ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2017 года № ФСР 2010/08997

На медицинское изделие
Набор контрольных растворов белков мочи "БМ-контроль"
по ТУ 9398-269-52208224-2010

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,
194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Производитель
Общество с ограниченной ответственностью "Медлакор С.-П."
(ООО "Медлакор С.-П."), Россия,
194100, Санкт Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П, офис 212

Место производства медицинского изделия
ООО "Медлакор С.-П.", Россия, 194100, Санкт-Петербург, ул. А. Матросова, д. 4, корп. 2, Лит. П

Номер регистрационного досье **№ РД-14955/64156 от 20.12.2016**

Вид медицинского изделия **206630**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 11 января 2017 года № 80
допущено к обращению на территории Российской Федерации.

Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0024833

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2017 года № ФСР 2010/08997

На медицинское изделие
Набор контрольных растворов белков мочи "БМ-контроль"
по ТУ 9398-269-52208224-2010:
- комплект 1 «БМ-контроль-ССК»;
- комплект 2 «БМ-контроль-ССК + глюкоза и pH»;
- комплект 3 «БМ-контроль-ССК с калибратором»;
- комплект 4 «БМ-контроль-ССК + глюкоза и pH с калибратором»;
- комплект 5 «БМ-контроль-ПГК»;
- комплект 6 «БМ-контроль-ПГК + глюкоза и pH» .

Заместитель руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0026953

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

от 05 ноября 2009 года

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),
Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
и подтверждает, что медицинское изделие
Набор реагентов для определения групп крови человека систем АВО, Резус и Kell (Цоликлоны анти-А, анти-В, анти-АВ, анти-А1, анти-Ас1, анти-D супер, анти-D (IgG), анти-С супер, анти-с супер, анти-Е супер, анти-е супер, анти-Kell супер) по ТУ 9398-101-51203590-2009
производства
Общество с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),
Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
место производства:
Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1

класс потенциального риска **2а** ОКП **93 9816**

вид медицинского изделия –

соответствующее регистрационному досье № 67875 от 22.09.2009

приказом Росздравнадзора от 05 ноября 2009 года № 8861-Пр/09

и приказом от 17 июля 2013 года № 3237-Пр/13 с замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

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

0001849

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

Лист 1

- цоликлон анти-А - моноклональные антитела (IgM) к антигену А;
- цоликлон анти-В - моноклональные антитела (IgM) к антигену В;
- цоликлон анти-АВ - моноклональные антитела (IgM) к антигенам А и В;
- цоликлон анти-А1 - фитогемагглютинин к антигену А1;
- цоликлон анти-Ас1 - моноклональные антитела (IgM) к антигенам А1 и А2;
- цоликлон анти-D супер - моноклональные антитела (IgM) к антигену D;
- цоликлон анти-D (IgG) - моноклональные антитела (IgG) к антигену D;
- цоликлон анти-С супер - моноклональные антитела (IgM) к антигену С;
- цоликлон анти-с супер - моноклональные антитела (IgM) к антигену с;
- цоликлон анти-Е супер - моноклональные антитела (IgM) к антигену Е;
- цоликлон анти-е супер - моноклональные антитела (IgM) к антигену е;
- цоликлон анти-Kell супер - моноклональные антитела (IgM) к антигену К;

Приказом от 17 июля 2013 года № 3237-Пр/13 с замене допущено к обращению на территории Российской Федерации.

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

05 ноября 2009 года

0001890

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH Eiffestrasse 80, 20537 Hamburg Germany
PRODUCT/ MODEL:	Hematology Analyzer/ H30 Pro, H31 Pro, iH30 Pro Reagents for Hematology Analyzer/ HD310 Diluent, HL310Lyse, HC310 Cleaner, ED-30D Hematology Controls, ED-CAL PLUS Hematology Calibrator.

The accessories are used together with the product

EDMA[Name/Code]: CC Hardware + accessories + consumables + software/23.01.10.01.00
CBC-Reagents(Cleaning-/Diluting-/Lysing-/Sheat-fluids)/13.01.01.01.00
Blood Multilevel Controls/ 13.01.50.03.00
Whole Blood Calibrators/ 13.01.50.07.00

CLASSIFICATION:General/other device, devices other than those covered by Annex II and devices for performance evaluation, non-self-testing, according to article 9 of IVDD.

CONFORMITY ASSESSMENT ROUTE: Annex III

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: **EN ISO 14971: 2012, IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN 62304:2006 +A1：2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002，EN ISO 17511:2003 ,EN ISO 23640：2015**

CE MARK	CE
START OF CE-MARKING:	2020-12-18
PLACE, DATE OF ISSUE:	SHENZHEN, 2020.12.18
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE

EDAN
A world of potential

CERTIFICATE
OF TRAINING

Sergiu Sorocovici,

From "GBG-MLD" SRL, has successfully completed H30 pro, H60 series training courses including operation and maintenance, and is qualified to offer technical support for above mentioned products.

深圳市理邦精密仪器股份有限公司
EDAN INSTRUMENTS, INC.

赖晓宇

International Customer Service Manager

Date Nov 1st, 2023

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

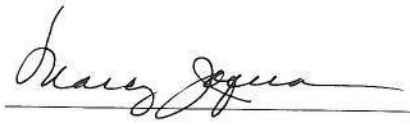
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	**Self-declared**
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	**Self-declared**
09H48-02	58237	CELL-DYN Emerald DILUENT	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-09H69

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H69-01	55866	CELL-DYN 18 Plus Control, Full Pack	**Self-declared**
09H69-02	55866	CELL-DYN 18 Plus Control, Half Pack	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18 June 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V5 February 26, 2015	Effective (Date or Lot Number):	JUL 06 2015

Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker® label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera™ 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyses		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter
3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459.9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832.9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823.1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431.1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

By Royal Charter

Certificate of Registration

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

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

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

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14
Expiry Date: 2027-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Declaration of Conformity

HL-7-0229DC DOI 2015/08 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5392	Thrombin Time	55987

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0512DC DOI 2015/08 (5)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5556	Clauss Fibrinogen 50	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 12 Aug 2015

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Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

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Helena Biosciences Europe
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United Kingdom

Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

Helena Biosciences Europe,
Gateshead, Tyne and Wear,
NE11 0SD, United Kingdom
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info@helena-biosciences.com
www.helena-biosciences.com

EC REP
Prince Technologies B.V.
Waanderweg 62,
7812 HZ Emmen,
The Netherlands

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

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www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

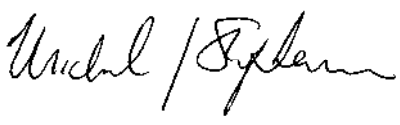
In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed:  Date: 31st October 2013

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Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 31st October 2013

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www.helena-biosciences.com

Helena Biosciences Europe
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Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Holder of Certificate: **Nova Biomedical Corporation**
200 Prospect Street
Waltham MA 02454
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; and Distribution of Lancets.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 02

Report No.: 72198686

Valid from: 2024-10-25
Valid until: 2027-10-24

Date, 2024-10-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments
.

Nova Biomedical Corporation
4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Analyzer System Family including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (two pages)
Classification:	Other/General
Near Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	**Medical devices. Quality management systems. Requirements for regulatory purposes**
EN ISO 14971:2012	**Medical devices – Application of risk management to medical devices**
EN 61010-1:2010	**Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements**
EN 61010-2:101:2015	**Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/22/2020

List of Catalog items covered:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
14631	Power Cord Int 230V	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38846	Nova Biomedical Capillary Tube Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38883	Stat Profile Critical Care Xpress Syringe Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42032	Prime Sensor Card CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42033	Prime Sensor Card CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42043	Prime Reference Cartridge	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52484	Prime Pump Harness	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52582	Prime Probe S Line 100 ul	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52616	Prime Tubing L1 L2 L3	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52617	Prime Tubing Harness ABG/CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52669	Prime Safety Sample Port 5 Pk	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52703	Prime Acc Pack	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52856	Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52857	Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53418	Remanufactured Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53420	Remanufactured Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53656	Prime CCS w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53657	Prime CCS Comp w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53666	Remanufactured Prime CCS w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53667	Remanufactured Prime CCS Comp w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55263	Prime Sensor Card CCS (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55264	Prime Sensor Card CCS Comp (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42031	Prime Sensor Card ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
52855	Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53421	Remanufactured Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53655	Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53665	Remanufactured Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
55262	Prime Sensor Card ABG (High Volume)	56671	Point-of-Care blood gas analyzer IVD	21-02-02
25217	Linearity Standard Set A Levels 1,2,3,4 Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
55229	Nova Linearity Level 1,2,3,4	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
56198	Linearity Standard Set G Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-90-00

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
45150	Prime Auto QC Cartridge CCS 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52714	Prime Ampuled Control ABG/CCS	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52864	Prime Auto QC Cartridge CCS 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53107	Prime Auto QC Cartridge ABG 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53108	Prime Auto QC Cartridge ABG 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53455	Prime Auto QC Cartridge CCS 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53456	Prime Auto QC Cartridge ABG 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52427	Prime Calibrator Cartridge CCS Comp 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52861	Prime Calibrator Cartridge CCS Comp 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52862	Prime Calibrator Cartridge CCS 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52863	Prime Calibrator Cartridge CCS 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53104	Prime Calibrator Cartridge ABG 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53105	Prime Calibrator Cartridge CCS Comp 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53359	Prime Calibrator Cartridge ABG 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53360	Prime Calibrator Cartridge ABG 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53364	Prime Calibrator Cartridge CCS 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53365	Prime Calibrator Cartridge CCS Comp 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53463	Prime Calibrator Cartridge ABG 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53464	Prime Calibrator Cartridge ABG 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53465	Prime Calibrator Cartridge ABG 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53466	Prime Calibrator Cartridge CCS 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53467	Prime Calibrator Cartridge CCS 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53468	Prime Calibrator Cartridge CCS 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53469	Prime Calibrator Cartridge CCS Comp 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53470	Prime Calibrator Cartridge CCS Comp 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52865	Stat Profile Prime Calibrator Flush Fixture	56672	Point-of-Care blood gas/haemoximetry analyzer IVD	21-02-02

nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Plus Analyzer System including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (Two Pages)
Classification:	Other/General
Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2:101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/24/2020

List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57400	Stat Profile Prime Plus® Analyzer	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
59508	Stat Profile Prime Plus® Analyzer (Remanufactured)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57820	Stat Profile Prime Plus MicroSensor Card™ with COOX	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57821	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57822	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57823	Stat Profile Prime Plus Reference Cartridge	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57845	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
58379	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58642	Stat Profile Prime Plus MicroSensor Card™	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58643	Stat Profile Prime Plus MicroSensor Card™ (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
55229	Nova Linearity Level 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
56198	Linearity Standard Set G Multipack	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00
61656	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1614112-1
Certificate Holder:	KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany
Scope:	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices: - cannulas for blood collection, - winged cannulas for blood collection and - capillaries for micro blood collection (KABE MBU capillaries).

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	1160508-40
Effective date:	2024-10-16
Expiry date:	2027-10-15
Issue date:	2024-09-24

Replaces certificate SX 1614112-1 issued 2021-10-25.

This certificate can be validated on https://www.certipedia.com

Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland® Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1614112-1

Certificate Holder: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse and shipping

This certificate can be validated on https://www.certipedia.com

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие
Краситель Азур-Эозин по Романовскому (МиниМед-Р)
по ТУ 9398-003-29508133-2011

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2-а

Номер регистрационного досье **№ РД-9275/51846 от 18.11.2015**

Вид медицинского изделия **232730**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

приказом Росздравнадзора от 07 декабря 2015 года № 9111
допущено к обращению на территории Российской Федерации.

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

0015715

Клиническая биохимия
Агат

ООО «Агат-Мед»
105173, г. Москва, ул. Главная, 6-12
тел. (495) 777-41-92
agat@agat.ru www.agat.ru

ПАСПОРТ

Набор реагентов для определения
концентрации **белка в моче**, 660 опр. х **3** мл
«Белок в моче - АГАТ».

Серия..... **66/830825** Дата выпуска... **08.2025** Годен до... **08.2027**
Количество наборов в серии... **500**

Наименование показателя	Требования НТД предприятия	Результаты анализа
1. Внешний вид		
1.1 Калибровочный раствор альбумина	Жидкость бесцветная прозрачная без посторонних включений	Жидкость бесцветная прозрачная
1.2 Сульфосалициловая кислота	ГОСТ 4478-78	Соответствует
2. Технические характеристики		
2.1 Значение pH калибровочного раствора альбумина, ед., в интервале	6,5-8,0	Соответствует
3. Показатели правильности определения		
3.1 Соответствие стандартному образцу, отклонение, %, не более	2,0	Соответствует

Заключение ОКК ООО «Агат-Мед»:
Набор серии **66/830825** требованиям НТД предприятия соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«14» августа 2025г.

"Агат-Мед"

МП

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор реактивов для предстерилизационного контроля

Азопирам Ст

ОКП 32.50.50.000

СЕРИЯ - 04 25

Дата изготовления АПР 2025

Изготовитель **НИИ ИТиМ**, г.Санкт-Петербург

№Показатель	Требования по ТУ	Результаты анализа
1.Внешний вид **1.1.** Реактив А **амидопирин** **1.2.** Реактив СА Солянокислый анилин **1.3** Гидроколлами солянокислый С	Порошок белого цвета Порошок белого (от серого до светло-зелёного) цвета Порошок белого цвета	СООТВЕТСТВУЕТ СООТВЕТСТВУЕТ СООТВЕТСТВУЕТ
2.Технические характеристики **2.1.**Чувствительность Азопирамовой пробы: из данных реагентов Положительная реакция при разведении крови не менее	1:100000	СООТВЕТСТВУЕТ

Заключение:требования ТУ СООТВЕТСТВУЕТ

Начальник ОТК Гавриков К.Е.

