail: **meus@tecnomeus.it**

identificazione dei prodotti / product identification -

AGHI - NEEDLES

- 1526502 Agli per prelievo sangue cannula 20G 1 1/2" giallo - NEEDLES 20G 1 1/2" YELLOW
- 1526501 Agli per prelievo sangue cannula 20G 1" giallo - NEEDLES 20G 1" YELLOW
- 1526504 Agli per prelievo sangue cannula 21G 1 1/2" verde - NEEDLES 21G 1 1/2" GREEN
- 152113 Agli per prelievo sangue cannula 21G 1" verde - NEEDLES 21G 1" GREEN
- 1526506 Agli per prelievo sangue cannula 22G 1 1/2" nero - NEEDLES 22G 1 1/2" BLACK
- 15225 Agli per prelievo sangue cannula 22G 1" nero - NEEDLES 22G 1" BLACK
- 15176 Agli per prelievo sangue cannula 18G 1 1/2" rosa - NEEDLES SINGLE SAMPLE 18G 1 1/2" PINK
- 15181 Agli per prelievo del sangue cannula 18G 1" rosa - NEEDLES SINGLE SAMPLE 18G 1" PINK
- 15164 Agli prelievi multipli del sangue 18G 1 1/2" rosa - NEEDLES 18G 1 1/2" PINK
- 15183 Agli prelievi multipli del sangue 18 G 1" rosa - NEEDLES 18G 1" PINK
- 15520 Agli con dispositivo di sicurezza 20G 1 1/2" giallo - NEEDLES WITH SAFETY DEVICE 20G 1 1/2" YELLOW
- 15501 Agli con dispositivo di sicurezza 21G 1 1/2" verde - NEEDLES WITH SAFETY DEVICE 21G 1 1/2" GREEN
- 15565 Agli con dispositivo di sicurezza 22G 1 1/2" nero - NEEDLES WITH SAFETY DEVICE 22G 1 1/2" BLACK
- 15566 Agli con dispositivo di sicurezza 20G 1" giallo - NEEDLES WITH SAFETY DEVICE 20G 1" YELLOW
- 15565 Agli con dispositivo di sicurezza 21G 1" verde - NEEDLES WITH SAFETY DEVICE 21G 1" GREEN
- 15567 Agli con dispositivo di sicurezza 22G 1" nero - NEEDLES WITH SAFETY DEVICE 22G 1" BLACK
- 156720 Agli Crystal con HOLDER 20G 1" giallo - CRYSTAL NEEDLES WITH HOLDER 20G 1" YELLOW
- 156721 Agli Crystal con HOLDER 21G 1" verde - CRYSTAL NEEDLES WITH HOLDER 21G 1" GREEN
- 156722 Agli Crystal con HOLDER 22G 1" nero - CRYSTAL NEEDLES WITH HOLDER 22G 1" BLACK
- 157520 Agli Crystal con dispositivo di sicurezza 20G 1 1/2" giallo - CRYSTAL NEEDLES WITH SAFETY DEVICE 20G 1 1/2" YELLOW
- 157521 Agli Crystal con dispositivo di sicurezza 21G 1" verde - CRYSTAL NEEDLES WITH SAFETY DEVICE 21G 1" GREEN
- 157522 Agli Crystal con dispositivo di sicurezza 22G 1" nero - CRYSTAL NEEDLES WITH SAFETY DEVICE 22G 1" BLACK

classificazione dei prodotti / Classificazione dei prodotti: **Classe IIa - sterili come da direttiva 93/42/CE e ss.mm.ii.**

Si dichiara
sotto la propria responsabilità che i dispositivi soprarielocati rispettano le disposizioni applicabili della Direttiva 93/42/CEE e ss.mm.ii. "Dispositivi Medici".
Tutta la documentazione tecnica richiesta dall'Allegato VII della succitata Direttiva, e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del fabbricante.
Hereby we declare
under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 93/42/CEE as amended on "Medical Devices".
All the supporting documents, as required by Annex VII of the 93/42/EC Directive, in order to prove conformity to the Annex VII of the Directive 93/42/CEE Dispositivi Medici e ss.mm.ii. according to Annex I, are retained under the premises of the Manufacturer.

luogo e data / place and date: **Piove di Sacco (PD), 02/01/2014**

firma / signature: **Giovanni Chiarin**

Assicuratore Qualità / Quality Manager: **Giovanni Chiarin**



articoli per laboratorio analisi
disposable labware

www.kima.it



Arzergrande, 02/11/2017

TO WHOM IT MAY CONCERN

We, "VACUTEST KIMA SRL – Via dell'Industria, 12 – 35020 ARZERGRANDE (PD) – ITALY", assign to "GLOBAL BIOMARKETING GROUP MOLDOVA – Str. Tighina 65, Of. 607 – 2001 Chisinau – Republic of Moldova", as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

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

KIMA s.a.s.
di Chiarin Renzo & C.
Via Leonardo Da Vinci, 22
35028 PIOVE DI SACCO (PD)
C.F. e P.IVA 04406290283

Chiarin Renzo

Sole Administrator



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 110 subsidiaries all over the globe.

CERTIFICATO n. **4264/4**
CERTIFICATE No.

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

GRUPPO VACUTEST KIMA

Sede / Head Office

Via dell'Industria, 12 - 35020 Arzergrande (PD) - Italia

Unità Operative / Operative Units

MEUS S.r.l. - Via Leonardo da Vinci, 24B - 26 - 28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

MEUS S.r.l. - Via dell'Industria, 2 - 16 - 35020 Arzergrande (PD) - Italia

ROLL S.R.L. - Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

KIMA S.R.L. - Via Leonardo da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

VACUTEST KIMA S.r.l. - Via dell'Industria, 12 - 35020 Arzergrande (PD) - Italia

VACUTEST KIMA S.r.l. via L. Da Vinci, 22 Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. 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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for 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. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

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
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A

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



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



CISQ is a member of



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. **4265/4**
CERTIFICATE No. _____

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

GRUPPO VACUTEST KIMA

Sede / Head Office

Via dell'Industria, 12 – 35020 Arzergrande (PD) - Italia

Unità Operative / Operative Units

MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

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VACUTEST KIMA S.r.l. - Via dell'Industria, 12 – 35020 Arzergrande (PD) – Italia

VACUTEST KIMA S.r.l. via L. Da Vinci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

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*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. 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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for 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. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Ritirarsi 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.

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 726341 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 726341 or email address info@icim.it.

Data emissione
First issue
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SGQ N° 004 A

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CISQ is the Italian Federation of management system Certification Bodies.



Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)**

SEDE OPERATIVA:
OPERATIONAL SITE:

**CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)**

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

**Progettazione e sviluppo, produzione e commercializzazione di
dispositivi medico diagnostici in-vitro: terreni di coltura per
batteriologia, sistemi di identificazione e antibiogramma, kit per la
determinazione di plasmaproteine (IAF 12, 29)**

**Design and development, production and sale of in-vitro diagnostic
medical devices: culture media for bacteriology, identification and
susceptibility testing systems, kits for plasma protein determination
(IAF 12, 29)**



SGQ N° 049A

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2019-02-11

Al / To: 2022-02-10

Data emissione / Issuing Date

2019-02-11

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2012-09-25

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 32.1 del 07.06.2017

24117	Fergola Broth	
24119	OH HAINA BROTH	20PV
24120	BILE AEscULIN BROTH	20PV
24124	Fluid Thioglycolato Medium	
24125	SERUM BROTH	20PV
24127	Fluid Thioglycolato Medium + 1% Tween 80	
24128	TRYPTIC SOY BROTH + TWEE 80 TM	20PV
24135	SALMONELLA DIFFERENTIAL BROTH	20PV
24136	TRYPTONE WATER	20PV
24137	MALONATE BROTH	20PV
24139	LYSINE DECARBOXYLASE BROTH	20PV
24141	BRAIN HEART INFUSION BROTH 2 ml	20PV
24142	PHYSIOLOGICAL SOLUTION 3ml	20PV
24143	Selenite Broth	
24144	TODD HEWITT Y AGar/Non-Haemolitic agar	20PV
24145	TODD HEWITT Y AGar/Coliforms/No. 2	20PV
24146	THIOGLYCOLATE 16 ml INDIATOR acc. USP 20PV	
24147	Thioglycolate 8ml	
24149	MR VP MEDIUM	20PV
24151	Sabouraud Dextrose Broth + CAF	
24151	Fluid Thioglycolato Medium	
24152	Mixity Test Medium	
24153	MM Semisolid Agar	
24155	O/F Medium with Oxidase	
24155	RAPPAPORT VASSILADIS SOY (RSV) BROTH	20PV
24155	BRYONE BROTH	20PV
24156	CAMPYLOBACTER BROTH	20PV
24157	S.F. BROTH	20PV
24157	STREPTOCOCCUS BROTH	20PV
24162	MOGEL AND MARTIN II MANNITOL	20PV
24166	UREA BROTH	20PV
24167	Wako Catalase Broth	
24168	SCHAEFER BROTH	20PV
24168	YERSINIA BROTH	20PV
24169	EVANS BROTH	20PV
24169	MIDDLEBROCK 7H6 BROTH	20PV
24169	PHENOL RED BROTH	20PV
24169	Rappaport Broth with Soy	
24181	Tetraselenite Broth	
24183	CASO BROTH (Double Concentration) CE	20PV
24183	SPM Broth	
24183	SPM Broth (double strength)	
24171	Urease Activity Medium	
24171	TRYPTIC SOY BROTH (4mm EP)	
24174	TRYPTIC SOY BROTH	
24176	UREA BROTH	
24176	Glycerol Broth	
24176	Fluid Thioglycolato Medium 100 x 10 ml	
24182	Mixity Test Medium	
24180	RAPPAPORT VASSILADIS SOY (RSV) BROTH	
24175	Tryptic Soy Agar	
24173	Tryptic Soy Broth	
24173	UREA MEDIUM	
24173	Fluid Soy Broth	
24173	Total Heat Broth	
24172	Bran Heart Infusion Broth	
24173	Mixed Broth	
24170	CHECK-SE BROTH (modified) 20 Test	
24170	CAMPYLOBACTER SELECTIVE THIOGLYCOLATE MEDIUM	
24170	CLOSTRIDIUM AGAR (Sheep Blood 6%)	