СЕРТИФИКАТ КАЧЕСТВА

Настоящим удостоверяется , что товар, идентифицированный как сухие компоненты реактива для определения скрытой крови при предстерилизационном контроле
Азопирам Ст код:382200000 ТНВЭД
Страна происхождения : Россия
Изготовитель: НИИ ИТи М
Дата изготовления: АПР 2025
Годен до: АПР 2027
№ партии: - 04 25
Соответствует требованиям:
1 ГОСТ 5822-78
2.СанПин № 8. 01. 013. 03
3. Методическим указаниям МЗ СССР 28-6/13 от 26,05,1988г.
4. ТУ 9398-004-90814321-2012

Подпись ответственного лица

пия для Электрогорск Соловьева Т.В. ИП к документу РасходнаяБН № 701196 от 25.08.25 к товару поз. 2

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ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

Цоликлон анти – А – моноклональные антитела (IgM) к антигену А
Цоликлон анти – В – моноклональные антитела (IgM) к антигену В
Цоликлон анти – АВ – моноклональные антитела (IgM) к антигенам А и В

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 255902 **Единица:** 100 мл

Изготовлен: 03.02.2025 **Количество единиц** 32

Годен до: 03.02.2027 **Объем серии:** 10000 мл.

Паспорт: А255902 от 03.02.2025

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная или слегка окрашенная жидкость.	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10сек.
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) – 1:32 - 1:64	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) – 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) – 1:32 - 1:64 и В(III) – 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

Цоликлон анти – А – моноклональные антитела (IgM) к антигену А
Цоликлон анти – В – моноклональные антитела (IgM) к антигену В
Цоликлон анти – АВ – моноклональные антитела (IgM) к антигенам А и В

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-АВ во флаконах по 10 мл

Серия: 059402 **Единица:** 100 мл

Изготовлен: 10.02.2025 **Количество единиц** 5

Годен до: 10.02.2027 **Объем серии:** 10000 мл.

Паспорт: АВ059402 от 10.02.2025

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная или слегка окрашенная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10сек.
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) – 1:32 - 1:64	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) – 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) – 1:32 - 1:64 и В(III) – 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

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ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

Цоликлон анти – А – моноклональные антитела (IgM) к антигену А
Цоликлон анти – В – моноклональные антитела (IgM) к антигену В
Цоликлон анти – АВ – моноклональные антитела (IgM) к антигенам А и В

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 256002 **Единица:** 100 мл

Изготовлен: 03.02.2025 **Количество единиц** 32

Годен до: 03.02.2027 **Объем серии:** 10000 мл.

Паспорт: В256002 от 03.02.2025

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная или слегка окрашенная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп B(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп A(II) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(I)	Соответствует Соответствует Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10сек.
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы A(II) – 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы B(III) – 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп A(II) – 1:32 - 1:64 и B(III) – 1:64	Соответствует 1:32 - 1:64 Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 259601 **Единица:** 100 мл

Изготовлен: 20.01.2025 **Количество единиц** 22

Годен до: 20.01.2027 **Объем серии:** 10000 мл.

Паспорт: Дс259601 от 20.01.2025

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная бесцветная или слегка окрашенная жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами.	Соответствует 30сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микроплате не ниже 1:256	Соответствует 1:32 Соответствует 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009 (ЦОЛИКЛОН Анти-Kell Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-Kell Супер

Серия: 150202 **Единица:** 100 мл

Изготовлен: 03.02.2025 **Количество единиц** 10

Годен до: 03.02.2027 **Объем серии:** 10000 мл.

Паспорт: К150202 от 03.02.2025

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная бесцветная или слегка окрашенная жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-)	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микропланшете не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая
ОТК ООО «Медиклон» К.В. Ющенко

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

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 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 e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I 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 and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

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° 505DM09

CERTIFICATE N° 505DM09

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 13485-2021 (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 e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

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

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P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI 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:

CONTENITORI PER CAMPIONI BIOLOGICI

SPECIMEN CONTAINERS

PRODOTTI NON STERILI – *NOT 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 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 do not fall under list A or B of annex II of the Directive 98/79/EC.

> **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/EC.

Rilasciato */ Released*
Canelli, 26.07.2015

Duilio BUONO
Responsabile Assicurazione Qualità

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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*
1011	Contenitori per feci 18ml, PS, con tappo a pressione con paletta	*Faeces containers 18ml, PS, with pressure cap and spoon*
1011/E	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1011/E/50	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta, in confezioni da 50 pezzi	*Faeces containers 18ml, PS, with pressure cap and spoon, with label, in bags of 50 pieces*
1011/E/AST	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1012	Contenitori per campioni biologici 18ml, PS, con tappo a pressione	*Specimen containers 18ml, PS, with pressure cap*
1013	Contenitori da 18ml, PS, senza tappo	*Containers 18ml, PS, without cap*
1030	Contenitori per urine 130ml, PS, graduati, tappo a pressione	*Graduated urine containers 130ml, PS, pressure cap*
1030/E	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 130ml, PS, pressure cap, with label*
1030/E/CS	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta, confezione singola	*Graduated urine containers 130ml, PS, pressure cap, with label, individually wrapped*
1030/MO	Contenitori per urine 130ml, PP, graduati, tappo a pressione	*Graduated urine containers 130ml, PP, pressure cap*
1030/MO/E	Contenitori urina 130ml, in PP tappo a pressione, graduati, etichetta	*Graduated urine containers 130ml, PP, pressure cap, label*
1030/MO/T	Contenitori urina 130ml, in PP tappo a pressione inserito, graduati	*Graduated urine containers 130ml, PP, pressure cap*
1030/R	Contenitori per urine 130ml, PS, graduati, tappo a pressione rosso	*Graduated urine containers 130ml, PS, red pressure cap*
1030/S	Contenitori per urine 130ml, PS, graduati, senza tappo	*Graduated urine containers 130ml, PS, without cap*
1030/T	Contenitori per urine 130ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 130ml, PS, with inserted pressure cap*
1040	Contenitori per urina 120ml, PP, con coperchio autoadesivo	*Graduated urine containers 120ml, PP, with self-adhesive cap*
1040/P	Contenitori per urina 120ml, PS, con coperchio autoadesivo	*Graduated urine containers 120ml, PS, with self-adhesive cap*
1040/P/S	Contenitori per urina 120ml, PS, senza coperchio autoadesivo	*Graduated urine containers 120ml, PS, without self-adhesive cap*
1040/S	Contenitori per urina 120ml, PP, senza coperchio autoadesivo	*Graduated urine containers 120ml, PP, without self-adhesive cap*
1041	Contenitori per campioni biologici 30ml, PS, con tappo a pressione	*Specimen containers 30ml, PS, with pressure cap*
1041/E	Contenitori per campioni biologici 30ml, PS, con tappo a pressione, con etichetta	*Specimen containers 30ml, PS, with pressure cap, with label*
1041/S	Contenitori per campioni biologici 30ml, PS, senza tappo	*Specimen containers 30ml, PS, without cap*
1041/T	Contenitori per campioni biologici 30ml, PS, con tappo a pressione inserito	*Specimen containers 30ml, PS, with inserted pressure cap*
1050	Contenitori per urine 150ml, PS, graduati, tappo a pressione	*Graduated urine containers 150ml, PS, pressure cap*
1050/E	Contenitori per urine 150ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 150ml, PS, pressure cap, with label*
1050/S	Contenitori per urine 150ml, PS, graduati, senza tappo	*Graduated urine containers 150ml, PS, without cap*
1050/T	Contenitori per urine 150ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 150ml, PS, with inserted pressure cap*
1051	Contenitori per espettorato 60ml, PS, con tappo a pressione	*Sputum containers 60ml, PS, with pressure cap*
1051/E	Contenitori per espettorato 60ml, PS, con tappo a pressione, con etichetta	*Sputum containers 60ml, PS, with pressure cap, with label*
1051/S	Contenitori per espettorato 60ml, PS, senza tappo a pressione	*Sputum containers 60ml, PS, without pressure cap*
1051/S/CS	Contenitori per espettorato 60ml, PS, senza tappo a pressione, in confezione singola	*Sputum containers 60ml, PS, without pressure cap, individually wrapped*
1051/T	Contenitori per espettorato 60ml, PS, con tappo a pressione inserito	*Sputum containers 60ml, PS, with inserted pressure cap*
1061	Contenitori per campioni biologici 35ml, PS, con tappo a pressione	*Specimen containers 35ml, PS, with pressure cap*
10621	Contenitori rotondi "SECURBOX" da 2.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 10 fori. Con manico	*Disposable container"SECURBOX"2,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 10 holes. With handle*
10622	Contenitori rettangolari "SECURBOX" da 5.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 99 fori. Con manico	*Disposable container"SECURBOX"5,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 99 holes. With handle*
10631	Contenitori da 5ml, PE, tappo a vite	*Containers 5ml, PE, screw cap*
10632	Contenitori da 30ml, PE, tappo a vite	*Containers 30ml, PE, screw cap*
10633	Contenitori da 90ml, PE, tappo a vite	*Containers 90ml, PE, screw cap*

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COD.	DESCRIZIONE	*DESCRIPTION*
1070	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap*
1070/E	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite, con etichetta	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap, with label*
1081	Contenitori per urine 150ml, PS, graduati, tappo a vite	*Graduated urine containers 150ml, PS, screw cap*
1081/CS	Contenitori per urine 150ml, PS, graduati, tappo a vite, in confezione singola	*Graduated urine containers 150ml, PS, screw cap, individually wrapped*
1081/E	Contenitori per urine 150ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PS, screw cap, with label*
1081/T	Contenitori urina 150ml, in PS con tappo a vite inserito,	*Graduated urine containers 150ml, PS, screw cap*
1211	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1211/CS	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1212	Contenitori per campioni biologici 60ml, PS, con tappo a pressione	*Specimen containers 60ml, PS, with pressure cap*
1212/CS	Contenitori per campioni biologici 60ml, PS, con tappo a pressione, confezione singola	*Specimen containers 60ml, PS, with pressure cap, individually wrapped*
1213	Contenitori da 60ml, PS, senza tappo	*Containers 60ml, PS, without cap*
1230	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/10	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/100	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/CS	Contenitori per urine 200ml, PS, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PS, screw cap, ind. wrapped*
1230/E	Contenitori per urine 200ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PS, screw cap, with label*
1230/S/E	Contenitori urina 200ml, in PS senza tappo, graduati,	*Graduated urine containers 200ml, PS, with label*
1230/T	Contenitori urina 200ml, in PS tappo a vite inserito,	*Graduated urine containers 200ml, PS, with inserted screw cap*
1230/TE	Contenitori per urine 200ml, PS, graduati, tappo a vite inserito, con etichetta	*Graduated urine containers 200ml, PS, with inserted screw cap, with label*
12731	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
12731/E	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
12731/SAC	Taniche in PE da 2.500ml per la raccolta urine 24ore,	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, individually wrapped*
12731K	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
14120	Contenitori per istologia da 20ml, in PP, tappo a vite verde	*20 ml Surgical specimen containers in PP, with yellow screw cap*
14120/B	Contenitori per istologia da 20ml, in PP, tappo a vite giallo, etichetta biohazard	*20 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14121	Contenitori per istologia da 40ml, in PP, tappo a vite giallo	*40 ml Surgical specimen containers in PP, with yellow screw cap*
14121/B	Contenitori per istologia da 40ml, in PP, tappo a vite giallo, etichetta biohazard	*40 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14122	Contenitori per istologia da 60ml, in PP, tappo a vite giallo	*60 ml Surgical specimen containers in PP, with yellow screw cap*
14122/B	Contenitori per istologia da 60ml, in PP, tappo a vite giallo, etichetta biohazard	*60 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14123	Contenitori per istologia da 90ml, in PP, tappo a vite giallo	*90 ml Surgical specimen containers in PP, with yellow screw cap*
14123/B	Contenitori per istologia da 90ml, in PP, tappo a vite giallo, etichetta biohazard	*90 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14124	Contenitori per istologia da 120ml, in PP, tappo a vite giallo	*120 ml Surgical specimen containers in PP, with yellow screw cap*
14124/B	Contenitori per istologia da 120ml, in PP, tappo a vite giallo, etichetta biohazard	*120 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14131	Contenitori per biopsie in PS, con tappo a pressione in PE, da 30ml	*Biopsy specimen containers in PS with pressure cap in PE, 30 ml*
14132	Contenitori per biopsie in PS, con tappo a pressione in PE, da 50ml	*Biopsy specimen containers in PS with pressure cap in PE, 50 ml*
14134	Contenitori per biopsie in PS, con tappo a pressione in PE, da 100ml	*Biopsy specimen containers in PS with pressure cap in PE, 100 ml*
14136	Contenitori per biopsie in PS, con tappo a pressione in PE, da 150ml	*Biopsy specimen containers in PS with pressure cap in PE, 150 ml*
14138	Contenitori per biopsie in PS, con tappo a pressione in PE, da 200ml	*Biopsy specimen containers in PS with pressure cap in PE, 200 ml*
14140	Contenitori per biopsie in PS, con tappo a pressione in PE, da 250ml	*Biopsy specimen containers in PS with pressure cap in PE, 250 ml*
14142	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap*