30009	HELOCACTER PYLORI AGAR	
30010	STREPTOCOCCAL KF + TTC AGAR	
30011	SMONONS CITRATE AGAR	
30013	NITRATI AGAR	
30014	MOSSAL AGAR	
30022	T.C.B.S. AGAR	
30023	Sabouraud CAF AGAR	
30024	SABOURAUD CAF + ACTINONE AGAR	
30030	M.R.S. AGAR	
30080	BORSET GENSOU AGAR (Sheep Blood 15%)	
30081	CHRISTENSEN UREA AGAR	
30082	Tryptic Soy Agar	
30083	NUTRIENT AGAR	
30084	BRAIN HEART INFUSION AGAR	
30085	PHENOLANINE AGAR	
30087	KLEIGER IRON AGAR	
30088	KLEIGER IRON AGAR + NCI 2%	
30090	Mayer Hinton II Agar	
30091	BIGGY (JACKERSON) AGAR	
30093	SABOURAUD AGAR	
30095	S.M. MEDIUM	
30096	T.S.I. AGAR	
30097	Tryptase Agar	
30118	LYSINE IRON AGAR	
30118	Chocolate Agar	
30118	LOEFFLER MEDIUM	
30117	REGGOLA MEDIUM	
30118	Lorenson Jensen Medium	
30118	LOWENSTEIN JENSEN MEDIUM with DL CYCEROL	
30121	Selenite S Medium	
30125	BORSET EGG MEDIUM	
30126	MIDDLEBROCK 7H10 AGAR	
31003	Sabouraud CAF AGAR	
31004	SPS Agar	
31075	Muller Hinton II Agar	
31082	Tryptic Soy Agar	
31083	Nutrient Agar ISO 16256	
31084	Muller Hinton II Agar	
31087	Tryptase Agar	
31088	Chocolate Agar	
31121	Selenite S Medium	
31084	MMU Agar	
31040	THAYER MARTIN AGAR	
31055	MYCOSEL AGAR	
31066	SERUM TELLURITE AGAR	
31068	D.P.F.C. AGAR	
31065	BILE AEscULIN AGAR	
31026	DERMATOPHYTE (D.T.M.) AGAR	
31118	L.I.T.M. MEDIUM	
31180	PETRAGNANI MEDIUM	
31070	CAMPYLOBACTER AGAR	
31071	CYTHINE TRYPTIC AGAR (CTA)	
31075	Muller Hinton II Agar	
31121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/ml	
31121	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/ml	
31122	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/ml	
31123	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/ml	
31124	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/ml	
31125	LOWENSTEIN JENSEN + RIFAMPICIN 80 µg/ml	
31126	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/ml	

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PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 32.1 del 07.06.2017

34122	LOWENSTEIN JENSEN + RIFAMPICIN 9 µg/ml	
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/ml	
34124	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/ml	
34125	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml	
34126	LOWENSTEIN JENSEN + ISONIAZID 5 µg/ml	
34127	LOWENSTEIN JENSEN + ISONIAZID 10 µg/ml	
34128	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/ml	
34129	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/ml	
34130	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/ml	
34131	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/ml	
34132	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/ml	
34133	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/ml	
34134	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/ml	
34135	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/ml	
34136	LOWENSTEIN JENSEN + ETHAMBUOTOL 2 µg/ml	
34137	LOWENSTEIN JENSEN + ETHAMBUOTOL 4 µg/ml	
34138	LOWENSTEIN JENSEN + ETHAMBUOTOL 8 µg/ml	
34139	LOWENSTEIN JENSEN + ETHAMBUOTOL 16 µg/ml	
34140	LOWENSTEIN JENSEN + ETHAMBUOTOL 32 µg/ml	
34141	LOWENSTEIN JENSEN + ETHAMBUOTOL 64 µg/ml	
34142	LOWENSTEIN JENSEN + ETHAMBUOTOL 128 µg/ml	
34143	LOWENSTEIN JENSEN + ETHAMBUOTOL 256 µg/ml	
34144	LOWENSTEIN JENSEN + ETHAMBUOTOL 512 µg/ml	
34145	LOWENSTEIN JENSEN + ETHAMBUOTOL 1024 µg/ml	
34146	LOWENSTEIN JENSEN + AMIKACIN 5 µg/ml	
34147	LOWENSTEIN JENSEN + AMIKACIN 10 µg/ml	
34148	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/ml	
34149	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml	
34150	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/ml	
34151	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml	
34152	LOWENSTEIN JENSEN + OFLOXACIN 80 µg/ml	
34153	LOWENSTEIN JENSEN + PAS 1 µg/ml	
34154	LOWENSTEIN JENSEN + PAS 2 µg/ml	
34155	LOWENSTEIN JENSEN + PAS 4 µg/ml	
34156	LOWENSTEIN JENSEN + PAS 8 µg/ml	
34157	LOWENSTEIN JENSEN + PAS 16 µg/ml	
34158	LOWENSTEIN JENSEN + PAS 32 µg/ml	
34159	LOWENSTEIN JENSEN + PAS 64 µg/ml	
34160	LOWENSTEIN JENSEN + PAS 128 µg/ml	
34161	LOWENSTEIN JENSEN + PAS 256 µg/ml	
34162	LOWENSTEIN JENSEN + PAS 512 µg/ml	
34163	LOWENSTEIN JENSEN + PAS 1024 µg/ml	
34164	LOWENSTEIN JENSEN + PAS 2048 µg/ml	
34165	LOWENSTEIN JENSEN + PAS 4096 µg/ml	
34166	LOWENSTEIN JENSEN + PAS 8192 µg/ml	
34167	LOWENSTEIN JENSEN + PAS 16384 µg/ml	
34168	LOWENSTEIN JENSEN + PAS 32768 µg/ml	
34169	LOWENSTEIN JENSEN + PAS 65536 µg/ml	
34170	LOWENSTEIN JENSEN + PAS 131072 µg/ml	
34171	LOWENSTEIN JENSEN + PAS 262144 µg/ml	
34172	LOWENSTEIN JENSEN + PAS 524288 µg/ml	
34173	LOWENSTEIN JENSEN + PAS 1048576 µg/ml	
34174	LOWENSTEIN JENSEN + PAS 2097152 µg/ml	
34175	LOWENSTEIN JENSEN + PAS 4194304 µg/ml	
34176	LOWENSTEIN JENSEN + PAS 8388608 µg/ml	
34177	LOWENSTEIN JENSEN + PAS 16777216 µg/ml	
34178	LOWENSTEIN JENSEN + PAS 33554432 µg/ml	
34179	LOWENSTEIN JENSEN + PAS 67108864 µg/ml	
34180	LOWENSTEIN JENSEN + PAS 134217728 µg/ml	
34181	LOWENSTEIN JENSEN + PAS 268435456 µg/ml	
34182	LOWENSTEIN JENSEN + PAS 536870912 µg/ml	
34183	LOWENSTEIN JENSEN + PAS 1073741824 µg/ml	
34184	LOWENSTEIN JENSEN + PAS 2147483648 µg/ml	
34185	LOWENSTEIN JENSEN + PAS 4294967296 µg/ml	
34186	LOWENSTEIN JENSEN + PAS 8589934592 µg/ml	
34187	LOWENSTEIN JENSEN + PAS 17179869184 µg/ml	
34188	LOWENSTEIN JENSEN + PAS 34359738368 µg/ml	
34189	LOWENSTEIN JENSEN + PAS 68719476736 µg/ml	
34190	LOWENSTEIN JENSEN + PAS 137438953472 µg/ml	
34191	LOWENSTEIN JENSEN + PAS 274877906944 µg/ml	
34192	LOWENSTEIN JENSEN + PAS 549755813888 µg/ml	
34193	LOWENSTEIN JENSEN + PAS 1099511627776 µg/ml	
34194	LOWENSTEIN JENSEN + PAS 2199023255552 µg/ml	
34195	LOWENSTEIN JENSEN + PAS 4398046511104 µg/ml	
34196	LOWENSTEIN JENSEN + PAS 8796093022208 µg/ml	
34197	LOWENSTEIN JENSEN + PAS 17592186444416 µg/ml	
34198	LOWENSTEIN JENSEN + PAS 35184372888832 µg/ml	
34199	LOWENSTEIN JENSEN + PAS 70368745777664 µg/ml	
34200	LOWENSTEIN JENSEN + PAS 140737491555328 µg/ml	
34201	LOWENSTEIN JENSEN + PAS 281474983110656 µg/ml	
34202	LOWENSTEIN JENSEN + PAS 562949966221312 µg/ml	
34203	LOWENSTEIN JENSEN + PAS 1125899932442624 µg/ml	
34204	LOWENSTEIN JENSEN + PAS 2251799864885248 µg/ml	
34205	LOWENSTEIN JENSEN + PAS 4503599729770496 µg/ml	
34206	LOWENSTEIN JENSEN + PAS 9007199459540992 µg/ml	
34207	LOWENSTEIN JENSEN + PAS 18014398919081984 µg/ml	
34208	LOWENSTEIN JENSEN + PAS 36028797838163968 µg/ml	
34209	LOWENSTEIN JENSEN + PAS 72057595676327936 µg/ml	
34210	LOWENSTEIN JENSEN + PAS 144115191352655872 µg/ml	
34211	LOWENSTEIN JENSEN + PAS 288230382705311744 µg/ml	
34212	LOWENSTEIN JENSEN + PAS 576460765410623488 µg/ml	
34213	LOWENSTEIN JENSEN + PAS 1152921530821246976 µg/ml	
34214	LOWENSTEIN JENSEN + PAS 2305843061642493952 µg/ml	
34215	LOWENSTEIN JENSEN + PAS 4611686123284987904 µg/ml	
34216	LOWENSTEIN JENSEN + PAS 9223372246569975808 µg/ml	
34217	LOWENSTEIN JENSEN + PAS 18446744893139951616 µg/ml	
34218	LOWENSTEIN JENSEN + PAS 36893489786279903232 µg/ml	
34219	LOWENSTEIN JENSEN + PAS 73786979572559806464 µg/ml	
34220	LOWENSTEIN JENSEN + PAS 147573951151119612928 µg/ml	
34221	LOWENSTEIN JENSEN + PAS 295147902302239225856 µg/ml	
34222	LOWENSTEIN JENSEN + PAS 590295804604478451712 µg/ml	
34223	LOWENSTEIN JENSEN + PAS 1180591609208956903424 µg/ml	
34224	LOWENSTEIN JENSEN + PAS 2361183218417913806848 µg/ml	
34225	LOWENSTEIN JENSEN + PAS 4722366436835827613696 µg/ml	
34226	LOWENSTEIN JENSEN + PAS 9444732873671655227392 µg/ml	
34227	LOWENSTEIN JENSEN + PAS 18889465747343304554784 µg/ml	
34228	LOWENSTEIN JENSEN + PAS 37778931494686609109568 µg/ml	
34229	LOWENSTEIN JENSEN + PAS 75557862989373218219136 µg/ml	
34230	LOWENSTEIN JENSEN + PAS 151115725978746436438272 µg/ml	
34231	LOWENSTEIN JENSEN + PAS 302231451957492872876544 µg/ml	
34232	LOWENSTEIN JENSEN + PAS 604462903914985745753088 µg/ml	
34233	LOWENSTEIN JENSEN + PAS 1208925807829971511506176 µg/ml	
34234	LOWENSTEIN JENSEN + PAS 241785161565994302301232 µg/ml	
34235	LOWENSTEIN JENSEN + PAS 483570323131988604602464 µg/ml	
34236	LOWENSTEIN JENSEN + PAS 967140646263977209204928 µg/ml	
34237	LOWENSTEIN JENSEN + PAS 1934281292527954418409856 µg/ml	
34238	LOWENSTEIN JENSEN + PAS 3868562585055908836819136 µg/ml	
34239	LOWENSTEIN JENSEN + PAS 7737125170111817673638272 µg/ml	
34240	LOWENSTEIN JENSEN + PAS 1547425034022363547276544 µg/ml	
34241	LOWENSTEIN JENSEN + PAS 3094850068044727094553088 µg/ml	
34242	LOWENSTEIN JENSEN + PAS 6189700136089454189110632 µg/ml	
34243	LOWENSTEIN JENSEN + PAS 12379400272178908378221264 µg/ml	
34244	LOWENSTEIN JENSEN + PAS 24758800544357816756442528 µg/ml	
34245	LOWENSTEIN JENSEN + PAS 49517601088715633512885056 µg/ml	
34246	LOWENSTEIN JENSEN + PAS 99035202177431267025770112 µg/ml	
34247	LOWENSTEIN JENSEN + PAS 19807040435486253405154224 µg/ml	
34248	LOWENSTEIN JENSEN + PAS 39614080870972506810308448 µg/ml	
34249	LOWENSTEIN JENSEN + PAS 79228161741945013620616896 µg/ml	
34250	LOWENSTEIN JENSEN + PAS 15845632343989007240123392 µg/ml	
34251	LOWENSTEIN JENSEN + PAS 31691264687978014480246784 µg/ml	
34252	LOWENSTEIN JENSEN + PAS 63382529375956028960493568 µg/ml	
34253	LOWENSTEIN JENSEN + PAS 126765058751912057920987136 µg/ml	
34254	LOWENSTEIN JENSEN + PAS 253530117503824115840194272 µg/ml	
34255	LOWENSTEIN JENSEN + PAS 507060235007648231680388544 µg/ml	
34256	LOWENSTEIN JENSEN + PAS 1014120470015376463360777088 µg/ml	
34257	LOWENSTEIN JENSEN + PAS 2028240940030752926721554176 µg/ml	
34258	LOWENSTEIN JENSEN + PAS 4056481880061505853443108352 µg/ml	
34259	LOWENSTEIN JENSEN + PAS 8112963760123011706886216704 µg/ml	
34260	LOWENSTEIN JENSEN + PAS 1622592752024603413777243408 µg/ml	
34261	LOWENSTEIN JENSEN + PAS 3245185504049206827554486816 µg/ml	
34262	LOWENSTEIN JENSEN + PAS 6490371008098413655108973632 µg/ml	
34263	LOWENSTEIN JENSEN + PAS 12980742016196827310217947264 µg/ml	
34264	LOWENSTEIN JENSEN + PAS 25961484032393654620435894528 µg/ml	
34265	LOWENSTEIN JENSEN + PAS 51922968064787309240871789056 µg/ml	
34266	LOWENSTEIN JENSEN + PAS 103845936129574618481735780112 µg/ml	
34267	LOWENSTEIN JENSEN + PAS 207691872259149236963471560224 µg/ml	
34268	LOWENSTEIN JENSEN + PAS 415383744518298473926943200448 µg/ml	
34269	LOWENSTEIN JENSEN + PAS 830767489036596947853886400896 µg/ml	
34270	LOWENSTEIN JENSEN + PAS 166153497807319389570777201792 µg/ml	
34271	LOWENSTEIN JENSEN + PAS 332306995614638779141554403584 µg/ml	
34272	LOWENSTEIN JENSEN + PAS 664613991229277558283108807168 µg/ml	
34273	LOWENSTEIN JENSEN + PAS 1329227982458555116556217614336 µg/ml	
34274	LOWENSTEIN JENSEN + PAS 2658455964917110311112528286784 µg/ml	