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COD.	DESCRIZIONE	*DESCRIPTION*
14142/B	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap, Biohazard label*
14143	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap*
14143/B	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap, Biohazard label*
14144	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap*
14144/B	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap, Biohazard label*
14150	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione	*Surgical specimens transparent containers 150ml, PP, with pressure cap*
14150/B	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 150ml, PP, with pressure cap, Biohazard label*
14151	Contenitori per istologia da 250ml, in PP, tappo a vite giallo	*250 ml Surgical specimen containers in PP, with yellow screw cap*
14151/B	Contenitori per istologia da 250ml, in PP, tappo a vite giallo, etichetta biohazard	*250 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14152	Contenitori per istologia da 500ml, in PP, tappo a vite giallo	*500 ml Surgical specimen containers in PP, with yellow screw cap*
14152/B	Contenitori per istologia da 500ml, in PP, tappo a vite giallo, etichetta biohazard	*500 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14153	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo	*1000 ml Surgical specimen containers in PP, with yellow screw cap*
14153/B	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo, etichetta biohazard	*1000 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14155	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione	*Surgical specimens transparent containers 250ml, PP, with pressure cap*
14155/B	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 250ml, PP, with pressure cap, Biohazard label*
14160	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione	*Surgical specimens transparent containers 500ml, PP, with pressure cap*
14160/S	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 500ml, PP, with pressure cap, serigraphed*
14170	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap*
14170/S	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap, serigraphed*
14175	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap*
14175/B	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap, Biohazard label*
14175/T	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione inserito	*Surgical specimens transparent containers 2.000ml, PP, with inserted pressure cap*
14180	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap*
14180/B	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, Biohazard label*
14180/S	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, serigraphed*
14185	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap*
14185/B	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap, Biohazard label*
14190	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione	*Big surgical specimens containers 5.600ml, PP, with pressure cap*
14190/B	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 5.600ml, PP, with pressure cap, biohazard label*
14192	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione	*Big surgical specimens containers 2,500ml, PP, with pressure cap*
14192/B	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 2,500ml, PP, with pressure cap, biohazard label*
14195	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione	*Big surgical specimens containers 11.000ml, PP, with pressure cap*
14195/B	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 11.000ml, PP, with pressure cap, biohazard label*
1560	Contenitori per saliva 30 ml, in PP, tappo a vite,	*Autoclavable sputum collection container 30 ml, in PP, screw cap*
1630	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
1630/E	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
19550	Contenitore per la raccolta delle urine per test antidoping	*Urine containers for testing drugs abuse*

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COD.	DESCRIZIONE	*DESCRIPTION*
2030	Contenitori per campioni biologici 30ml, PP, tappo a vite	*Specimen containers 30ml, PP, with screw cap*
2030/E	Contenitori per campioni biologici 30ml, PP, tappo a vite, etichetta	*Specimen containers 30ml, PP, with screw cap, label*
2030/P	Contenitori per campioni biologici 30ml, PP, tappo a vite rosso non inserito	*Specimen containers 30ml, PP, with red screw cap not inserted*
2030/S	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte	*Specimen containers 30ml, PP, with screw cap in separate bag*
2030/S/R	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte rosso	*Specimen containers 30ml, PP, with red screw cap in separate bag*
2040	Contenitori per campioni biologici 60ml, PS, tappo a vite	*Specimen containers 60ml, PS, with screw cap*
2040/B	Contenitori per campioni biologici 60ml, PS, tappo a vite bianco	*Specimen containers 60ml, PS, with white screw cap*
2040/E	Contenitori per campioni biologici 60ml, PS, tappo a vite, con etichetta	*Specimen containers 60ml, PS, with screw cap, with label*
2040/E/R	Contenitori campioni biologici 60ml, PS, tappo inserito rosso	*Specimen containers 60ml, PS, with screw cap, with label*
2040/P	Contenitori campioni biologici 60ml, in PS, Ø35 x 70 mm,	*Specimen containers 60ml, PS, with screw cap*
2040/P/E	Contenitori campioni biologici 60ml, PS, Ø35x70mm, etichetta,	*Specimen containers 60ml, PS, with screw cap, with label*
2040/R	Contenitori per campioni biologici 60ml, PS, tappo a vite rosso	*Specimen containers 60ml, PS, with red screw cap*
2042	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta	*Specimen containers 60ml, PS, with screw cap and spoon*
2042/E	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta, con etichetta	*Specimen containers 60ml, PS, with screw cap and spoon, with label*
2050	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/100	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/B	Contenitori di colore blu per campioni biologici 60ml, PP, tappo a vite	*Specimen containers blue colour 60ml, PP, with screw cap*
2050/C	Tappi a vite colore giallo per contenitori cod. 2050	*Yellow screw cap for containers cod 2050*
2050/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2050/DDK	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito rosso	*Specimen containers 60ml, PP, with red inserted screw cap*
2050/E	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 60ml, PP, with inserted screw cap, with label*
2050/E/S	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito, con etichetta	*Specimen containers 60ml, PP, with screw cap not inserted, with label*
2050/P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/P/E	Contenitori campioni biologici 60ml, PP, Ø35x70mm, graduati,	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/PR	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito colore rosso	*Specimen containers 60ml, PP, with screw cap not inserted red colour*
2050/R	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito colore rosso	*Specimen containers 60ml, PP, with screw cap inserted red colour*
2050/S	Contenitori per campioni biologici 60ml, PP, senza tappo	*Specimen containers 60ml, PP, without cap*
2050/T	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito	*Specimen containers 60ml, PP, with inserted screw cap*
2050/TAPPO/B	Tappi a vite colore blu per contenitori cod. 2050	*Blue screw cap for containers cod 2050*
2050P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2052	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/10	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/100	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, individually wrapped*
2052/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2052/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2052/R	Contenitori per feci 60ml, PP, con tappo a vite rosso con paletta	*Faeces containers 60ml, PP, with red screw cap and spoon*
2052/T5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2062	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/10	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/E	Contenitori per feci da 60ml, in PP, tappo vite con paletta, etichetta	*Faeces containers in PP 60ml, screw cap, with label*
2062/P	Contenitori per feci da 60 ml, in PP, tappo a vite a parte	*Faeces containers in PP 60ml, not assembled screw cap*

APTACA PLASTIC DISPOSABLE ITEMS FOR LABORATORIES OF ANALYSIS

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COD.	DESCRIZIONE	*DESCRIPTION*
2072	Contenitori per feci da 60 ml, in PS, tappo a vite	*Faeces containers in PS 60ml, screw cap*
2072/E	Contenitori per feci da 60ml, in PS, tappo vite con paletta, etichetta	*Faeces containers in PS 60ml, screw cap, with label*
2072/P	Contenitori per feci da 60 ml, in PS, tappo a vite a parte	*Faeces containers in PS 60ml, not assembled screw cap*
2120	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/100	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/50	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/B	Contenitori per urine 150ml, PP, graduati, tappo a vite bianco	*Graduated urine containers 150ml, PP, white screw cap*
2120/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/M	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/MI	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/E	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PP, screw cap, with label*
2120/E/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici, con etichetta	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic, with label*
2120/ES	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta non applicata	*Graduated urine containers 150ml, PP, screw cap, with label in separate bag*
2120/N	Contenitori per urine 150ml, PP, graduati, tappo a vite neutro	*Graduated urine containers 150ml, PP, neutral screw cap*
2120/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 150ml, PP, red screw cap*
2120/S	Contenitori per urine 150ml, PP, graduati, senza tappo	*Graduated urine containers 150ml, PP, without cap*
2120/T	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T/100	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 100 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 100 pcs*
2120/T/N	Contenitore urina 150ml, in PP tappo a vite neutro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T5	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 5 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 5 pcs*
2120/T50	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 50 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 50 pcs*
2120/TB	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito bianco	*Graduated urine containers 150ml, PP, with inserted white screw cap*
2120/TB	Contenitori urina 150ml, in PP con tappo a vite bianco	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TE	Contenitori urina 150ml, in PP tappo vite azzurro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TN	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito di colore neutro	*Graduated urine containers 150ml, PP, with inserted screw cap neutral colour*
2120/TR	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito colore rosso	*Graduated urine containers 150ml, PP, with red inserted screw cap*
2120/V/500	Contenitori per urine 150ml, PP, graduati, tappo a vite verde	*Graduated urine containers 150ml, PP, screw cap green colour*
2220	Contenitori per urine 200ml, PP, graduati, tappo a vite	*Graduated urine containers 200ml, PP, screw cap*
2220/250	Contenitori urina 200ml, in PP tappo a vite, graduati,	*Graduated urine containers 200ml, PP, screw cap*
2220/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped*
2220/E	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PP, screw cap, with label*
2220/E/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta, confezione singola	*Graduated urine containers 200ml, PP, screw cap, with label, individually wrapped*
2220/R	Contenitori per urine 200ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 200ml, PP, red screw cap*
2220/S	Contenitori per urine 200ml, PP, graduati, senza tappo a vite	*Graduated urine containers 200ml, PP, without screw cap*
2220/T	Contenitori per urine 200ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 200ml, PP, with inserted screw cap*
2250	Contenitori campioni biologici da 40 ml, in PP	*Specimen containers 40 ml, in PP*
2420	Contenitori per urine 150ml, PP, graduati, tappo a vite e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, screw cap and plug*
2420/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, with screw cap and plug red colour*
2420/TR	Contenitori urine 150ml, PP, graduati, tappo a vite rosso e tappino prelievo campioni inserito	*Graduated urine containers 150ml, PP, with inserted screw cap and plug red colour*
2440	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm.	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm*

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COD.	DESCRIZIONE	*DESCRIPTION*
2440/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, individually wrapped*
2440/E	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label*
2440/E/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label, individually wrapped*
2440/P	Contenitori campioni biologici 60ml, PS, con tappo a parte,	*Specimen containers in PS with screw cap, 60 ml, Ø 38 x 65 mm*
2442	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2442/E	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm, con etichetta.	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm, with label*
2442/R	Contenitori per feci in PS con tappo a vite rosso e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with red screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2450	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2450/B	Contenitori per campioni biologici 60ml, PP, tappo a vite bianco	*Specimen containers 60ml, PP, with white screw cap*
2450/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2450/E	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	*Specimen containers 60ml, PP, with screw cap, with label*
2450/P	Contenitori campioni biologici 60ml, in PP, Ø38 x 65 mm,	*Specimen containers 60ml, PP, with screw cap, with label*
2450/R	Contenitori per campioni biologici 60ml, PP, tappo a vite colore rosso	*Specimen containers 60ml, PP, with red screw cap*
2452	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2452/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2452/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2452/R	Contenitori per feci 60ml, PP, con tappo a vite rosso e con paletta	*Faeces containers 60ml, PP, with red screw cap and with spoon*
2452/T/5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2580	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, with screw cap*
2580/B	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco	*Specimen containers 25ml, PS, with white screw cap*
2580/E	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/E/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, confezione singola	*Specimen containers 25ml, PS, with screw cap, with label, individually wrapped*
2580/E/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/P/W	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/EB	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PS, with screw cap, with white label*
2580/ER	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with not inserted screw cap, with label*
2580/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/PB	Contenitori campioni biologici 25ml, in PS, Ø25 x 90 mm,	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/S	Contenitori per campioni biologici 25ml, PS, senza tappo	*Specimen containers 25ml, PS, without cap*
2580/TAPPO/A	Tappo a vite colore azzurro per contenitori cod. 2580/2680	*Light blue screw cap for containers cod. 2580/2680*
2580/TBIANCO	Tappo a vite colore bianco per contenitori cod. 2580/2680	*White screw cap for containers cod. 2580/2680*
2580/W	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco non inserito	*Specimen containers 25ml, PS, with white not inserted screw cap*
2580P	Contenitori campioni biologici 25ml, PS, con tappo a vite	*Specimen containers 25ml, PS, with white not inserted screw cap*
2588	Contenitori per feci 25ml, PS, con tappo a vite con paletta	*Faeces containers 25ml, PS, with screw cap and spoon*
2588/E	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, with screw cap and spoon, with label*
2588/E/CS	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 25ml, PS, with screw cap and spoon, with label, individually wrapped*
2588/EB	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta bianca	*Faeces containers 25ml, PS, with screw cap and spoon, with white label*
2588/P	Contenitori per feci 25ml, PS, con tappo a vite con paletta a parte	*Faeces containers 25ml, PS, with screw cap and spoon in separate bag*
2588P	Paletta in polipropilene bianco	*Spoon in white polypropylene*

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COD.	DESCRIZIONE	*DESCRIPTION*
2640	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
2640/E	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
2680	Contenitori per campioni biologici 25ml, PP, tappo a vite	*Specimen containers 25ml, PP, with screw cap*
2680/E	Contenitori per campioni biologici 25ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 25ml, PP, with inserted screw cap, with label*
2680/P	Contenitori per campioni biologici 25ml, PP, tappo a vite non inserito	*Specimen containers 25ml, PP, with not inserted screw cap*
2680/S	Contenitori per campioni biologici 25ml, PP, senza tappo a vite	*Specimen containers 25ml, PP, without screw cap*
2688	Contenitori per feci 25ml, PP, con tappo a vite con paletta	*Faeces containers 25ml, PP, with screw cap and spoon*
2688/E	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PP, with screw cap and spoon, with label*
2688/E/CS	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta, in confezione singola	*Faeces containers 25ml, PP, with screw cap and spoon, with label, individually wrapped*
5024	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5024/E	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
5024/F	"24 ore" da 2.500 ml tipo bottiglia in pe	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap*
5024K	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5050/S	Contenitori per feci da 60ml, in PP, senza tappo	*Faeces containers in PP 60ml, without cap*
5120	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto.	*120 ml urine containers in PP, with screw cap with device for vacuum tube*
5120/CS	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, confezione singola	*120 ml urine containers in PP, with screw cap with device for vacuum tube, individually wrapped*
5434	Contenitori per la raccolta delle urine nelle 24 ore, 2.000ml, PE, tappo a vite, graduata	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap*
5434/M	Contenitori per la raccolta delle urine nelle 24 ore, 2000ml, PE, tappo vite, graduata, marrone	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap, brown*
5471	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes.*
5472	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes.*
5671	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5672	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5731	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes*
5732	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
6840	Contenitore per trasporto campioni con coperchio ermetico	*Test tubes securbox with hermetic lid*

Duilio BUONO
Responsabile Assicurazione Qualità

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CERTIFIED COMPANY UNI ISO 9001:2008 & UNI CEI 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:

PROVETTE CON ANTICOAGULANTE, SEPARATORI DI SIERO

BLOOD COLLECTIONS TUBES AND SERUM SEPARATORS

PRODOTTI NON STERILI – *NOT 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 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 do not fall under list A or B of annex II of the Directive 98/79/EC.
- **Classificazione EDMA: 1302808000 Coated tubes (Citrate, Heparin etc.)**
  EDMA code: 1302808000 Coated tubes (Citrate, Heparin 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 to Directive 98/79/EC.