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS
Rev. 32.1 del 07.06.2017

80351	RAPID ANTIBIOTIC TEST	50 Testi
80350	NONVONUM COLOR KIT	2 x 250 ml
80349	FIXUR I	10 viali
80348	ICONE SOLUTION 10 x 10 ml	10 viali
80347	XLT 4 SUPPLEMENT 4 x 50 ml	4 x 50 ml
80346	POTASSIUM TELLURITE 1% Supplement	10 x 10 ml
80345	TTC 1% Supplement	10 x 10 ml
80344	TWEEN 80 Supplement 4 x 100 ml	4 x 100 ml
80343	VTAMIN K 1% SUPPLEMENT 10 x 5 ml	10 x 5 ml
80342	AMPICILLIN supplement 10 viali	10 viali
80341	LEGIONELLA (BMPA) supplement 10 viali	10 viali
80340	BRUCELLA supplement 10 viali	10 viali
80339	CAMPYLOBACTER Positivum supplement 10 viali	10 viali
80338	CN (Pseudomonas) supplement 10 viali	10 viali
80337	CLOSTRIDIUM difficile supplement 10 viali	10 viali
80336	LEISOFELLA (CVPK) supplement 10 viali	10 viali
80335	ICONE solution 1 x 10 viali	1 x 10 viali
80334	LCAT supplement 10 viali	10 viali
80333	BORDETTELLA supplement 10 viali	10 viali
80332	HAEMOPHILUS supplement 10 viali	10 viali
80331	CAMPYLOBACTER butane supplement 10 viali	10 viali
80330	BACILLUS cereus supplement 10 viali	10 viali
80329	CALGRAMMIDOL supplement 10 viali	10 viali
80328	LEGIONELLA (MAY) supplement 10 viali	10 viali
80327	MMS supplement 10 viali	10 viali
80326	V.C.N. supplement 10 viali	10 viali
80325	VITALEX growth supplement 10 viali	10 viali
80324	V.C.N.T. supplement 10 viali	10 viali
80323	DEFAMATOPHYTE supplement 10 viali	10 viali
80322	LISTERIA PALCUM supplement 10 viali	10 viali
80321	DMG 1% Supplement 10 viali	10 viali
80320	GENTAMYCIN supplement 10 viali	10 viali
80319	HIDROBROCK 2H 10 supplement 4 x 50 ml	4 x 50 ml
80318	CAMPYLOBACTER KARMALI Supplement 10 viali	10 viali
80317	CAMPYLOBACTER CODA supplement 10 viali	10 viali
80316	CAMPYLOBACTER C.T.V.A. Supplement 10 viali	10 viali
80315	YERGINA supplement 10 viali	10 viali
80314	CAMPYLOBACTER Shigella Supplement 10 viali	10 viali
80313	V.C.A.T. supplement 10 viali	10 viali
80312	LISTERIA FRASER supplement (112mg/10 viali)	10 viali
80311	CR6 (Sal/Sig) supplement 10 viali	10 viali
80310	CAMPYLOBACTER growth supplement 10 viali	10 viali
80309	CAMPYLOBACTER Bacter Wang supp 10 viali	10 viali
80308	SCHAEFFER supplement 10 viali	10 viali
80307	CAMPYLOBACTER Shigella supp 10 viali	10 viali
80306	LEGIONELLA (CVC) supplement 10 viali	10 viali
80305	WACOMYCHIN Supplement for VITE 10 viali	10 viali
80304	CAMPYLOBACTER C.T.V.A. Supplement 10 viali	10 viali
80303	CHROMATIK™ MBSA Supplement	10 viali
80302	CHROMATIK™ E56L Supplement	10 viali
80301	CHROMATIK™ E56L-Ampo Supplement	10 viali
80300	Legionella BCVE Growth Supplement w/o L-Cystine	10 viali