Rilasciato / *Released*
Canelli, 26.07.2015

Duilio BUONO
Responsabile Assicurazione Qualità

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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*
10110/16	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
10110/PR	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
2000	Provette fondo piatto PP Ø12x56 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø12x56 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2000/1	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, tappo verde chiaro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light green cap, for paediatric use.*
2000/1/V	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, con tappo, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light with cap, for paediatric use.*
2001	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2002	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2003	Provette PP Ø12x86 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2004	Provette PP Ø12x86 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2005	Provette PP Ø13x75 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2007	Provette PP Ø16x100 mm., con K_2EDTA per 10 ml di sangue, tappo verde chiaro.	*PP test tubes Ø16x100 mm., with K_2EDTA for 10 ml of blood, light green cap.*
2008	Provette PP Ø13x75 mm., con K_2EDTA per 4 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 4 ml of blood, light green cap.*
2100	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2100/1	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo verde scuro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark green cap, for paediatric use.*
2100/1/V	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo viola, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark violet cap, for paediatric use.*
2100/TM	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, con tappo	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, with cap*
2101	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2102	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2103	Provette PP Ø12x86 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2104	Provette PP Ø12x86 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2105	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, dark green cap. Quantity for box 1,000 pieces*
2105/TM	Provetta PP Ø13x75 mm, con K_3EDTA per 2,5ml di sangue, tappo viola.	*PP test tubes Ø13x75 mm, with K_3EDTA for 2,5ml of blood, violet cap.*
2105/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo viola	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, violet cap.*
2107	Provette PP Ø16x100 mm., con K_3EDTA per 10 ml di sangue, tappo verde scuro.	*PP test tubes Ø16x100 mm., with K_3EDTA for 10 ml of blood, dark green cap.*
2108	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood, dark green cap.*
2108/5	Provette PP Ø13x75 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2108/TM	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2108/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2200	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2200/G	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo giallo.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, yellow cap.*
2201	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2201/G	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo giallo.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 2,5 ml of blood, yellow cap.*
2202	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 5 ml of blood, orange cap.*
2202/G	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 5 ml di sangue,	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 5 ml of blood,*

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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*
	tappo giallo.	*yellow cap.*
2203	Provette PP Ø12x86 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP test tubes Ø12x86 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2204	Provette PP Ø12x86 mm., con KF+Na_2 EDTA per 5 ml di sangue, tappo arancione.	*PP test tubes Ø12x86 mm., with KF-Na_2 EDTA for 5 ml of blood, orange cap.*
2205	Provette PP Ø13x75 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP test tubes Ø13x75 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap. Quantity for box 1,000 pieces*
2205/TG	Provetta PP Ø13x75 mm, con KF+NA_2 EDTA per 2,5ml di sangue, tappo grigio.	*PP test tubes Ø13x75 mm, with KF+NA_2 EDTA for 2,5ml of blood, grey cap.*
2207	Provette PP Ø16x100 mm., con KF+Na_2 EDTA per 10 ml di sangue, tappo arancione.	*PP test tubes Ø16x100 mm., with KF-Na_2 EDTA for 10 ml of blood, orange cap.*
2208	Provette PP Ø13x75 mm., con KF+Na_2 EDTA per 4 ml di sangue, tappo arancione.	*PP test tubes Ø13x75 mm., with KF-Na_2 EDTA for 4 ml of blood, orange cap.*
2300	Provette fondo piatto PP Ø12x56 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2301	Provette fondo piatto PP Ø16x60 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2302	Provette fondo piatto PP Ø16x60 mm., con Sodio Eparina per 5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Heparin for 5 ml of blood, violet cap.*
2303	Provette PP Ø12x86 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP test tubes Ø12x86 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2304	Provette PP Ø12x86 mm., con Sodio Eparina per 5 ml di sangue, tappo viola.	*PP test tubes Ø12x86 mm., with Sodium Heparin for 5 ml of blood, violet cap.*
2305	Provette fondo piatto PP Ø13x75 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø13x75 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2307	Provette PP Ø16x100 mm., con Sodio Eparina per 10 ml di sangue, tappo viola.	*PP test tubes Ø16x100 mm., with Sodium Heparin for 10 ml of blood, violet cap.*
2308	Provette fondo piatto PP Ø13x75 mm., con Sodio Eparina per 4 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø13x75 mm., with Sodium Heparin for 4 ml of blood, violet cap.*
2400	Provette fondo piatto PP Ø12x56 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø12x56 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2400/1	Provette PP Ø12x56 mm., con Litio Eparina per 1 ml di sangue, tappo blu, per uso pediatrico.	*PP test tubes Ø12x56 mm., with Lithium Heparin for 1 ml of blood, blue cap, for paediatric use.*
2400/TV	Provette fondo piatto PP Ø12x56 mm., con Litio Eparina per 2,5 ml di sangue, tappo verde.	*PP flat bottom test tubes Ø12x56 mm., with Lithium Heparin for 2,5 ml of blood, green cap.*
2401	Provette fondo piatto PP Ø16x60 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø16x60 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2402	Provette fondo piatto PP Ø16x60 mm., con Litio Eparina per 5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø16x60 mm., with Lithium Heparin for 5 ml of blood, blue cap.*
2403	Provette PP Ø12x86 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2404	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo blu.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, blue cap.*
2404/TV	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo verde.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, green cap.*
2404/VERDE	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo verde.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, green cap.*
2405	Provette PP Ø13x75 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2405/TV	Provetta PP Ø13x75 mm, con Litio Eparina per 2,5ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm, with Lithium Heparin for 2,5ml of blood, dark green cap.*
2407	Provette PP Ø16x100 mm., con Litio Eparina per 10 ml di sangue, tappo blu.	*PP test tubes Ø16x100 mm., with Lithium Heparin for 10 ml of blood, blue cap.*
2408	Provette PP Ø13x75 mm., con Litio Eparina per 4 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 4 ml of blood, blue cap. Quantity for box 1,000 pieces*
2408/VERDE	Provette PP Ø13x75 mm., con Litio Eparina per 4 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 4 ml of blood, blue cap. Quantity for box 1,000 pieces*
2500	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500/N	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/N*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/SE	Provette in PP con K3 EDTA tappo perforabile verde, senza tappo	*PP test tubes Ø13x75 mm., with K_3EDTA, without cap, for 3 ml of blood.*
2500/SE/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue, senza etichetta.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood, without label*
2500/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*

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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

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COD.	DESCRIZIONE	*DESCRIPTION*
2500/V*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*
2500/V/2	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 2 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood.*
2500/V/SG	Provette in PP con K3 EDTA sterili,tappo perf,viola	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood, sterile*
2501	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation.*
2502	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation*
2503	Provette in PP Ø16x100 mm, con Sodio Citrato 0,4ml, tappo giallo	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,4 ml, yellow cap*
2505	Provette PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo giallo.	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, yellow cap*
2505/1	Provette PP Ø12x56 mm, con Sodio Citrato 0,1ml, tappo giallo per coagulazione uso pediatrico.	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,1 ml, yellow cap for coagulation, for paediatric use.*
2508	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation*
2508/BLU	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo blu per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, blue cap for coagulation*
2511	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2512	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2512/TB	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml for coagulation.*
2513	Provette PP Ø16x100 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2515/BLU	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo blu	*PP test tubes Ø113x75 mm., with Sodium Citrate 0,5 ml, yellow cap*
2515/TB/F	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo blu	*PP test tubes Ø113x75 mm., with Sodium Citrate 0,5 ml, yellow cap*
2520	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2520/TB	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo blu per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, blue cap for coagulation.*
2520/TR	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml for coagulation.*
2521	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2522	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2522/R	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo rosa per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, pink cap for coagulation.*
2525	Provette PP Ø13x75 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2525/2	Provetta PP Ø13x75 mm, con 0,20 ml di Sodio Citrato per coagulazione, tappo giallo	*PP test tubes Ø13x75 mm, with 0,20ml of Sodium Citrate for coagulation, yellow cap.*
2525/32/BLU	Provette in PP tappo blu con 0,25ml di Sodio Citrato 3,2%,	*PP test tubes Ø13x75 mm, with 0,25ml of Sodium Citrate for coagulation, blue cap.*
2600	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2600/1	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,1ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,1 ml, pink cap for ESR.*
2600/TN	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo nero per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, black cap for ESR.*
2601	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2602	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2603	Provette PP Ø16x100 mm, con Sodio Citrato 0,25ml, tappo rosa	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,25 ml, pink cap*
2605	Provette PP Ø13x75 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2610	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2610/G	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo giallo per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, yellow cap for ESR.*
2611	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2612	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*

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2615	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2615/TN	Provetta PP Ø13x75 mm, con 0,4ml di Sodio Citrato per VES, tappo nero.	*PP test tubes Ø13x75 mm, with 0,4ml of Sodium Citrate for ESR, black cap.*
2620	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2621	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2622	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2625	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2632	Provette Ø12x56 mm in PP, con 0,25ml di Sodio Citrato x 1 ml di sangue	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, pierceable black rubber cap for ESR.*
2635	Provette Ø13x75 mm in PP, con 0,4ml di Sodio Citrato x 1,6ml di sangue	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, pierceable black rubber cap for ESR.*
2661/E/TB	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
2662/E	Provette Ø16 x 100 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø16 x 100 mm*
2662/E/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap*
2662/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2662/TM	in prov.16x100 in metacr. x 10 ml di sangue t/marrone	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2663/E/TB	Provette Ø13x75 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø13x75 mm, low cap*
2664/E/TB	Provette Ø12x86 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø12x86 mm, low cap*
2665/E	Provette Ø13 x 75 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm*
2665/E/TB	Provette Ø13 x 75 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2665/TB	gel separ.+acc. in prov.13x75 pmma per 5 ml sangue	*PMMA test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2666/E/TB	Provette Ø16 x 100 mm, in PP, con gel separatore + acceleratore, con etichetta, tappo basso	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2666/TB	gel separ.+acc.in prov.16x100 pp x 10 ml di sangue	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2668/E	Provette Ø12 x 86 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø12 x 86 mm*
2668/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap*
2668/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap, without label*
2678/E/TB	Provette con gel+acceleratore per 5ml di sangue, in PP,	#N/D
2700	Provette Ø13x75 mm in PP con 0,3ml di Sodio Citrato per coagulazione, tappo azzurro in gomma perforabile	*PP test tubes Ø13x75 mm with 0.3ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2700/2	Provette in PP tappo azzurro perforabile con 0,2 ml di	*PP test tubes Ø13x75 mm with 0.2ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2705	Provette in PP tappo blu con 0,35 ml di Sodio Citrato	*PP test tubes Ø13x75 mm with 0.35 ml of Sodium Citrate for coagulation, with blue cap*
2710	Provette Ø12x56 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x56 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2711	Provette Ø16x60 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø16x60 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2712	Provette Ø12x86 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x86 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2715	Provette Ø13x75 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø13x75 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
3553/E	Provette Ø16 x 100 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø16x100 mm*
3555/E	Provette Ø13 x 75 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø13 x 75 mm*
3556/E	Provette Ø16 x 100 mm in PP, con acceleratore	*PP test tubes with clot accelerator, Ø16 x 100 mm*
3558/E	Provette Ø12 x 86 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø12 x 86 mm*
3771/E/TB	Provette Ø16 x 100 mm. in PP, con gel separatore, tappo rosso basso	*PP test tubes with separating gel, Ø16 x 100 mm, with low red cap*
3772/E/TB	Provette Ø13x75 mm. in PP, con gel separatore, tappo rosso basso	*PP test tubes with separating gel, Ø13x75 mm, red low cap*
3773/E	Provette Ø16 x 100 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø16 x 100 mm*
3773/E/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separating gel, Ø16 x 100 mm, low cap*
3773/TB	gel separatore in prov. 16x100 pmma per 10 ml di sangue	*PMMA test tubes with separating gel, Ø16 x 100 mm, low cap*
3774/E/TB	Provette Ø12x86 mm. in PP, con gel separatore, tappo basso	*PP test tubes with separating gel, Ø12x86 mm, low cap*