81899	D-Cytosine 4-MP Supplement	30 Testi
85501	CORPO KIT (SELENITE BROTH)	30 Testi
85502	CORPO KIT 2 (SALMONELLA BROTH)	30 Testi
87901	KOVACS Reagent	30 Testi
87902	VP (NASH) Reagent	30 Testi
87903	CATALASE Reagent	30 Testi
87904	PHENYLALANINE Reagent	30 Testi
87905	OXIDASE Reagent	30 Testi
87906	Vaseline Oil	30 Testi
87907	VP (NASH) Reagent	30 Testi
87908	Lactopon Cotton Blue Droppers	30 Testi
87909	Methyl Red Droppers	30 Testi
87910	GRAM COLOR KIT	30 Testi
88003	OXIDASE TEST SWABS 30 Testi	30 Testi
88004	OXIDASE TEST DISCS 30 Discs	30 Discs
88005	O.M.P. TEST 30 Testi	30 Testi
88006	E.COLI TEST 30 Testi	30 Testi
88007	HPIRATE TEST 30 Testi	30 Testi
88008	ASCULIN OLE TEST 30 Testi	30 Testi
88009	NTRAIT TEST 30 Testi	30 Testi
88010	LISTERIA MONO TEST 30 Testi	30 Testi
88011	LISTERIA RAPID TEST 30 Testi	30 Testi
88012	HS RAPID TEST 30 Testi	30 Testi
88013	LYSINE DECARBOXYLASE TEST 30 Testi	30 Testi
88014	ORNITHINE DECARBOXYLASE TEST 30 Testi	30 Testi
88015	ARGININE DECARBOXYLASE TEST 30 Testi	30 Testi
88016	INDOLE TEST 30 Testi	30 Testi
88017	S.F. RAPID TEST 30 Testi	30 Testi
88018	CAMP TEST-G 30 Testi	30 Testi
88019	CATALASE/COXY TEST 30 Testi	30 Testi
88020	VITEK INDICO TEST 50 Testi	50 Testi
88021	CAMP TEST-B 30 Testi	30 Testi
88022	PEPTIDASE A TEST 30 Testi	30 Testi
88023	OXIDASE TEST STICKS 50 Testi	50 Testi
88024	Dalston Test Stick	30 Testi
88025	COAGULASE TEST 40 Testi	40 Testi
88026	DRAM TEST STICK 30 Testi	30 Testi
88027	INDOLE TEST STICK 30 Testi	30 Testi
88028	RYTALACTAMASE STICKS 30 Testi	30 Testi
88029	PEPTIDASE A STICKS 30 Testi	30 Testi
88030	VP TEST KIT	30 Testi
88031	C 390 50 Discs	50 Discs
88032	Bilimat Green 100 µg	100 µg
88033	CHIRATE TEST	30 Testi
88034	OTN Dip 150 µg	150 µg
88035	OTN Dip 10 µg	10 µg
88036	D.M.P. TEST	30 Testi
88037	GALACTOSE TEST 30 Testi	30 Testi
88038	GLUCOSE TEST 30 Testi	30 Testi
88039	MALTOSE TEST 30 Testi	30 Testi
88040	RAF FALGATE TEST 30 Testi	30 Testi
88041	SUCROSE TEST 30 Testi	30 Testi
88042	ARABINOTEST 30 Testi	30 Testi
88043	ADONITOL TEST 30 Testi	30 Testi
88044	ADONITOL TEST 30 Testi	30 Testi
88045	DULCITOL TEST 30 Testi	30 Testi
88046	INOSITOL TEST 30 Testi	30 Testi
88047	INULIN TEST 30 Testi	30 Testi
88048	LEVULOSE TEST 30 Testi	30 Testi

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88214	MANNITOL TEST	30 Testi
88215	MANNOSE TEST	30 Testi
88216	FRAMMOSE TEST	30 Testi
88217	SALICIN TEST	30 Testi
88218	SORBITOL TEST	30 Testi
88219	TRENALOSE TEST	30 Testi
88220	XILOSE TEST	30 Testi
88221	CultControl™ Acetabacterium brasiliense ATCC® 18404™	10 viali
88222	CultControl™ Bacillus cereus ATCC® 11776™	10 viali
88223	CultControl™ Bacillus subtilis ATCC® 6053™	10 viali
88224	CultControl™ Candida albicans ATCC® 90028™	10 viali
88225	CultControl™ Enterococcus faecalis ATCC® 29212™	10 viali
88226	CultControl™ Escherichia coli ATCC® 25922™	10 viali
88227	CultControl™ Listeria innocua ATCC® 35091™	10 viali
88228	CultControl™ Listeria monocytogenes ATCC® 19111™	10 viali
88229	CultControl™ Listeria seeligeri ATCC® 19112™	10 viali
88230	CultControl™ Listeria monocytogenes ATCC® 19111™	10 viali
88231	CultControl™ Proteus mirabilis ATCC® 29624™	10 viali
88232	CultControl™ Pseudomonas aeruginosa ATCC® 27853™	10 viali
88233	CultControl™ Pseudomonas aeruginosa ATCC® 27853™	10 viali
88234	CultControl™ Rhodococcus equi ATCC® 49219™	10 viali
88235	CultControl™ Saccharomyces cerevisiae ATCC® 9790™	10 viali
88236	CultControl™ Salmonella typhimurium ATCC® 14028™	10 viali
88237	CultControl™ Shigella flexneri ATCC® 10282™	10 viali
88238	CultControl™ Staphylococcus aureus ATCC® 12228™	10 viali
88239	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88240	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88241	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88242	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88243	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88244	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88245	CultControl™ Staphylococcus aureus ATCC® 29213™	10 viali
88246	CultControl™ Streptococcus agalactiae ATCC® 18819™	10 viali
88247	CultControl™ Streptococcus pneumoniae ATCC® 49619™	10 viali
88248	CultControl™ Streptococcus pyogenes ATCC® 19619™	10 viali
88249	CultControl™ Proteus mirabilis ATCC® 12228™	10 viali
88250	CultControl™ Yersinia enterocolitica ATCC® 48124™	10 viali
88251	CultControl™ Listeria monocytogenes ATCC® 19111™	10 viali
88252	CultControl™ Legionella pneumophila subsp. pneumophila ATCC® 34291™	10 viali
88253	CultControl™ Salmonella enterica subsp. enterica serovar typhimurium ATCC® 19111™	10 viali
88254	CultControl™ Lactobacillus pasteurii subsp. pasteurii ATCC® BAA-32™	10 viali
88255	CultControl™ Yersinia paratyphoetypus ATCC® 18390™	10 viali
88256	CultControl™ Acetabacterium brasiliense ATCC® 18404™	10 viali
88257	CultControl™ Shigella sonnei ATCC® 35051™	10 viali
88258	CultControl™ Oshelium sordidum ATCC® 9714™	10 viali
88259	CultControl™ Listeria monocytogenes ATCC® 19111™	10 viali
88260	CultControl™ Streptococcus bovis ATCC® 33171™	10 viali
88261	CultControl™ Streptococcus bovis ATCC® 33171™	10 viali
88262	CultControl™ Streptococcus pneumoniae ATCC® 49619™	10 viali
88263	CultControl™ Streptococcus pneumoniae ATCC® 49619™	10 viali
88264	CultControl™ Streptococcus pneumoniae ATCC® 49619™	10 viali
88265	CultControl™ Enterobacter cloacae subsp. cloacae ATCC® BAA-114™	10 viali
88266	CultControl™ Enterococcus faecalis ATCC® 49593™	10 viali
88267	CultControl™ Escherichia coli HCTC 11954™	10 viali
88268	CultControl™ Klebsiella pneumoniae ATCC® BAA-2146™	10 viali

86070	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 700603™	10 viali
86071	CultControl™ Candida parapsilosis ATCC® 90018™	10 viali
86072	CultControl™ Candida albicans ATCC® 90028™	10 viali
86073	CultControl™ Acetabacterium brasiliense ATCC® 18404™	10 viali
86074	CultControl™ Klebsiella pneumoniae ATCC® 19424™	10 viali
86075	CultControl™ Klebsiella pneumoniae ATCC® 31416™	10 viali
86076	CultControl™ Haemophilus influenzae ATCC® 43256™	10 viali
86077	CultControl™ Haemophilus influenzae ATCC® 43247™	10 viali
86078	CultControl™ Bacillus thuringiensis ATCC® 25269™	10 viali
86079	CultControl™ Bacillus thuringiensis ATCC® 25269™	10 viali
86080	CultControl™ Lactobacillus acidophilus ATCC® 43217™	10 viali
86081	CultControl™ Lactobacillus reuteri ATCC® 49317™	10 viali
86082	CultControl™ Lactobacillus reuteri ATCC® 49317™	10 viali
86083	CultControl™ Proteus mirabilis ATCC® 29624™	10 viali
86084	CultControl™ Salmonella enterica subsp. enterica serovar Enteritidis ATCC® 13029™	10 viali
86085	CultControl™ Listeria monocytogenes ATCC® 19111™	10 viali
86086	CultControl™ Campylobacter jejuni ATCC® 35061™	10 viali
86087	CultControl™ Klebsiella pneumoniae ATCC® BAA-705™	10 viali
86088	CultControl™ Klebsiella pneumoniae ATCC® BAA-705™	10 viali
86089	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86090	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86091	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86092	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86093	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86094	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86095	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86096	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86097	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86098	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86099	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86100	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86101	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86102	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86103	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86104	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86105	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86106	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86107	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86108	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86109	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86110	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86111	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86112	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86113	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86114	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86115	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86116	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86117	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86118	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86119	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86120	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86121	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali
86122	CultControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 18819™	10 viali

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89125	CultControl™ Haemophilus haemolyticus ATCC® 33391™	10 viali
89124	CultControl™ Haemophilus influenzae ATCC® 33291™	10 viali
89123	CultControl™ Pseudomonas stuartii ATCC® 33027™	10 viali
89122	CultControl™ Staphylococcus haemolyticus ATCC® 29212™	10 viali
89121	CultControl™ Streptococcus anginosus ATCC® 33397™	10 viali
89120	CultControl™ Streptococcus agalactiae subsp. agalactiae ATCC® 12263™	10 viali
89119	CultControl™ Streptococcus mitis ATCC® 8243™	10 viali
89118	CultControl™ Streptococcus pyogenes ATCC® 49399™	10 viali
89117	CultControl™ Streptococcus salivarius ATCC® 19419™	10 viali
89116	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89115	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89114	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89113	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89112	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89111	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89110	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89109	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89108	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89107	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89106	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89105	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89104	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89103	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89102	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89101	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89100	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89099	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89098	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89097	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89096	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89095	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89094	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89093	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89092	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89091	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89090	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89089	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89088	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89087	CultControl™ Streptococcus pneumoniae subsp. pneumoniae ATCC® 49619™	10 viali
89086	CultControl™ Strept	

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9061/1	CEFOOTAM CTI 30 ug	50 Dose
9062	TYLOSIN TV 30 ug	250 Dose
9062/1	TYLOSIN TV 30 ug	50 Dose
9063	TRIMETHOPRIM TM 2,5 ug	250 Dose
9063/1	TRIMETHOPRIM TM 2,5 ug	50 Dose
9064	SULFAMETHOXAZOLE SMX 50 ug	250 Dose
9064/1	SULFAMETHOXAZOLE SMX 50 ug	50 Dose
9065	Impenem + Phenylboronic acid IM + BO	250 Dose
9065/1	Impenem + Phenylboronic acid IM + BO	50 Dose
9066	Impenem + Cloxacilin IM + CL	250 Dose
9066/1	Impenem + Cloxacilin IM + CL	50 Dose
9067	EDIA ED	250 Dose
9067/1	EDIA ED	50 Dose
9068	SPIRAMICIN SPI 100 ug	250 Dose
9068/1	SPIRAMICIN SPI 100 ug	50 Dose
9069	CEFIME CFM 5 ug	250 Dose
9069/1	CEFIME CFM 5 ug	50 Dose
9070	Daploxylin DAP 30 ug	250 Dose
9070/1	Daploxylin DAP 30 ug	50 Dose
9071	PEFLOXACIN PEF 8 ug	250 Dose
9071/1	PEFLOXACIN PEF 8 ug	50 Dose
9072	DICLOXACILIN DDX 1 ug	250 Dose
9072/1	DICLOXACILIN DDX 1 ug	50 Dose
9073	TRIAMETER TR 30 ug	250 Dose
9073/1	TRIAMETER TR 30 ug	50 Dose
9074	IMIPENEM IMI 100 ug	250 Dose
9074/1	IMIPENEM IMI 100 ug	50 Dose
9075	IMIPENEM/CLAVULANIC ACID TIC 80 ug	250 Dose
9075/1	IMIPENEM/CLAVULANIC ACID TIC 80 ug	50 Dose
9076	IMIPENEM/CLAVULANIC ACID TIC 80 ug	250 Dose
9076/1	IMIPENEM/CLAVULANIC ACID TIC 80 ug	50 Dose
9077	CLORIMAMCLOLO CLO 60 ug	250 Dose
9077/1	CLORIMAMCLOLO CLO 60 ug	50 Dose
9078	CLARITRAMICIN CLR 10 ug	250 Dose
9078/1	CLARITRAMICIN CLR 10 ug	50 Dose
9079	CLARETHROMICIN CLT 10 ug	250 Dose
9079/1	CLARETHROMICIN CLT 10 ug	50 Dose
9080	FURAZOLIDON FR 40 ug	250 Dose
9080/1	FURAZOLIDON FR 40 ug	50 Dose
9100	PIPERACILIN/TAZOBACTAM TAP 110 ug	250 Dose
9100/1	PIPERACILIN/TAZOBACTAM TAP 110 ug	50 Dose
9101	CEFTUREM CTR 30 ug	250 Dose
9101/1	CEFTUREM CTR 30 ug	50 Dose
9102	LEVOFLOXACIN LEV 5 ug	250 Dose
9102/1	LEVOFLOXACIN LEV 5 ug	50 Dose
9103	LEVOFLOXACIN LEV 5 ug	250 Dose
9103/1	LEVOFLOXACIN LEV 5 ug	50 Dose
9104	MOXIFLOXACIN MOX 5 ug	250 Dose
9104/1	MOXIFLOXACIN MOX 5 ug	50 Dose
9105	ADITRIFAMPICIN AZM 15 ug	250 Dose
9105/1	ADITRIFAMPICIN AZM 15 ug	50 Dose
9106	MYCOAMICIN MK 15 ug	250 Dose
9106/1	MYCOAMICIN MK 15 ug	50 Dose
9107	IRACONAZOLE ITC 50 ug	250 Dose
9107/1	IRACONAZOLE ITC 50 ug	50 Dose
9108	CEFOPERAZONE CFP 75 ug	250 Dose
9108/1	CEFOPERAZONE CFP 75 ug	50 Dose
9109	CEFOPERAZONE CFP 75 ug	250 Dose
9109/1	CEFOPERAZONE CFP 75 ug	50 Dose
9110	TRIMETHOPRIM TM 5 ug	250 Dose
9110/1	TRIMETHOPRIM TM 5 ug	50 Dose
9111	FUSIDIC ACID FC 30 ug	250 Dose
9111/1	FUSIDIC ACID FC 30 ug	50 Dose
9112	CEPROZOL CPR 30 ug	250 Dose

9112/1	CEPROZOL CPR 30 ug	50 Dose
9113	LOMEFLOXACIN LOM 10 ug	250 Dose
9113/1	LOMEFLOXACIN LOM 10 ug	50 Dose
9114	AMPCILLIN AMP 2 ug	250 Dose
9114/1	AMPCILLIN AMP 2 ug	50 Dose
9115	LINDACICLIN LY 15 ug	250 Dose
9115/1	LINDACICLIN LY 15 ug	50 Dose
9116	NOVOBOIDON NO 5 ug	250 Dose
9116/1	NOVOBOIDON NO 5 ug	50 Dose
9117	NOVOBOIDON NO 5 ug	250 Dose
9117/1	NOVOBOIDON NO 5 ug	50 Dose
9118	RIFAMPICIN RD 5 ug	250 Dose
9118/1	RIFAMPICIN RD 5 ug	50 Dose
9119	METRONIDAZOLE MTZ 50 ug	250 Dose
9119/1	METRONIDAZOLE MTZ 50 ug	50 Dose
9120	POLYMYXIN B PB 200 U	250 Dose
9120/1	POLYMYXIN B PB 200 U	50 Dose
9121	FOSFOMYON (includes G & P)	100 ug 250 Dose
9121/1	FOSFOMYON (includes G & P)	50 ug 250 Dose
9122	AMPLICLOX (Amoxicillin-Cloxacilin) ACL	30 ug 250 Dose
9122/1	AMPLICLOX (Amoxicillin-Cloxacilin) ACL	50 ug 250 Dose
9123	GENTAMICIN CN 120 ug	250 Dose
9123/1	GENTAMICIN CN 120 ug	50 Dose
9124	GENTAMICIN CN 120 ug	250 Dose
9124/1	GENTAMICIN CN 120 ug	50 Dose
9125	GENTAMICIN CN 20 ug	250 Dose
9125/1	GENTAMICIN CN 20 ug	50 Dose
9126	SALFAPIRIL SXT 50 ug	250 Dose
9126/1	SALFAPIRIL SXT 50 ug	50 Dose
9127	RENOLIN G P 2 R	250 Dose
9127/1	RENOLIN G P 2 R	50 Dose
9128	CHLORAMPHENICOL C	180 ug 250 Dose
9128/1	CHLORAMPHENICOL C	50 ug 250 Dose
9129	SULBACTAM SU 20 ug	250 Dose
9129/1	SULBACTAM SU 20 ug	50 Dose
9130	PENCILLIN G P 1 R	250 Dose
9130/1	PENCILLIN G P 1 R	50 Dose
9131	SODIUM FUSIDATE FC 20	250 Dose
9131/1	SODIUM FUSIDATE FC 20	50 Dose
9132	SALFAPIRIL SXT 50 ug	250 Dose
9132/1	SALFAPIRIL SXT 50 ug	50 Dose
9133	AMOXICILLIN AMX 10 ug	250 Dose
9133/1	AMOXICILLIN AMX 10 ug	50 Dose
9134	CEFOTAXIME CTX 75 ug	250 Dose
9134/1	CEFOTAXIME CTX 75 ug	50 Dose
9135	OXACILIN OX 5 ug	250 Dose
9135/1	OXACILIN OX 5 ug	50 Dose
9136	LINEZOLID LZZ 30 ug	250 Dose
9136/1	LINEZOLID LZZ 30 ug	50 Dose
9137	AMPHOTERICIN B AMB 10 ug	250 Dose
9137/1	AMPHOTERICIN B AMB 10 ug	50 Dose
9138	IRACONAZOLE ITC 50 ug	250 Dose
9138/1	IRACONAZOLE ITC 50 ug	50 Dose
9139	IRACONAZOLE ITC 50 ug	250 Dose
9139/1	IRACONAZOLE ITC 50 ug	50 Dose
9140	HETICOXAZOLE HCA 15 ug	250 Dose
9140/1	HETICOXAZOLE HCA 15 ug	50 Dose
9141	COLISTIN SULFATE CS 30 U	250 Dose
9141/1	COLISTIN SULFATE CS 30 U	50 Dose
9142	CEFTAZIDIME/CLAVULANIC ACID CAL	40 ug 250 Dose
9142/1	CEFTAZIDIME/CLAVULANIC ACID CAL	50 ug 250 Dose
9143	Cefotaxime/Clavulanic Acid CAL	40 ug 250 Dose
9143/1	Cefotaxime/Clavulanic Acid CAL	50 ug 250 Dose
9144	CEFTAZIDIME/CLAVULANIC ACID CAL	40 ug 250 Dose
9144/1	CEFTAZIDIME/CLAVULANIC ACID CAL	50 ug 250 Dose
9145	CLINDAMYCIN CD 10 ug	250 Dose
9145/1	CLINDAMYCIN CD 10 ug	50 Dose
9146	TIGECYCLIN TCC 15 ug	250 Dose