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3775/E	Provette Ø13 x 75 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø13 x 75 mm*
3775/E/TB	Provetta Ø13 x 75 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separatine gel, Ø13 x 75 mm, low cap*
3776/E/TB	Provetta Ø16 x 100 mm. in PP, con gel separatore, tappo basso marrone	*PP test tubes with separatine gel Ø 16 x 100 mm, brown low cap.*
3776/TB	gel separatore in prov. 16x100 pp+etichetta x 10 ml di sangue	*PP test tubes with separatine gel Ø 16 x 100 mm, low cap.*
3778/E	Provette Ø12 x 86 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø12 x 86 mm*
3778/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separating gel, Ø12 x 86 mm, low cap*
4875/E	Provette Ø13 x 75 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E/TB	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/ETB	Provette con granuli + acc. per 5ml di sangue, in PP,	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/TR/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4878/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo azzurro	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light blue cap*
4878/TR/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo rosso	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light red cap*
4883/E	Provette Ø13 x 100 mm in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 100 mm*
4883/E/TN	Provette Ø13 x 100 mm in PP, con granuli separatori + acceleratore, tappo nero	*PP test tubes with separating granules + clot accelerator, Ø13 x 100 mm, black cap*
4884/E	Provette Ø16 x 100 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885/E	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885/R	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore, tappo rosso	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm, red cap*
4886/E	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4886/TR/E	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4888/E	Provette Ø12 x 86 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø12 x 86 mm*
4888/EB	Provette Ø12 x 86 mm. in PMMA, con granuli separatori + acceleratore, tappo bianco	*PMMA test tubes with separating granules + clot accelerator, Ø12 x 86 mm, white cap*
5975/E	Provette Ø13 x 75 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø13 x 75 mm*
5976/E	Provette Ø13 x 75 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø13 x 75 mm*
5978/E	Provette Ø12 x 86 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø12 x 86 mm*
5990	Granuli separatori in PS confezione da 1 Kg	Separating granules in PS
5993/E	Provette Ø13 x 100 mm in PP, con granuli separatori	*PP test tubes with separating granules, Ø13 x 100 mm*
5995/E	Provette Ø16 x 100 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø16 x 100 mm*
5995/ER	Provette con granuli per 10ml di sangue, in PMMA,	*PMMA test tubes with separating granules, Ø16 x 100 mm*
5996/E	Provette Ø16 x 100 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø16 x 100 mm*
5998/E	Provette Ø12 x 86 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø12 x 86 mm*

Dulio BUONO
Responsabile Assicurazione Qualità

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CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI 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:

PROVETTE E TAPPI
TEST TUBES AND CAPS

PRODOTTI NON STERILI – *NOT 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 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 do not fall under list A or B of annex II of the Directive 98/79/EC.

> **Classificazione EDMA:** 51091001 - Other containers for samples of human origin
EDMA code: 51091001 - Other containers for samples of human origin

> **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/EC.

Rilasciato / *Released*
Canelli, 26.07.2015

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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*
1005	Provetta cilindrica 10ml, PS	*Cylindrical test tubes 10ml, PS*
1005/S	Provetta cilindrica 10ml, PS	*Cylindrical test tubes 10ml, PS*
1006	Provetta cilindrica 3ml, PS	*Cylindrical test tubes 3ml, PS*
1006/MO	Provetta cilindrica 3ml, PP	*Cylindrical test tubes 3ml, PP*
10061	Provetta cilindrica in TPX 7ml	*TPX cylindrical test tubes 7ml*
10062	Provetta cilindrica in TPX 10ml	*TPX cylindrical test tubes 10ml*
10063	Provetta cilindrica in TPX 16ml	*TPX cylindrical test tubes 16ml*
10064	Provetta cilindrica in TPX 26ml	*TPX cylindrical test tubes 26ml*
10065	Provetta cilindrica in TPX 30ml	*TPX cylindrical test tubes 30ml*
10066	Provetta cilindrica in TPX 31ml	*TPX cylindrical test tubes 31ml*
10067	Provetta cilindrica in TPX 48ml	*TPX cylindrical test tubes 48ml*
10068	Provetta cilindrica in TPX 75ml	*TPX cylindrical test tubes 75ml*
10069	Provetta cilindrica in TPX 110ml	*TPX cylindrical test tubes 110ml*
10070	Provetta cilindrica in TPX 160ml	*TPX cylindrical test tubes 160ml*
10071	Provetta cilindrica in TPX 200ml	*TPX cylindrical test tubes 200ml*
1008/C	Tappo per art. 1014/C	*Cap for art. 1014/C*
1009/C/E	Provetta conica 10ml, PS, etichetta	*Conical test tubes 10ml, PS, label*
1009/C/T	Provetta conica 10ml, PS, tappo	*Conical test tubes 10ml, PS, cap*
1009/C/TBE/CS	Provetta conica 10ml, PS, tappo bianco, etichetta, confezione singola	*Conical test tubes 10ml, PS, white cap, label, individually wrapped*
1009/C/T/CS	Provette coniche 10ml, PS, con bordo, graduate, Ø16x100 mm,	*Conical test tubes 10ml, PS, cap*
1009/C/TB	Provetta conica 10ml, PS, tappo bianco	*Conical test tubes 10ml, PS, white cap*
1009/C/TB/E	Provetta conica 10ml, PS, tappo bianco, etichetta	*Conical test tubes 10ml, PS, white cap, label*
1009/C/TE	Provetta conica 10ml, PS, tappo, etichetta	*Conical test tubes 10ml, PS, cap, label*
1009/C/TE/CS	Provette coniche 10ml in PS con bordo, graduate,Ø16x100 mm	*Conical test tubes 10ml, PS, cap, label*
1009/C/TG	Provetta conica 10ml, PS, tappo giallo	*Conical test tubes 10ml, PS, yellow cap*
1009/C/TR	Provetta conica 10ml, PS, tappo rosso	*Conical test tubes 10ml, PS, red cap*
1009/E	Provetta cilindrica 10ml, PS, etichetta	*Cylindrical test tubes 10ml, PS, label*
1009/MO/E	Provetta cilindrica 10ml, PP, etichetta	*Cylindrical test tubes 10ml, PP, label*
1009/MO/T	Provetta cilindrica 10ml, PP, tappo	*Cylindrical test tubes 10ml, PP, cap*
1009/MO/T/100	Provetta cilindrica 10ml, PP, tappo	*Cylindrical test tubes 10ml, PP, cap*
1009/MO/T/AL	Provetta cilindrica 10ml, PP, tappo alettato	*Cylindrical test tubes 10ml, PP, cap with tongue*
1009/MO/T/CS	Provetta cilindrica 10ml, PP, tappo, confezione singola	*Cylindrical test tubes 10ml, PP, cap, individually wrapped*
1009/MO/TB	Provetta cilindrica 10ml, PP, tappo bianco	*Cylindrical test tubes 10ml, PP, white cap*
1009/MO/TB/E	Provetta cilindrica 10ml, PP, tappo bianco, con etichetta	*Cylindrical test tubes 10ml, PP, white cap, with label*
1009/MO/TE	Provetta cilindrica 10ml, PP, tappo, etichetta	*Cylindrical test tubes 10ml, PP, cap, label*
1009/MO/TG	Provetta cilindrica 10ml, PP, tappo giallo	*Cylindrical test tubes 10ml, PP, yellow cap*
1009/MO/TR	Provetta cilindrica 10ml, PP, tappo rosso	*Cylindrical test tubes 10ml, PP, red cap*
1009/MOC/E	Provetta conica 10ml, PP, etichetta	*Conical test tubes 10ml, PP, label*
1009/MOC/T	Provetta conica 10ml, PP, tappo	*Conical test tubes 10ml, PP, cap*
1009/MOC/TB	Provetta conica 10ml, PP, tappo	*Conical test tubes 10ml, PP, cap*
1009/MOC/TE	Provetta conica 10ml, PP, tappo, etichetta	*Conical test tubes 10ml, PP, cap, label*
1009/MOC/TR	Provetta conica 10ml, PP, tappo rosso	*Conical test tubes 10ml, PP, red cap*
1009/MOC/TR/E	Provetta conica 10ml, PP, tappo rosso ed etichetta	*Conical test tubes 10ml, PP, red cap and label*
1009/T	Provetta cilindrica 10ml, PS, tappo	*Cylindrical test tubes 10ml, PS, cap*
1009/TB	Provette cilindriche da 10ml, PS, bordo, graduate, Ø16x100mm	*Cylindrical test tubes 10ml, PS, cap*
1009/TBE/CS	Provette cilindriche da 10ml, PS, bordo, graduate, Ø16x100mm	*Cylindrical test tubes 10ml, PS, cap*
1009/TB/E	Provetta cilindrica 10ml, PS, tappo bianco, etichetta	*Cylindrical test tubes 10ml, PS, white cap, label*
1009/TB/E/RACK	Provetta cilindrica 10ml, PS, tappo bianco, etichetta, in rack da 100 pcs	*Cylindrical test tubes 10ml, PS, white cap, label, in rack of 100 pieces*
1009/TE	Provetta cilindrica 10ml, PS, tappo, etichetta	*Cylindrical test tubes 10ml, PS, cap, label*
1009/TE/CS	Provette cilindriche 10ml, PS, Ø16x100mm, con bordo e tappo,	*Cylindrical test tubes 10ml, PS, cap, label*
1009/TR	Provetta cilindrica 10ml, PS, tappo rosso	*Cylindrical test tubes 10ml, PS, red cap*
1009/TR/E	Provette cilindr.da 10ml in PS graduate con bordo e etichetta	*Cylindrical test tubes 10ml, PS, red cap*
1010/E	Provetta cilindrica 3ml, PS, etichetta	*Cylindrical test tubes 3ml, PS, label*
1010/MO/E	Provetta cilindrica 3ml, PP, etichetta	*Cylindrical test tubes 3ml, PP, label*
1010/MO/T	Provetta cilindrica 3ml, PP, tappo	*Cylindrical test tubes 3ml, PP, cap*
1010/MO/TE	Provetta cilindrica 3ml, PP, tappo, etichetta	*Cylindrical test tubes 3ml, PP, cap, label*
1010/T	Provetta cilindrica 3ml, PS, tappo	*Cylindrical test tubes 3ml, PS, cap*
1010/TE	Provetta cilindrica 3ml, PS, tappo, etichetta	*Cylindrical test tubes 3ml, PS, cap, label*
10121	Provetta cilindrica in polipropilene 7ml	*Polypropylene cylindrical test tubes 7ml*
10122	Provetta cilindrica in polipropilene 10ml	*Polypropylene cylindrical test tubes 10ml*
10123	Provetta cilindrica in polipropilene 16ml	*Polypropylene cylindrical test tubes 16ml*
10124	Provetta cilindrica in polipropilene 26ml	*Polypropylene cylindrical test tubes 26ml*
10125	Provetta cilindrica in polipropilene 30ml	*Polypropylene cylindrical test tubes 30ml*