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9147/1	TIGECYCLIN TCC 15 ug	50 Dose
9148	FLUCYTOSINE AFY 10 ug	250 Dose
9148/1	FLUCYTOSINE AFY 10 ug	50 Dose
9150	SULFADIAZINE SUD 300 ug	250 Dose
9150/1	SULFADIAZINE SUD 300 ug	50 Dose
9151	AMOXICILLIN AMX 2 ug	250 Dose
9151/1	AMOXICILLIN AMX 2 ug	50 Dose
9152	CEFOVALXIME CVX 5 ug	250 Dose
9152/1	CEFOVALXIME CVX 5 ug	50 Dose
9153	CEFTAZIDIME CAZ 10 ug	250 Dose
9153/1	CEFTAZIDIME CAZ 10 ug	50 Dose
9154	DOXIPHEM DOP 10 ug	250 Dose
9154/1	DOXIPHEM DOP 10 ug	50 Dose
9155	LINEZOLID LZZ 10 ug	250 Dose
9155/1	LINEZOLID LZZ 10 ug	50 Dose
9156	MECILLINAM MEC 10 ug	250 Dose
9156/1	MECILLINAM MEC 10 ug	50 Dose
9157	MUPIROCIN MUP 300 ug	250 Dose
9157/1	MUPIROCIN MUP 300 ug	50 Dose
9158	NETROFRANTON F 100 ug	250 Dose
9158/1	NETROFRANTON F 100 ug	50 Dose
9159	PERACILLIN PRL 30 ug	250 Dose
9159/1	PERACILLIN PRL 30 ug	50 Dose
9160	PIPERACILIN/TAZOBACTAM TAP	36 ug 250 Dose
9160/1	PIPERACILIN/TAZOBACTAM TAP	50 ug 250 Dose
9161	QUINUPROSTIN DIALFORNESTIN QDA	15 ug 250 Dose
9161/1	QUINUPROSTIN DIALFORNESTIN QDA	50 ug 250 Dose
9162	STREPTOLYGIN S 300 ug	250 Dose
9162/1	STREPTOLYGIN S 300 ug	50 Dose
9163	TOPOLIN TOP 30 ug	250 Dose
9163/1	TOPOLIN TOP 30 ug	50 Dose
9164	VANCOMICIN VA 5 ug	250 Dose
9164/1	VANCOMICIN VA 5 ug	50 Dose
9165	CASPORUNGIN CAS 5 ug	250 Dose
9165/1	CASPORUNGIN CAS 5 ug	50 Dose
9166	FLUCONAZOLE FLU 50 ug	250 Dose
9166/1	FLUCONAZOLE FLU 50 ug	50 Dose
9167	POSACONAZOLE POS 5 ug	250 Dose
9167/1	POSACONAZOLE POS 5 ug	50 Dose
9168	VORICONAZOLE VO 1 ug	250 Dose
9168/1	VORICONAZOLE VO 1 ug	50 Dose
9169	GATIFLOXACIN GAT 5 ug	250 Dose
9169/1	GATIFLOXACIN GAT 5 ug	50 Dose
9170	METALICIN NET 10 ug	250 Dose
9170/1	METALICIN NET 10 ug	50 Dose
9171	PHENOKSIMETHYLPENICILLIN PVP	100 ug 250 Dose
9171/1	PHENOKSIMETHYLPENICILLIN PVP	50 ug 250 Dose
9172	TELUROLICIN TEL 15 ug	250 Dose
9172/1	TELUROLICIN TEL 15 ug	50 Dose
9173	LORACARBEF LOR 30 ug	250 Dose
9173/1	LORACARBEF LOR 30 ug	50 Dose
9174	MARILIN MAF 1 ug	250 Dose
9174/1	MARILIN MAF 1 ug	50 Dose
9175	MEROPENEM/CLAVULANIC ACID MCL	250 Dose
9175/1	MEROPENEM/CLAVULANIC ACID MCL	50 Dose
9176	Meropenem + Phenylboronic acid IM + BO	250 Dose
9176/1	Meropenem + Phenylboronic acid IM + BO	50 Dose
9177	MEROPENEM/DIRIPLICIN ACID MDP	250 Dose
9177/1	MEROPENEM/DIRIPLICIN ACID MDP	50 Dose
9178	Meropenem + EDTA IM + ED	250 Dose

9178/1	Meropenem + EDTA IM + ED	50 Dose
9179	AMOXICILLIN AMX 25 ug	250 Dose
9179/1	AMOXICILLIN AMX 25 ug	50 Dose
9180	ERYTHROMICIN E 2 ug	250 Dose
9180/1	ERYTHROMICIN E 2 ug	50 Dose
9181	NITROFRANTON F 50 ug	250 Dose
9181/1	NITROFRANTON F 50 ug	50 Dose
9182	CEFTAZIDIME/CLAVULANIC ACID CTL	40 ug 250 Dose
9182/1	CEFTAZIDIME/CLAVULANIC ACID CTL	50 ug 250 Dose
9183	Impenem + EDTA IM + ED	250 Dose
9183/1	Impenem + EDTA IM + ED	50 Dose
9184	COLISTIN SULFATE CS 30 ug	250 Dose
9184/1	COLISTIN SULFATE CS 30 ug	50 Dose
9185	CEFRIME CE 30 ug	250 Dose
9185/1	CEFRIME CE 30 ug	50 Dose
9186	TEMOKILLIN TMO 30 ug	250 Dose
9186/1	TEMOKILLIN TMO 30 ug	50 Dose
9187	Sulfamethoxazole SMX 100 ug	250 Dose
9187/1	Sulfamethoxazole SMX 100 ug	50 Dose
9188	Metronidazole MTZ 10 ug	250 Dose
9188/1	Metronidazole MTZ 10 ug	50 Dose
9189	MUPIROCIN MUP 300 ug	250 Dose
9189/1	MUPIROCIN MUP 300 ug	50 Dose
9190	CEFTAZIDIME/CLAVULANIC ACID PCL	11 ug 250 Dose
9190/1	CEFTAZIDIME/CLAVULANIC ACID PCL	11 ug 50 Dose
9191	AMOXICILLIN/CLAVULANIC ACID ACD	30 ug 250 Dose
9191/1	AMOXICILLIN/CLAVULANIC ACID ACD	30 ug 50 Dose
9192	HOKITAMICIN HOK 20 ug	250 Dose
9192/1	HOKITAMICIN HOK 20 ug	50 Dose
9193	Phenylboronic acid BO	250 Dose
9193/1	Phenylboronic acid BO	50 Dose
9194	IMPICOLIC ACID IP	250 Dose
9194/1	IMPICOLIC ACID IP	50 Dose
9195	CEFTAZIDIME CPT 5 ug	250 Dose
9195/1	CEFTAZIDIME CPT 5 ug	50 Dose
9196	CEFTAZIDIME CPT 5 ug	250 Dose
9196/1	CEFTAZIDIME CPT 5 ug	50 Dose
9197	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9197/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9198	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9198/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9199	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9199/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9200	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9200/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9201	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9201/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9202	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9202/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9203	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9203/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9204	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9204/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9205	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9205/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9206	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9206/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9207	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9207/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9208	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9208/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9209	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9209/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9210	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9210/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9211	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9211/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9212	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9212/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9213	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9213/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9214	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9214/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9215	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9215/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9216	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9216/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9217	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9217/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9218	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9218/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9219	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9219/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9220	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9220/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9221	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9221/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9222	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9222/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9223	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9223/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9224	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9224/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9225	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9225/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9226	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9226/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9227	ERTAPENEM/CLAVULANIC ACID ETC	250 Dose
9227/1	ERTAPENEM/CLAVULANIC ACID ETC	50 Dose
9228	ERTAPENEM/CLAVUL	

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the *in vitro* medical-diagnostic device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco



CERTIFICATE

The certification body confirms to

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

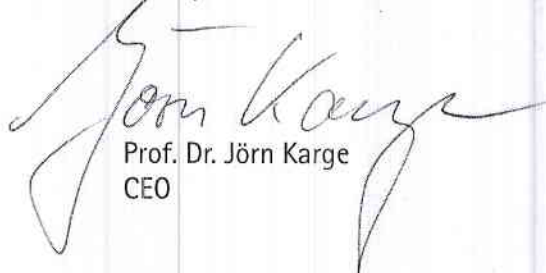
for the development, manufacturing and sale of products for human and veterinary medical in-vitro-diagnostics as well as for the microbiological examination of water and food and other diagnostic applications the conformity of the introduced quality management system with the standard

DIN EN ISO 9001:2015

Start of validity:	07.07.2017
End of validity:	06.07.2020
Report and certificate number:	IC00016 038 17
The certificate consists of	1 page

This certificate includes an annual examination of the QMS by IFTA AG, according to the specified standard.

Berlin, 06.07.2017


Prof. Dr. Jörn Karge
CEO



Certificate

mdc medical device certification GmbH
certifies that

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

**development, manufacturing and distribution of
in vitro diagnostic medical devices for the product groups:
blood grouping, bacteriological test reagents and culture media as well as
manufacturing of raw materials for manufacturing of
in vitro diagnostic medical devices**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2018-10-23
Valid until	2021-10-22
Registration no.	D1058700042
Report no.	P18-00745-121758
Stuttgart	2018-07-16



Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>

For electronic publication only

sifin

EG-Konformitätserklärung CE-Declaration of Conformité / EC-Declaration of Conformity

CE
Nr./No. 103

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD);
le dispositif médical (IVD);
the medical device (IVD):

Anti-Salmonella A-67 + Vi, omnivalent
Anti-Salmonella I (A-E + Vi)
Anti-Salmonella II (F-67)

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité / Safety Officer

sifin

EG-Konformitätserklärung CE-Declaration de Conformité / EC-Declaration of Conformity

CE
Nr./No. 105

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):

le dispositif médical (IVD):

the medical device (IVD):

Anti-Salmonella O:2	Anti-Salmonella O:19	Anti-Salmonella O:43	Anti-Salmonella O:58
Anti-Salmonella O:4	Anti-Salmonella O:20	Anti-Salmonella O:44	Anti-Salmonella O:59
Anti-Salmonella O:5	Anti-Salmonella O:21	Anti-Salmonella O:45	Anti-Salmonella O:60
Anti-Salmonella O:6 ₁	Anti-Salmonella O:25	Anti-Salmonella O:46	Anti-Salmonella O:61
Anti-Salmonella O:7	Anti-Salmonella O:27	Anti-Salmonella O:47	Anti-Salmonella O:62
Anti-Salmonella O:8	Anti-Salmonella O:28	Anti-Salmonella O:48	Anti-Salmonella O:63
Anti-Salmonella O:9	Anti-Salmonella O:30	Anti-Salmonella O:50	Anti-Salmonella O:65
Anti-Salmonella O:10	Anti-Salmonella O:34	Anti-Salmonella O:51	Anti-Salmonella O:66
Anti-Salmonella O:11	Anti-Salmonella O:35	Anti-Salmonella O:52	Anti-Salmonella O:67
Anti-Salmonella O:13	Anti-Salmonella O:38	Anti-Salmonella O:53	Anti-Salmonella Vi
Anti-Salmonella O:14	Anti-Salmonella O:39	Anti-Salmonella O:54	
Anti-Salmonella O:15	Anti-Salmonella O:40	Anti-Salmonella O:55	
Anti-Salmonella O:16	Anti-Salmonella O:41	Anti-Salmonella O:56	
Anti-Salmonella O:17	Anti-Salmonella O:42	Anti-Salmonella O:57	

Sonstiges Produkt

Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2013, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz 

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité / Safety Officer

sifin

EG-Konformitätserklärung CE-Declaration de Conformité / EC-Declaration of Conformity

CE
Nr./No. 110

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Shigella I
Anti-Shigella II
Anti-Shigella III
Anti-Shigella flexneri

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015


Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz 

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité / Safety Officer



**EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity**

**CE
Nr./No. 111**

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Shigella dysenteriae type 1
Anti-Shigella dysenteriae type 2
Anti-Shigella flexneri type 1
Anti-Shigella flexneri type 2
Anti-Shigella flexneri type 3
Anti-Shigella flexneri type 4
Anti-Shigella flexneri type 5
Anti-Shigella flexneri type 6
Anti-Shigella flexneri group 3,4 (y)
Anti-Shigella flexneri group 6
Anti-Shigella flexneri group 7,8 (x)
Anti-Shigella sonnei S-form (phase I)
Anti-Shigella sonnei F-form (phase II)
Anti-Shigella sonnei S- and F-form (phase I and II)

Sonstiges Produkt

Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz 

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 17 октября 2011 года № ФСР 2007/00003

На медицинское изделие

Набор реагентов для бактериологических исследований «Питательная среда для выделения коринебактерий (Коринебакагар)» по ТУ 9398-019-78095326-2006

Настоящее регистрационное удостоверение выдано

Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека, (ФБУН ГИЦ ПМБ), Россия, 142279, Московская область, Серпуховский р-н, п. Оболенск

Производитель

Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека, (ФБУН ГИЦ ПМБ), Россия, 142279, Московская область, Серпуховский р-н, п. Оболенск

Место производства медицинского изделия

142279, Московская область, Серпуховский р-н, п. Оболенск

Номер регистрационного досье № 36341 от 08.09.2011

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 17 октября 2011 года № 6723-Пр/11
и приказом от 30 мая 2016 года № 4607 о замене
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения


М.А. Мурашко

0019559



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

**РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**
от 01 ноября 2011 года № ФСР 2008/03064

На медицинское изделие

Набор реагентов для бактериологических исследований "Питательная среда для идентификации коринебактерий по тесту расщепления цистина сухая (среда Пизу)" по ТУ 9398-047-78095326-2008

Настоящее регистрационное удостоверение выдано

Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека, (ФБУН ГНЦ ПМБ), Россия, 142279, Московская область, Серпуховский район, п. Оболенск

Производитель

Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека, (ФБУН ГНЦ ПМБ), Россия, 142279, Московская область, Серпуховский район, п. Оболенск

Место производства медицинского изделия

ФБУН ГНЦ ПМБ, 142279, Московская область, Серпуховский район, п. Оболенск

Номер регистрационного досье № 38756 от 26.09.2011

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 01 ноября 2011 года № 7115-Пр/11
и приказом от 06 сентября 2016 года № 9381 о замене
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения

М.А. Мурашко

0023543



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 17 октября 2011 года № ФСР 2008/03236

На медицинское изделие

Набор реагентов для бактериологических исследований "Питательная среда для культивирования и выделения бифидобактерий сухая (Бифидум-среда)" по ТУ 9398-041-78095326-2008

Настоящее регистрационное удостоверение выдано
Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека (ФБУН ГНЦ ПМБ) Россия, 142279, Московская область, Серпуховский район, п. Оболенск

Производитель
Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека (ФБУН ГНЦ ПМБ) Россия, 142279, Московская область, Серпуховский район, п. Оболенск

Место производства медицинского изделия
ФБУН ГНЦ ПМБ, 142279, Россия, Московская область, Серпуховский район, п. Оболенск

Номер регистрационного досье № 35007 от 31.08.2011

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 17 октября 2011 года № 6730-Пр/11
и приказом от 15 июля 2016 года № 6982 о замене
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

Д.В. Пархоменко

0018548



LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director



File No A12241;
ISO 13485:2003; ISO 9001:2008

Lorne Laboratories Limited
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www.lornelabs.com

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A


has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

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Eddy Velthuis
Technical Director



File No A12241;
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EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A


has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



File No A12241;
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EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Manufacturer: nal von minden GmbH, Carl-Zeiss Str. 12, 47445 Moers
Classification: Other Products

We herewith declare on our sole responsibility that all batches of below mentioned In-vitro-diagnostic devices are conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices. The products are suitable for the intended application (only professional users).

Relevant standards and guidelines are applied.

141000	NADAL® EARLY hCG Pregnancy dipstick	NADAL® hCG Pregnancy TEST 10 mIU/ml – Urin/Serum
141000_SSL	NADAL® EARLY hCG Pregnancy dipstick	NADAL® hCG 25 mIU/ml/min Dipstick
141002	NADAL® hCG Pregnancy Test 25 mIU/ml dipstick	NADAL® hCG 25 mIU/ml Dipstick
142000	NADAL® EARLY hCG 10 mIU/ml cassette	NADAL® hLH Ovulation rapid test
142002	NADAL® hCG Pregnancy Cassette Test 25 mIU/ml	NADAL® hLH Ovulation rapid test
143003	NADAL® hCG Pregnancy Tests 10 mIU/ml dipstick	NADAL® hLH Ovulation rapid test
143004	NADAL® hCG t 25 mIU/ml dipstick	NADAL® hLH Ovulation 30 mIU/ml Midstream
143004_SSL	NADAL® hCG t 25 mIU/ml dipstick	NADAL® hLH Ovulation 30 mIU/ml dipstick
144001N-10	NADAL® hCG Pregnancy Test, Midstream 20 mIU/ml cassette	NADAL® hLH Ovulation 30 mIU/ml dipstick
151002	NADAL® hCG Pregnancy	NADAL® hLH Ovulation rapid tests (2,5mm)
151002SE	NADAL® hCG Pregnancy rapid test	NADAL® hLH Ovulation rapid test
151003	NADAL® hCG Test 10mIU/ml Urin/Serum Dipstick	NADAL® hLH Ovulation rapid test
152000	NADAL® hCG Pregnancy 10 mIU/ml cassette	NADAL® hLH Ovulation 30 mIU/ml cassette
152002	NADAL® hCG Pregnancy 25 mIU/ml cassette	NADAL® FSH cassette
152003	NADAL® hCG Pregnancy Test 20 mIU/ml cassette S/P/W	NADAL® FSH cassette
		NADAL® FSH cassette
		NADAL® pH-Test