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COD.	DESCRIZIONE	*DESCRIPTION*
10126	Provetta cilindrica in polipropilene 31ml	*Polypropylene cylindrical test tubes 31ml*
10127	Provetta cilindrica in polipropilene 48ml	*Polypropylene cylindrical test tubes 48ml*
10128	Provetta cilindrica in polipropilene 75ml	*Polypropylene cylindrical test tubes 75ml*
10129	Provetta cilindrica in polipropilene 110ml	*Polypropylene cylindrical test tubes 110ml*
10130	Provetta cilindrica in polipropilene 160ml	*Polypropylene cylindrical test tubes 160ml*
10131	Provetta cilindrica in polipropilene 200ml	*Polypropylene cylindrical test tubes 200ml*
1014	Provetta cilindrica per RIA 4ml, PS	*Cylindrical test tubes for RIA 4ml, PS*
1014/C	Provetta cilindrica per RIA 3ml, PS	*Cylindrical test tubes for RIA 3ml, PS*
1014/C/T	Provetta cilindrica per RIA 3ml, PS, tappo	*Cylindrical test tubes for RIA 3ml, PS, cap*
1014/C+1008/C	Provetta cilindrica per RIA 3ml, PS + tappo cod. 1008/C non inserito	*Cylindrical test tubes for RIA 3ml, PS + cap cod. 1008/C not inserted*
1014+1128	Provetta cilindrica per RIA 4ml, PS + tappo cod. 1128 non inserito	*Cylindrical test tubes for RIA 4ml, PS + cap cod. 1128 not inserted*
10150	Provetta con tappo a vite e base appoggio 10ml, in PP, graduata, Ø16x100	*Test tubes with screw cap and selfstanding base 10ml, in PP, graduated, Ø16x100*
10150/E	Provetta con tappo a vite e base appoggio 10ml, in PP, graduata, Ø16x100, con etichetta	*Test tubes with screw cap and selfstanding base 10ml, in PP, graduated, Ø16x100, with label*
10160	Provetta con tappo a vite e base appoggio 5ml, in PP, graduata, Ø16x50	*Test tubes with screw cap and selfstanding base 5ml, in PP, graduated, Ø16x50*
10160/E	Provetta tappo a vite e base appoggio 5ml, in PP, graduata, Ø16x50, etichetta	*Test tubes crew cap, selfstanding base 5ml, in PP, graduated, Ø16x50, label*
1018	Provetta cilindrica 5ml, PS	*Cylindrical test tubes 5ml, PS*
1018/MO	Provetta cilindrica 5ml, PP	*Cylindrical test tubes 5ml, PP*
10181	Provetta cilindrica in polistirolo cristallo 7ml	*Polystyrene crystal cylindrical test tubes 7ml*
10182	Provetta cilindrica in polistirolo cristallo 10ml	*Polystyrene crystal cylindrical test tubes 10ml*
10183	Provetta cilindrica in polistirolo cristallo 16ml	*Polystyrene crystal cylindrical test tubes 16ml*
10184	Provetta cilindrica in polistirolo cristallo 26ml	*Polystyrene crystal cylindrical test tubes 26ml*
10185	Provetta cilindrica in polistirolo cristallo 30ml	*Polystyrene crystal cylindrical test tubes 30ml*
10186	Provetta cilindrica in polistirolo cristallo 31ml	*Polystyrene crystal cylindrical test tubes 31ml*
10187	Provetta cilindrica in polistirolo cristallo 48ml	*Polystyrene crystal cylindrical test tubes 48ml*
10188	Provetta cilindrica in polistirolo cristallo 75ml	*Polystyrene crystal cylindrical test tubes 75ml*
10189	Provetta cilindrica in polistirolo cristallo 110ml	*Polystyrene crystal cylindrical test tubes 110ml*
10190	Provetta cilindrica in polistirolo cristallo 160ml	*Polystyrene crystal cylindrical test tubes 160ml*
10191	Provetta cilindrica in polistirolo cristallo 200ml	*Polystyrene crystal cylindrical test tubes 200ml*
10205	Provette cilindriche da 5ml, in PP, con tappo attaccato,	Cylindrical test tubes 5ml, in PP, with hinged lid
10206	Provette cilindriche da 10ml, in PP, con tappo attaccato,	Cylindrical test tubes 10ml, in PP, with hinged lid
10241	Provetta conica in TPX 10ml	*TPX conical test tubes 10ml*
10242	Provetta conica in TPX 16ml	*TPX conical test tubes 16ml*
1025	Provetta cilindrica fondo piatto 5ml, PS	*Flat bottom cylindrical test tubes 5ml, PS*
1025/B	Provetta cilindrica fondo piatto 5ml, PS	*Flat bottom cylindrical test tubes 5ml, PS*
1025/MO	Provetta cilindrica fondo piatto 5ml, PP	*Flat bottom cylindrical test tubes 5ml, PP*
1025/MO/B	Provetta cilindrica fondo piatto 5ml, PP	*Flat bottom cylindrical test tubes 5ml, PP*
10251	Provette in polietilene da 3 ml	*3 ml test tubes in polyethylene*
10252	Provette in polietilene da 5 ml	*5 ml test tubes in polyethylene*
1027	Tappo chiuso sul fondo per provetta Ø16, PE	*Stoppers closed at the bottom for test tubes Ø16, PE*
10271	Provetta conica in polipropilene 10ml	*Polypropylene conical test tubes 10ml*
10272	Provetta conica in polipropilene 16ml	*Polypropylene conical test tubes 16ml*
1028	Tappo chiuso sul fondo per provetta Ø12, PE	*Stoppers closed at the bottom for test tubes Ø12, PE*
1029	Tappo chiuso sul fondo per provetta Ø13, PE	*Stoppers closed at the bottom for test tubes Ø13, PE*
1031	Provetta per urina 12ml, PS, tappo	*Urine test tubes 12ml, PS, cap*
1031/500+1017	Provetta per urina 12ml, PS, tappo + etichette cod. 1017	*Urine test tubes 12ml, PS, cap + labels cod. 1017*
1031/CS	Provetta per urina 12ml, PS, tappo, confezione singola	*Urine test tubes 12ml, PS, cap, individually wrapped*
1031/CS/PI	Provetta per urina 12ml, PS, tappo presa igienica, confezione singola	*Urine test tubes 12ml, PS, cap, individually wrapped*
1031/E	Provetta per urina 12ml, PS, tappo, etichetta	*Urine test tubes 12ml, PS, cap, label*
1031/E/500	Provetta per urina 12ml, PS, tappo, etichetta	*Urine test tubes 12ml, PS, cap, label*
1031/E/CS	Provette per urina da 12ml, in PS, graduate, Ø17x105 mm,	*Urine test tubes 12ml, PS, cap, label*
1031/E/S	Provetta per urina 12ml, PS, etichetta	*Urine test tubes 12ml, PS, label*
1031/G	Provetta per urina 12ml, PS, tappo giallo non inserito	*Urine test tubes 12ml, PS, yellow cap not inserted*
1031/S	Provetta per urina 12ml, PS	*Urine test tubes 12ml, PS*
1031/S/1500	Provetta per urina 12ml, in PS, confezioni da 1500pcs	*Urine test tubes 12ml, in PS, pack of 1500 pcs*
1031/T	Provetta per urina 12ml, PS, tappo	*Urine test tubes 12ml, PS, cap*
1031/TE	Provetta per urina 12ml, PS, tappo ed etichetta	*Urine test tubes 12ml, PS, cap and label*
1034	Tappo per art. 1031/S, PE	*Caps for art. 1031/S, PE*
1034.01	Tappo per art. 1031/S, PE, colore rosso	*Caps for art. 1031/S, PE, red colour*
1034.02	Tappo per art. 1031/S, PE, colore giallo	*Caps for art. 1031/S, PE, yellow colour*
1034/R	Tappo per art. 1031/S, PE, colore rosso	*Caps for art. 1031/S, PE, colour red*
1035/E	Provetta cilindrica fondo piatto 5ml, PS, etichetta	*Flat bottom cylindrical test tubes 5ml, PS, label*
1035/MO/E	Provetta cilindrica fondo piatto 5ml, PP, etichetta	*Flat bottom cylindrical test tubes 5ml, PP, etichetta*

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1035/MO/T	Provetta cilindrica fondo piatto 5ml, PP, tappo	*Flat bottom cylindrical test tubes 5ml, PP, cap*
1035/MO/TE	Provetta cilindrica fondo piatto 5ml, PP, tappo, etichetta	*Flat bottom cylindrical test tubes 5ml, PP, cap, label*
1035/T	Provetta cilindrica fondo piatto 5ml, PS, tappo	*Flat bottom cylindrical test tubes 5ml, PS, cap*
1035/TE	Provetta cilindrica fondo piatto 5ml, PS, tappo, etichetta	*Flat bottom cylindrical test tubes 5ml, PS, cap, label*
10351	Provette coniche 50ml, PP, tappo a vite	*Conical test tubes 50ml, PP, screw cap*
10351/E	Provette coniche 50ml, PP, tappo a vite, etichetta	*Conical test tubes 50ml, PP, screw cap, label*
10351/R	Provette coniche 50ml, PP, tappo a vite rosso	*Conical test tubes 50ml, PP, red screw cap*
10351/S	Provette coniche 50ml, PP, tappo a vite azzurro non inserito	*Conical test tubes 50ml, PP, light blue cap not inserted*
10352	Provetta conica 15ml, PP, tappo a vite	*Conical test tubes 15ml, PP, screw cap*
10352/E	Provetta conica 15ml, PP, tappo a vite, etichetta	*Conical test tubes 15ml, PP, screw cap, label*
10352/R	Provetta conica 15ml, PP, tappo a vite rosso	*Conical test tubes 15ml, PP, red screw cap*
10361	Provetta cilindrica 10ml, PS, tappo a vite	*Cylindrical test tubes 10ml, PS, screw cap*
10361/B	Provetta cilindrica 10ml, PS, tappo a vite	*Cylindrical test tubes 10ml, PS, screw cap*
10361/E	Provetta cilindrica 10ml, PS, tappo a vite, etichetta	*Cylindrical test tubes 10ml, PS, screw cap, label*
10361/MO	Provetta cilindrica 10ml, PP, tappo a vite	*Cylindrical test tubes 10ml, PP, screw cap*
10361/MO/S	Provetta cilindrica 10ml, PP, senza tappo a vite	*Cylindrical test tubes 10ml, PP, without screw cap*
10361/R	Provetta cilindrica 10ml, PS, tappo a vite rosso	*Cylindrical test tubes 10ml, PS, red screw cap*
10361/S	Provette cilindriche 10ml, PS tappo a vite a parte	*Cylindrical test tubes 10ml, PS, red screw cap not assembled*
10362	Provetta cilindrica 15ml, PS, tappo a vite	*Cylindrical test tubes 15ml, PS, screw cap*
10363	Provetta cilindrica 20ml, PS, tappo a vite	*Cylindrical test tubes 20ml, PS, screw cap*
10363/R	Provetta cilindrica 20ml, PS, tappo a vite rosso	*Cylindrical test tubes 20ml, PS, red screw cap*
1038/E	Provetta cilindrica 5ml, PS, etichetta	*Cylindrical test tubes 5ml, PS, label*
1038/MO/E	Provetta cilindrica 5ml, PP, etichetta	*Cylindrical test tubes 5ml, PP, label*
1038/MO/T	Provetta cilindrica 5ml, PP, tappo	*Cylindrical test tubes 5ml, PP, cap*
1038/MO/T/100	Provetta cilindrica 5ml, PP, tappo, confezioni da 100 pcs	*Cylindrical test tubes 5ml, PP, cap, bags of 100 pcs*
1038/MO/TE	Provetta cilindrica 5ml, PP, tappo, etichetta	*Cylindrical test tubes 5ml, PP, cap, label*
1038/MO/TN	Provetta cilindrica 5ml, PP, tappo	*Cylindrical test tubes 5ml, PP, cap*
1038/T	Provetta cilindrica 5ml, PS, tappo	*Cylindrical test tubes 5ml, PS, cap*
1038/TE	Provetta cilindrica 5ml, PS, tappo, etichetta	*Cylindrical test tubes 5ml, PS, cap, label*
1038/TR/E	Provetta cilindrica 5ml, PS, tappo, etichetta	*Cylindrical test tubes 5ml, PS, cap, label*
10401	Tappo per provetta Ø12, PE	*Caps for test tubes Ø12, PE*
10402	Tappo per provetta Ø16, PE	*Caps for test tubes Ø16, PE*
10403	Tappo per provetta Ø14,5, PE	*Caps for test tubes Ø14.5 PE*
10404	Tappo per provetta Ø18, PE	*Caps for test tubes Ø18, PE*
10405	Tappo per provetta Ø24, PE	*Caps for test tubes Ø24, PE*
10406	Tappo per provetta Ø30, PE	*Caps for test tubes Ø30, PE*
10407	Tappo per provetta Ø35, PE	*Caps for test tubes Ø35, PE*
10408	Tappo per provetta Ø40, PE	*Caps for test tubes Ø40, PE*
10409	Tappo per provetta Ø45, PE	*Caps for test tubes Ø45, PE*
10410	Tappo per provetta Ø50, PE	*Caps for test tubes Ø50, PE*
10411	Tappo per provetta Ø20, PE	*Caps for test tubes Ø20, PE*
1075	Provetta cilindrica 5ml tipo SORVALL CW1, PS	*Cylindrical test tubes 5ml SORVALL CW1 type, PS*
1075/250	Provetta cilindrica 5ml tipo SORVALL CW1, PS, confezioni da 250 pezzi	*Cylindrical test tubes 5ml SORVALL CW1 type, PS, bags of 250 pieces*
1075/C	Provetta conica da 4,5 ml in PS, Ø12 x 75 mm	*4.5 ml conical test tubes in PS, Ø12 x 75 mm*
1075/C/T	Provetta conica da 4,5 ml in PS, Ø12 x 75 mm, con tappo	*4.5 ml conical test tubes in PS, Ø12 x 75 mm, with cap*
1075/E	Provetta cilindrica 5ml tipo SORVALL CW1, PS, etichetta	*Cylindrical test tubes 5ml SORVALL CW1 type, PS, label*
1075/MO	Provetta cilindrica 5ml tipo SORVALL CW1, PP	*Cylindrical test tubes 5ml SORVALL CW1 type, PP*
1075/MO/T	Provetta cilindrica 5ml tipo SORVALL CW1, PP, etichetta	*Cylindrical test tubes 5ml SORVALL CW1 type, PP, label*
1075/MOC	Provetta conica 5ml tipo SORVALL CW1, PP	*Conical test tubes 5ml SORVALL CW1 type, PP*
1075/S	Provetta cilindrica 5ml tipo SORVALL CW1, PS	*Cylindrical test tubes 5ml SORVALL CW1 type, PS*
1075/S	Provetta cilindrica 5ml tipo SORVALL CW1, PS	*Cylindrical test tubes 5ml SORVALL CW1 type, PS*
1075/T	Provetta cilindrica 5ml tipo SORVALL CW1, PS, tappo	*Cylindrical test tubes 5ml SORVALL CW1 type, PS, cap*
1075/TE	Provetta cilindrica 5ml tipo SORVALL CW1, PS, tappo, etichetta	*Cylindrical test tubes 5ml SORVALL CW1 type, PS, cap, label*
1075+1128	Provetta cilindrica 5ml tipo SORVALL CW1, PS + tappo cod. 1128	*Cylindrical test tubes 5ml SORVALL CW1 type, PS + cap cod. 1128*
1075+1128.02	Provette cilindriche 5ml PS tipo Sorvall, Ø12x75 mm con	*Cylindrical test tubes 5ml SORVALL CW1 type, PS + cap cod. 1128.02*
1124	Tappo antievaporazione, PE	*Anti-Evaporation caps, PE*
1127	Tappo alettato per provetta Ø16, PE	*Stoppers with tongues for test tubes Ø16, PE*
1128	Tappo alettato per provetta Ø12, PE	*Stoppers with tongues for test tubes Ø12, PE*
1130	Tappo alettato per provetta Ø13, PE	*Stoppers with tongues for test tubes Ø13, PE*
1131	Provetta speciale per urina 12ml, PS, tappo	*Special urine test tubes 12ml, PS, cap*
1131/E	Provetta speciale per urina 12ml, PS, tappo, etichetta	*Special urine test tubes 12ml, PS, cap, label*
1131/E/S	Provetta speciale per urina 12ml, PS, etichetta	*Special urine test tubes 12ml, PS, etichetta*
1131/G	Provetta speciale per urina 12ml, PS, tappo giallo	*Special urine test tubes 12ml, PS, yellow cap*
1131/S	Provetta speciale per urina 12ml, PS	*Special urine test tubes 12ml, PS*
1131/S/1500	Provetta speciale per urina 12ml, PS, confezioni da 1500 pcs	*Special urine test tubes 12ml, PS, pack of 1500 pcs*

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COD.	DESCRIZIONE	*DESCRIPTION*
1131/T	Provetta speciale per urina 12ml, PS, tappo inserito	*Special urine test tubes 12ml, PS, with inserted cap*
1134	Tappo presa igienica per art. 1131/S, PE, colore azzurro	*Caps with sanitari grip for art. 1131/S, PE, light blue colour*
1134.01	Tappo presa igienica per art. 1131/S, PE, colore rosso	*Caps with sanitari grip for art. 1131/S, PE, red colour*
1134.02	Tappo presa igienica per art. 1131/S, PE, colore giallo	*Caps with sanitari grip for art. 1131/S, PE, yellow colour*
11452	Provetta conica 15ml, PS, tappo a vite giallo	*Conical test tubes 15ml, PS, yellow screw cap*
11452/E	Provetta conica 15ml, PS, tappo a vite giallo, etichetta	*Conical test tubes 15ml, PS, yellow screw cap, label*
11452/S	Provetta conica 15ml, PS, tappo a vite giallo	*Conical test tubes 15ml, PS, yellow screw cap*
1147	Tappo chiuso sul fondo per provetta Ø16, PE	*Stoppers closed at the bottom for test tubes Ø16, PE*
1148	Tappo chiuso sul fondo per provetta Ø12, PE	*Stoppers closed at the bottom for test tubes Ø12, PE*
11581	Provette coniche per centrifuga da 13,5ml in PS, graduate a 5ml e 10ml, Ø16x110mm, tappo a vite	*13,5ml centrifuge conical test tubes in PS, graduated at 5ml and 10ml, Ø16x110mm, screw cap*
1164	Provetta cilindrica 11x64, PS	*Cylindrical test tubes 11x64, PS*
1168	Provette cilindriche da 1 ml in PS	*Cylindrical test tubes 1 ml in PS*
11681	Provette coniche per centrifuga da 13,5ml in PP, graduate a 5ml e 10ml, Ø16x110mm, tappo a vite	*13,5ml centrifuge conical test tubes in PP, graduated at 5ml and 10ml, Ø16x110mm, screw cap*
11681/E	Provette coniche per centrifuga da 13,5ml in PP, graduate a 5ml e 10ml, Ø16x110mm, tappo a vite, con etichetta	*13,5ml centrifuge conical test tubes in PP, graduated at 5ml and 10ml, Ø16x110mm, screw cap, with label*
1375	Provetta cilindrica 13x75, PS	*Cylindrical test tubes 13x75, PS*
1375/E	Provetta cilindrica 13x75, PS, etichetta	*Cylindrical test tubes 13x75, PS, label*
1375/MO	Provetta cilindrica 13x75, PP	*Cylindrical test tubes 13x75, PP*
1375/MO/T	Provetta cilindrica 13x75, PP, tappo	*Cylindrical test tubes 13x75, PS, cap*
1375/MO/TE	Provetta cilindrica 13x75, PP, tappo, etichetta	*Cylindrical test tubes 13x75, PS, cap, label*
1375/S	PROVETTE CILINDRICHE 13X75 PS SENZA BORDO	*Cylindrical test tubes 13x75, PS*
1375/T	Provetta cilindrica 13x75, PS, tappo	*Cylindrical test tubes 13x75, PS, tappo*
1375/T/E	Provetta cilindrica 13x75, PS, tappo, etichetta	*Cylindrical test tubes 13x75, PS, cap, label*
15331/TE/R	Provetta per urina per strumenti automatici 10ml, PS, tappo, etichetta, in rack	*Urine test tubes for instruments 10ml, PS, cap, label, in rack*
15361	Provette cilindriche da 10ml in PS, scala graduate e banda di scrittura serigrafata, Ø16x100mm, tappo a vite	*10 ml cylindrical test tubes in PS, writing surface and scree-printed graduation, Ø16x100 mm, screw cap*
15361/MO	Provette cilindriche 10ml in PP, graduate serigrafate, con	*10 ml cylindrical test tubes in PP, writing surface and scree-printed graduation, Ø16x100 mm, screw cap*
15362	Provette cilindriche da 15ml in PS, scala graduate e banda di scrittura serigrafata, Ø16x120mm, tappo a vite	*15 ml cylindrical test tubes in PS, writing surface and scree-printed graduation, Ø16x120 mm, screw cap*
1625	Provetta cilindrica fondo piatto 5ml, PS	*Flat bottom cylindrical test tubes 5ml, PS*
1625/MO	Provetta cilindrica fondo piatto 5ml, PP	*Flat bottom cylindrical test tubes 5ml, PP*
1650.01	Provette cilindriche in PS da 20 ml, Ø16 x 150 mm, non graduate, senza bordo, colore BLU	*20 ml cylindrycal test tubes in PS, Ø16 x 150 mm, non graduated, without rim, BLUE colour*
1650.02	Provette cilindriche in PS da 20 ml, Ø16 x 150 mm, non graduate, senza bordo, colore ROSSO	*20 ml cylindrycal test tubes in PS, Ø16 x 150 mm, non graduated, without rim, RED colour*
1650.03	Provette cilindriche in PS da 20 ml, Ø16 x 150 mm, non graduate, senza bordo, colore VERDE	*20 ml cylindrycal test tubes in PS, Ø16 x 150 mm, non graduated, without rim, GREEN colour*
1675	Provetta cilindrica 16x75, PS	*Cylindrical test tubes 16x75, PS*
1675/MO	Provetta cilindrica 16x75, PP	*Cylindrical test tubes 16x75, PP*
1675MO+1147+CUP	Kit di provetta in PP Ø16x75 + tappo presa igienica bianco +	*Cylindrical test tubes 16x75, PP*
20351	Provetta conica 50ml, PP, tappo a vite, base di appoggio	*Conical test tubes 50ml, PP, with screw cap, selfstanding base*
20351/P	Provette coniche PP 50ml, con base d'appoggio, tappo a vite	*Conical test tubes 50ml, PP, with screw cap, selfstanding base*
20351/S	Provette coniche PP 50ml, base d'appoggio, senza tappo,	*Conical test tubes 50ml, PP, without screw cap, selfstanding base*
5005	Provetta cilindrica 10ml, PS	*Cylindrical test tubes 10ml, PS*
5005/C	Provetta conica 10ml, PS	*Conical test tubes 10ml, PS*
5005/C/S	Provetta conica 10ml, PS	*Conical test tubes 10ml, PS*
5005/MO	Provetta cilindrica 10ml, PP	*Cylindrical test tubes 10ml, PP*
5005/MO/S	Provetta cilindrica 10ml, PP	*Cylindrical test tubes 10ml, PP*
5005/MO/T	Provette cilindriche da 10ml, in PP, senza bordo, Ø16x100 mm	*Cylindrical test tubes 10ml, PP*
5005/MOC	Provette coniche da 10ml in PP non graduate, senza bordo,	*Conical test tubes 10ml, PP*
5005/MOC/S	Provetta conica 10ml, PP	*Conical test tubes 10ml, PP*
5005/MOC/T	Provetta conica 10ml, PP, con tappo	*Conical test tubes 10ml, PP, with cap*
5005/S	Provetta cilindrica 10ml, PS	*Cylindrical test tubes 10ml, PS*
5005/S/K	Provette cilindriche da 10ml, in PS, senza bordo, Ø16x100 mm	*Cylindrical test tubes 10ml, PS*
5005/S/K/100	Provette cilindriche da 10ml, PS, senza bordo, Ø 16x100 mm,	*Cylindrical test tubes 10ml, PS*
5005/S/TE	Provetta cilindrica 10ml, PS, con tappo ed etichetta	*Cylindrical test tubes 10ml, PS, with cap and label*
5006	Provetta cilindrica 11,5x55, PS	*Cylindrical test tubes 11,5x55, PS*
5006/C/T	Provetta cilindrica 11,5x55, PS, con tappo	*Cylindrical test tubes 11,5x55, PS, con tappo*
5006/MO	Provetta cilindrica 11,5x55, PP	*Cylindrical test tubes 11,5x55, PP*
5006/T	Provetta cilindrica 11,5x55, PS, tappo	*Cylindrical test tubes 11,5x55, PS, cap*
5006T	Provette cilindriche da 3ml, in PS non graduate, con tappo,	*Cylindrical test tubes 11,5x55, PS, cap*
5018	Provetta cilindrica 5ml, PS	*Cylindrical test tubes 5ml, PS*

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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*
5018/1000	Provetta cilindrica 5ml, PS	*Cylindrical test tubes 5ml, PS*
5018/MO	Provetta cilindrica 5ml, PP	*Cylindrical test tubes 5ml, PP*
50351	Provette coniche 50ml in PP, con tappo a vite, Ø30x115 mm, con scala graduata ed area di scrittura serigrafata	*50ml conical test tubes in PP, screw cap, Ø30x115 mm, serigraphed graduated scale and writing surface*
50352	Provette coniche 15ml in PP, con tappo a vite, Ø17x120 mm, con scala graduata ed area di scrittura serigrafata	*15ml conical test tubes in PP, screw cap, Ø17x120 mm, serigraphed graduated scale and writing surface*
5038/E	Provetta cilindrica 5ml, PS, etichetta	*Cylindrical test tubes 5ml, PS, label*
5038/MO/E	Provetta cilindrica 5ml, PP, etichetta	*Cylindrical test tubes 5ml, PP, label*
5112	Provetta cilindrica fondo piatto 3ml, PS	*Flat bottom cylindrical test tubes 3ml, PS*
5112/E	Provetta cilindrica fondo piatto 3ml, PS, etichetta	*Flat bottom cylindrical test tubes 3ml, PS, label*
5112/MO	Provetta cilindrica fondo piatto 3ml, PP	*Flat bottom cylindrical test tubes 3ml, PP*
5112/MO/E	Provetta cilindrica fondo piatto 3ml, PP, etichetta	*Flat bottom cylindrical test tubes 3ml, PP, label*
5112/MO/T	Provetta cilindrica fondo piatto 3ml, PP, tappo	*Flat bottom cylindrical test tubes 3ml, PP, cap*
5112/MO/TAL	Provetta cilindrica fondo piatto 3ml, PP, tappo alettato	*Flat bottom cylindrical test tubes 3ml, PP, cap with tongues*
5112/MO/TE	Provetta cilindrica fondo piatto 3ml, PP, tappo, etichetta	*Flat bottom cylindrical test tubes 3ml, PP, cap, label*
5112/MOR	Provette cilindriche 3ml in PP Random, fondo piatto, graduate	*Flat bottom cylindrical test tubes 3ml, PP, cap, label*
5112/T	Provetta cilindrica fondo piatto 3ml, PS, tappo	*Flat bottom cylindrical test tubes 3ml, PS, cap*
5112/T/100	Provette cilindriche 3ml in PS fondo piatto,graduate,bordo	*Flat bottom cylindrical test tubes 3ml, PS, cap*
5112/TE	Provetta cilindrica fondo piatto 3ml, PS, tappo, etichetta	*Flat bottom cylindrical test tubes 3ml, PS, cap, label*
5122	Tappi esterni per provette sottovuoto Ø12-13, PE	*External caps for vacuum test tubes Ø12-13, PE*
5126	Tappi esterni per provette sottovuoto Ø15-16, PE	*External caps for vacuum test tubes Ø15-16, PE*
5127	Re-Cap - Tappi per richiusura provette sottovuoto, rosso, x provette Ø16 mm	*Re-Cap - Reclosing caps for vacuum test tubes, red, for test tubes Ø16 mm*
5129	Re-Cap - Tappi per richiusura provette sottovuoto, rosso, x provette Ø13 mm	*Re-Cap - Reclosing caps for vacuum test tubes, red, for test tubes Ø13 mm*
5140	Provetta cilindrica 20ml, PS	*Cylindrical test tubes 20ml, PS*
5140/E	Provetta cilindrica 20ml, PS, etichetta	*Cylindrical test tubes 20ml, PS, label*
5140/MO	Provetta cilindrica 20ml, PP	*Cylindrical test tubes 20ml, PP*
5140/MO/E	Provette cilindriche da 20ml, in PP, senza bordo, Ø16x150 mm	*Cylindrical test tubes 20ml, PP, label*
5140/MO/T	Provetta cilindrica 20ml, PP, tappo	*Cylindrical test tubes 20ml, PP, cap*
5140/MO/TE	Provetta cilindrica 20ml, PP, etichetta, tappo	*Cylindrical test tubes 20ml, PP, label, cap*
5140/T	Provetta cilindrica 20ml, PS, tappo	*Cylindrical test tubes 20ml, PS, cap*
5140/TE	Provetta cilindrica 20ml, PS, etichetta, tappo	*Cylindrical test tubes 20ml, PS, label, cap*
5140MO/E	Provetta cilindrica 20ml, PP, etichetta	*Cylindrical test tubes 20ml, PP, label*
5250	Provetta cilindrica 25ml, PP	*Cylindrical test tubes 25ml, PP*
5250/MO	Provetta cilindrica 25ml, PS	*Cylindrical test tubes 25ml, PS*
5331	Provetta per urina per strumenti automatici 10ml, PS, tappo	*Urine test tubes for instruments 10ml, PS, cap*
5331/S	Provetta per urina per strumenti automatici 10ml, PS	*Urine test tubes for instruments 10ml, PS*
5331/ST	Provetta per urina per strumenti automatici 10ml, PS	*Urine test tubes for instruments 10ml, PS*
5331/TE	Provetta per urina per strumenti automatici 10ml, PS, tappo, etichetta	*Urine test tubes for instruments 10ml, PS, cap, label*
5555	Provetta cilindrica 10ml, PMMA	*Cylindrical test tubes 10ml, PMMA*
5555/E	Provetta cilindrica 10ml, PMMA, etichetta	*Cylindrical test tubes 10ml, PMMA, label*
5555/T	Provetta cilindrica 10ml, PMMA, tappo	*Cylindrical test tubes 10ml, PMMA, cap*
5555/TE	Provetta cilindrica 10ml, PMMA, tappo, etichetta	*Cylindrical test tubes 10ml, PMMA, cap, label*
5558	Provetta cilindrica 5ml, PMMA	*Cylindrical test tubes 5ml, PMMA*
5558/E	Provetta cilindrica 5ml, PMMA, etichetta	*Cylindrical test tubes 5ml, PMMA, label*
5558/T	Provetta cilindrica 5ml, PMMA, tappo	*Cylindrical test tubes 5ml, PMMA, cap*
5558/TE	Provetta cilindrica 5ml, PMMA, tappo, etichetta	*Cylindrical test tubes 5ml, PMMA, cap, label*
5575	Provetta cilindrica 5ml, PMMA	*Cylindrical test tubes 5ml, PMMA*
5575/E	Provetta cilindrica 5ml, PMMA, etichetta	*Cylindrical test tubes 5ml, PMMA, label*
6005	Provetta cilindrica 10ml, PS	*Cylindrical test tubes 10ml, PS*
6005/250	Provette cilindriche da 10ml, in PS, con bordo, graduate,	*Cylindrical test tubes 10ml, PS*
6005/C	Provetta conica 10ml, PS	*Conical test tubes 10ml, PS*
6005/C/50	Provetta conica 10ml, PS, confezioni da 50 pezzi	*Conical test tubes 10ml, PS, bags of 50 pieces*
6005/C/500	Provetta conica 10ml, PS, confezioni da 500 pezzi	*Conical test tubes 10ml, PS, bags of 500 pieces*
6005/C/T	Provetta conica 10ml, PS, con tappo	*Conical test tubes 10ml, PS, with cap*
6005/MO	Provetta cilindrica 10ml, PP	*Cylindrical test tubes 10ml, PP*
6005/MO/250	Provette cilindriche da 10ml, in PP, con bordo, graduate,	*Cylindrical test tubes 10ml, PP*
6005/MOC	Provetta conica 10ml, PP	*Conical test tubes 10ml, PP*
6009/C/E	Provetta conica 10ml, PS, etichetta	*Conical test tubes 10ml, PS, label*
6009/C/T	Provetta conica 10ml, PS, tappo	*Conical test tubes 10ml, PS, cap*
6009/C/TR/E	Provetta conica 10ml, PS, etichetta, tappo rosso	*Conical test tubes 10ml, PS, label, red cap*
6009/E	Provetta cilindrica 10ml, PS, etichetta	*Cylindrical test tubes 10ml, PS, label*
6009/MO/E	Provetta cilindrica 10ml, PP, etichetta	*Cylindrical test tubes 10ml, PP, label*
6009/MO/T	Provetta cilindrica 10ml, PP, tappo	*Cylindrical test tubes 10ml, PP, cap*
6009/MO/TB/E	Provetta cilindrica 10ml, PP, etichetta, tappo bianco	*Cylindrical test tubes 10ml, PP, label, white cap*
6009/MO/TE	Provetta cilindrica 10ml, PP, etichetta, tappo	*Cylindrical test tubes 10ml, PP, label, cap*