201001	NADAL® Syphilis dipstick	NADAL® Syphilis dipstick
201001_SSL	NADAL® Syphilis dipstick	NADAL® Syphilis dipstick
202001	NADAL® Syphilis cassette	NADAL® Syphilis cassette
202001_SSL	NADAL® Syphilis cassette	NADAL® Syphilis cassette
203001	NADAL® Syphilis rapid tests	NADAL® Syphilis rapid tests
203002	NADAL® Syphilis rapid tests	NADAL® Syphilis rapid tests
203002_SSL	NADAL® Syphilis rapid tests	NADAL® Syphilis rapid tests
221001A	NADAL® Strep A dipstick	NADAL® Strep A dipstick
221005	NADAL® Strep A reagent 1	NADAL® Strep A reagent 1
221006	NADAL® Strep A reagent 2	NADAL® Strep A reagent 2
221050N-50	NADAL® Strep A plus rapid tests	NADAL® Strep A plus rapid tests
222001A	NADAL® Strep A cassette	NADAL® Strep A cassette
222007	NADAL® Strep A plus cassette	NADAL® Strep A plus cassette
222008	NADAL® Strep A plus cassette	NADAL® Strep A plus cassette
222011	NADAL® Strep A plus cassette	NADAL® Strep A plus cassette
222049BUL	NADAL® Strep A Scan cassette	NADAL® Strep A Scan cassette
222049BUL-20	NADAL® Strep A Scan cassette	NADAL® Strep A Scan cassette
232001	NADAL® Strep B cassette	NADAL® Strep B cassette
232001_SSL	NADAL® Strep B cassette	NADAL® Strep B cassette
232005	NADAL® Strep B reagent 1	NADAL® Strep B reagent 1
232006	NADAL® Strep B reagent 2	NADAL® Strep B reagent 2
241005N-10	NADAL® Influenza A+B dipstick	NADAL® Influenza A+B dipstick
241006N-25	NADAL® Influenza A+B dipstick	NADAL® Influenza A+B dipstick
242001	NADAL® Influenza A+B cassette	NADAL® Influenza A/B cassette
242006N-10	NADAL® Mononucleosis cassette	NADAL® Mononucleosis cassette
252001	NADAL® Mononucleosis dipstick (2,5mm)	NADAL® Mononucleosis dipstick
252003	NADAL® Mononucleosis cassette	NADAL® Mononucleosis cassette
252003N-20	NADAL® Mononucleosis cassette	NADAL® Mononucleosis cassette
252005	NADAL® Mononucleosis positive control	NADAL® Mononucleosis positive control
252006	NADAL® Mononucleosis negative control	NADAL® Mononucleosis negative control
252017N-05	NADAL® Mononucleosis cassette	NADAL® Mononucleosis cassette
262001	NADAL® H.Pylori Antikörper cassette	NADAL® H.Pylori Antikörper cassette
262001_SSL	NADAL® H.Pylori Antikörper cassette	NADAL® H.Pylori Antikörper cassette
262002	NADAL® Syphilis dipstick	NADAL® Syphilis dipstick
262003	NADAL® H. pylori Ab cassette	NADAL® H. pylori Ab cassette
262004BUL	NADAL® H. pylori Scan Ab cassette	NADAL® H. pylori Scan Ab cassette
262004BUL-N-10	NADAL® H. pylori Scan Ab cassette	NADAL® H. pylori Scan Ab cassette
272001	NADAL® FOB cassette	NADAL® FOB cassette
272001_SSL	NADAL® FOB cassette	NADAL® FOB cassette
272008	NADAL® FOB cassette	NADAL® FOB cassette
272009	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272010	NADAL® FOB cassette	NADAL® FOB cassette
272011	NADAL® Hb/Hp cassette	NADAL® Hb/Hp cassette
272011N-25	NADAL® Hb/Hp cassette	NADAL® Hb/Hp cassette
272015	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272015_SSL	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272016	NADAL® FOB plus cassette	NADAL® FOB plus cassette
272031RU	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272031RU-01	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272031RU_SSL	NADAL® Hb/Hp Complex cassette	NADAL® Hb/Hp Complex cassette
272035	NADAL® FOB60 plus cassette	NADAL® FOB60 plus cassette
272035_SSL	NADAL® FOB60 plus cassette	NADAL® FOB60 plus cassette
272037	NADAL® FOB & Hb/Hp patient set	NADAL® FOB & Hb/Hp patient set
272040	NADAL® FOB II Cassettes	NADAL® FOB II Cassettes
272041	NADAL® FOB60 Cassette	NADAL® FOB60 Cassette
272041_SSL	NADAL® FOB60 Cassette	NADAL® FOB60 Cassette
272042	NADAL® FOB75 Cassette	NADAL® FOB75 Cassette
272043	NADAL® FOB75 II Cassette	NADAL® FOB75 II Cassette
282000	NADAL® Troponin I cassette	NADAL® Troponin I cassette
282001	NADAL® Troponin I cassette	NADAL® Troponin I cassette
282001_SSL	NADAL® Troponin I cassette	NADAL® Troponin I cassette
282003	NADAL® Trop I, CK-MB, Myoglobin Combicassette	NADAL® Trop I, CK-MB, Myoglobin Combicassette
282015	NADAL® Troponin I cassette	NADAL® Troponin I cassette
292001	NADAL® Myoglobin cassette	NADAL® Myoglobin cassette
292001N-05	NADAL® Myoglobin cassette	NADAL® Myoglobin cassette



302001	NADAL® CK-MB cassette		
302001_SSL	NADAL® CK-MB cassette	NADAL® Malaria 4 species cassette	472003N-10
311003	NADAL® CRP Dipstick	NADAL® Malaria 4 species cassette	472003_SSL
311004	NADAL® CRP plus Dipstick	NADAL® Malaria 4 species cassette	472008
311006	NADAL® CRP plus Dipstick	NADAL® Malaria Pf/Pv Ab cassette	472009
312001	NADAL® CRP cassette	NADAL® Malaria Pf/Pan Ag 4species cassette	472030N-25
312002	NADAL® high sensitive CRP cassette	NADAL® Malaria Pf/Pan Ag 4species cassette	472030N-10
312017	NADAL® CRP Quant RFID chip	NADAL® Malaria Pf/Pan Ag 4species cassette	472036N-25
312021BUL	NADAL® CRP Quant cassette	NADAL® Adenovirus rapid tests	481002
312021NBUL	NADAL® CRP Quant cassette	NADAL® Adenovirus rapid tests	481003
322003N-30	NADAL® Tuberkulose IgG/IgM cassette	NADAL® Rotavirus rapid tests	481004
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM cassette	NADAL® Rotavirus rapid tests	481005
331001	NADAL® Mikroalbumin Dipstick	NADAL® Adenovirus 40/41 strips	481006
331004N-50	NADAL® Mikroalbumin Dipstick	NADAL® Adenovirus 40/41 strips	481007
333001	NADAL® Mikroalbumin Dipstick	NADAL® Adenovirus Respiratory rapid tests	481008
351006	NADAL® D-Dimer cassette	Adenovirus Positive Control	481013
351007	NADAL® D-Dimer cassette	NADAL® Rota-Adenovirus cassette	481015
374018	qLabs aPTT-INR Control	NADAL® Rota-Adenovirus cassette	481015_SSL
431001N-03	NADAL® PROM Test Dipstick	NADAL® Rota-Adenovirus cassette	481015N-20
431001N-03_SSL	NADAL® PROM Test Dipstick	NADAL® Adenovirus cassette	481016
431001N-10	NADAL® PROM Test Dipstick	NADAL® Adenovirus cassette	481016_SSL
431001N-10_SSL	NADAL® PROM Test Dipstick	NADAL® Rotavirus cassette	481017
431001N-20	NADAL® PROM Test Dipstick	NADAL® Rota-Adenovirus Scan cassette	481049BUL
431006N-03	NADAL® PROM Amniotic fluid Dipstick	NADAL® Rota-Adenovirus Scan cassette	481049BUL-10
431006N-10	NADAL® PROM Amniotic fluid Dipstick	NADAL® RSV plus Dipstick	491000N-10
431006N-20	NADAL® PROM Amniotic fluid Dipstick	NADAL® RSV plus Dipstick	491000N-10_SSL
472001N-25	NADAL® Malaria Pf Ag test cassette	NADAL® RSV Dipstick	491003N-25
472001N-25_SSL	NADAL® Malaria Pf Ag test cassette	NADAL® RSV cassette	491005
472003N-25	NADAL® Malaria 4 species cassette	NADAL® RSV scan cassette	491008BUL
		NADAL® RSV-Adeno Resp cassette	491009
		NADAL® RSV Dipstick	491015
		NADAL® MRSA Screen Latex- Agglutinationstest	495001



495001_SSL	NADAL® MRSA Screen Latex- Agglutinationstest	NADAL® Legionella Urine Antigen test	552020
501006	NADAL® E.coli O157 Cassette	NADAL® BCA/HB inkl.	562003N-10
501006_SSL	NADAL® EHEC O157 Cassette	NADAL® BCA/HB inkl.	562003RU
501012	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10	NADAL® Streptococcus pneumoniae cassette	572004N-10
501012_SSL	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10	NADAL® Legionella/S. pneumonia cassette	572005
511002	NADAL® Cryptosporidium Dipstick	NADAL® TSH cassette	580005N-25
511006	NADAL® Cryptosporidium cassette	NADAL® C. difficile Toxin A/B cassette	582003
511006_SSL	NADAL® Cryptosporidium cassette	NADAL® C. difficile Toxin A/B cassette	582003_SSL
521001	NADAL® Giardia Dipstick	NADAL® C. difficile Toxin A/B cassette	582004
521004	NADAL® Crypto/Giardia Test strips	NADAL® Clostridium Difficile GDH A&B cassette	582008
521006	NADAL® Giardia cassette	NADAL® C. perfringens Ag cassette	582009
521009	NADAL® Giardia cassette	NADAL® C. perfringens Ag cassette A&B/GDH Cassette	582009_SSL
521010	NADAL® Giardia-Crypto-Combo cassette	NADAL® Clostridium Difficile Toxin A+B/GDH Cassette	582016N-10
521010_SSL	NADAL® Giardia-Crypto-Combo cassette	NADAL® Rheumatoid Factor test cassette	600002N-30
532001_SSL	NADAL® Dengue cassette	NADAL® Gonorrhea cassette	611003N-10
532001N-25	NADAL® Dengue cassette	NADAL® Gonorrhea cassette	611003N-10_SSL
532002N-25	NADAL® Dengue cassette	NADAL® Gonorrhea cassette	611005N-10
532003N-25	NADAL® Dengue cassette	NADAL® CCA (Bilharzia) cassette	612004N-25
532004N-25	NADAL® Dengue cassette	NADAL® HAV IgM test cassette	622001N-30
532004N-25_SSL	NADAL® Dengue cassette	NADAL® HEV IgM cassette	622040N-30
532011	NADAL® Dengue IgG/IgM cassette	NADAL® HAV IgG/IgM cassette	622070N-30
532011N-25	NADAL® Dengue IgG/IgM cassette	NADAL® HAV IgG/IgM cassette	622070N-30_SSL
532012N-25	NADAL® Dengue NS1 Ag Cassette	NADAL® Chagas IgG cassette	652001N-30
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Cassette	NADAL® Chagas IgG cassette	652001N-30_SSL
542001N-25	NADAL® Tetanus cassette	NADAL® Leishmania cassette	662001N-30
552005	NADAL® Legionella Urin Antigen cassette	NADAL® Filariasis cassette	672001N-30
552005_SSL	NADAL® Legionella Urin Antigen cassette	NADAL® Filariasis cassette	672001N-30_SSL
552006	NADAL® Legionella Urin Antigen cassette	NADAL® Chikungunya IgM Cassette	682002N-20
552006_SSL	NADAL® Legionella Urin Antigen cassette		