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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*
6009/MOC/E	Provetta conica 10ml, PP, etichetta	*Conical test tubes 10ml, PP, label*
6009/T	Provetta cilindrica 10ml, PS, tappo	*Cylindrical test tubes 10ml, PS, cap*
6013	Provetta cilindrica 7ml, PS	*Cylindrical test tubes 7ml, PS*
6013/MO	Provetta cilindrica 7ml, in PP	*Cylindrical test tubes 7ml, in PP*
65351	Provette coniche 50ml in PP, con tappo a vite, Ø30x115 mm, con scala graduata ed area di scrittura serigrafata, in rack	*50ml conical test tubes in PP, screw cap, Ø30x115 mm, serigraphed graduated scale and writing surface, in rack*
65352	Provette coniche 15ml in PP, con tappo a vite, Ø17x120 mm, con scala graduata ed area di scrittura serigrafata, in rack	*15ml conical test tubes in PP, screw cap, Ø17x120 mm, serigraphed graduated scale and writing surface, in rack*

Duilio BUONO
Responsabile Assicurazione Qualità

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
21.01.2021

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **1009/C/TE**

DESCRIZIONE / *DESCRIPTION*

PROVETTA CONICA DA 10ML
Provette coniche Ø16x100 mm da 10 ml, graduata, con bordo. Prodotte in polistirolo cristallo (PS) ad alta trasparenza. Provette fornite con tappo in polietilene (PE) di colore azzurro con bordo zigrinato che garantisce una apertura ed una chiusura facile e sicura. Con etichetta autoadesiva applicata. Non sterili in sacchetti da 250 pezzi. Dispositivo Latex free

10ML CONICAL TEST TUBE
Conical test tubes Ø16x100 mm, graduated, with rim. Manufactured in crystal polystyrene (PS), high transparency. Test tubes supplied with inserted light blue polyethylene (PE) cap with milled rim allowing a safe and easy opening/closing. With applied self-adhesive label. Not sterile in bags of 250 pieces. Latex free device

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000

CE Marked product - manufactured in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbilogical status*
Materiale impiegato provetta	POLISTIROLO / *POLYSTYRENE*	*Raw material – Test tube*
Materiale impiegato tappo	POLIETILENE / *POLYETHYLENE*	*Raw material - cap*
Temperature tollerate provetta	MIN -10°C MAX +70°C	*Temperature range - test tube*
Temperature tollerate tappo	MIN -50°C MAX +80°C	*Temperature range - cap*
Dimensioni provetta (mm)	Ø 16 X 100	*Dimensions - test tube (mm)*
Dimensione tappo (mm)	Ø 17 X 20	*Dimensions – cap (mm)*
Volume (ml)	10,0	*Volume (ml)*
Volume nominale (ml)	12,5	*Nominal volume (ml)*
Scala graduata	0,5 - 1,0 - 2,5 - 5,0 - 10,0	*Graduated scale*
Spessore (mm)	1,0	*Thickness (mm)*
Peso provetta (gr.)	4,05	*Weight - test tube (gr.)*
Peso tappo (gr.)	1,0	*Weight – cap (gr.)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

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DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (per esempio urina, sangue, sperma, saliva, espettorato, pus, etc) al fine di effettuare analisi diagnostiche di laboratorio.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale Dispositivi Medici (CND) > W050301020102 (Provette senza additivi in materiale plastico per analisi)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1896379/R
Classificazione EDMA > 51091001 - Other containers for samples of human origin

Intended purpose is "IN VITRO MEDICAL DEVICE" adapted to contain a human biological sample (for example urine, blood, semen, saliva, sputum, pus, etc) in order to perform diagnostic analysis laboratory. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > W050301020102 *(Samples analyses, plastic tubes without additives).*
EDMA code > 51091001 - Other containers for samples of human origin

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

L'uso in centrifuga non deve superare la velocità massima di 3.000 r.p.m. per un massimo di 20 min.
For a maximum centrifuge speed of 3,000 r.p.m to be kept for 20" max

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	3.000	Confezione interna (pz): *Internal packing (pcs):*	250	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	60,5 x 43 x 54,5	Peso (Kg): *Weight (Kg):*	18,2	Volume (m^3): *Volume (m^3):*	0,142

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Stool Container**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

General Manager

BOEN HEALTHCARE CO.,LTD 91320594550110388530

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Mascia Brunelli S.p.A.
Viale Monza 272
20128 Milano
Italy

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 9001

in the scope

Design, manufacturing and distribution of haemostatic medical devices, in-vitro diagnostic microbiological culture media, platelet aggregation reagents and rapid tests for the detection of infectious diseases
Distribution of medical devices and in-vitro diagnostic devices

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015
Quality management systems – Requirements

Valid from	2024-03-07	Registration No.	D1016000056
Valid until	2027-03-06	Report No.	P22-01687-252242

Stuttgart, 2023-12-19

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

Sites included in the certification:

Location	Scope
Mascia Brunelli S.p.A. Viale Monza 272 20128 Milano Italy	Design, manufacturing and distribution of haemostatic medical devices, in-vitro diagnostic microbiological culture media, platelet aggregation reagents and rapid tests for the detection of infectious diseases Distribution of medical devices and in-vitro diagnostic devices
Biolife Italiana Srl Viale Monza 272 20128 Milano Italy	Design, manufacturing and distribution of in-vitro diagnostic microbiological culture media Distribution of in-vitro diagnostic devices

Stuttgart, 2023-12-19

Certification Body

For electronic distribution only
Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Mascia Brunelli S.p.A.
Viale Monza 272
20128 Milano
Italy

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Design, manufacturing and distribution of haemostatic medical devices, in-vitro diagnostic microbiological culture media, platelet aggregation reagents and rapid tests for the detection of infectious diseases. Distribution of medical devices and in-vitro diagnostic devices.

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2024-03-07	Registration No.	D1016000055
Valid until	2027-03-06	Report No.	P22-01687-252240

Stuttgart, 2024-03-07

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16002-06-00

INSTRUCTIONS FOR USE

L.E.S. LATEX

LATEX AGGLUTINATION SLIDE TEST FOR THE DETERMINATION OF ANTI-N-DNA ANTIBODIES ASSOCIATED WITH SYSTEMIC LUPUS ERYTHEMATOSUS (S.L.E.)

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

For ***in Vitro*** diagnostic use only

Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause that affects multiple organ systems (articulations, skin, kidneys, central nervous system, heart, lungs). Immunologic abnormalities, especially the production of a number of antinuclear antibodies (ANA), are another prominent feature of this disease. The clinical course is marked by spontaneous remissions and relapses. Its multisystemic manifestations and the complications from the use of immunosuppressive agents make the diagnosis and management of this entity challenging. The detection of ANA antibodies by laboratory methods include immunofluorescence, LE Cells test and agglutination of coated latex particles. These antibodies anti-DNP are believed to cause the formation of the LE cell in vitro, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE. Some patients having symptoms suggestive for SLE had been found negative with LE Cells Test. In these individuals, ANA antibodies may be demonstrated by methods other than the LE cell test, as latex agglutination or immunofluorescence.

L.E.S. LATEX is a rapid agglutination procedure, developed for the direct detection and the semi-quantitation on a slide of antideoxyribonucleoprotein antibodies (anti-DNP) in human serum.

2 - PRINCIPLE OF THE METHOD

The assay is performed by testing a suspension of latex particles coated with DNP against unknown serums. The presence or absence of a visible agglutination indicates the presence or absence of anti-DNP antibodies in the samples tested.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
L.E.S. LATEX CND: W0102100116 EDMA: 12.10.01.16; RDM: 1555421/R	Latex agglutination test	**UB80800** (62 tests)	1 glass bottle containing latex for L.E.S., suspension of polystyrene latex particles coated with DNP (calf thymus) in a buffered solution. Contain Sodium azide < 0.1% (3,1 mL = 62 tests) 1 glass bottle containing Positive Control: human serum with anti-DNP activity. Contain Sodium azide < 0.1% (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide < 0.1% (0,5 mL) Slide, 6 test areas: plastic waterproof sheets for reaction (11 items) Sticks (1x25): plastic sticks for mixing (3 items) Secondary packaging: cardboard box.
L.E.S. CONTROLLI CND: W0102100116 EDMA: 12.50.01.13; RDM: 1555441/R	Controls for latex agglutination test	**UD80802** (2x0,5 mL)	1 glass bottle containing Positive Control: human serum with anti-DNP activity. Contain Sodium azide <0.1% (0.5 mL) 1 glass bottle containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (0,5 mL) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Mechanical rotator with adjustable speed at 80-100 r.p.m. Timer or clock. Pipettes. Saline solution (9 g/L NaCl, only for semi-quantitation procedure).

5 - PRECAUTIONS AND WARNINGS

- L.E.S. LATEX is a kit for in vitro diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- Components of human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- The sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use to have best results.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device. complaint@masciabrunelli.it

6 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Mix reagents gently before use.

Reagents deterioration: Presence of particles and turbidity in controls; don't use it. Bacterial contamination of reagents or specimens may cause false positive results.

7 – SPECIMENS COLLECTION

Fresh, clear serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Do not use highly hemolysed or lipemic samples.

8 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

Qualitative test

1. Gently shake the suspension for homogenization of the latex particles.

2. Always use positive and negative controls as references.
3. Place **30 µL of the serum** under test into one of the circles on the slide. Dispense **1 drop of each Positive and Negative control** into two additional circles.
4. Add **1 drop or 40 µL of Latex reagent** to each circle next to the sample to be tested (serum, positive and negative control).
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide, either manually or with a mechanical stirrer 80 to 100 rpm for **1 minute***.
7. Observe the presence or absence of visible agglutination immediately.

**Samples giving indeterminate results may be retested increasing the rotation period to 2 minutes. Reaction times longer that 2 minutes might cause false positive results.*

Semiquantitative test

For each specimen to be tested place with a pipette 30 µl of saline solution (NaCl 9 g/L) into each of the 6 circles of a slide.
To circle one add 30 µl of specimen to the saline solution and, using the same tip, mix the saline solution with the sample by repeated aspiration and expulsion of the fluid and transfer 30 µl of the mixture to the saline solution in the second circle.
Continue with the 2-fold serial dilutions in a similar manner up to the sixth circle, and discard 30 µl from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64.
Test each dilution as described in steps 4-7 for the Qualitative Test.

9 – READING, INTERPRETATION AND CALCULATION

Qualitative test: Nonreactive: smooth suspension with no visible agglutination, as shown by negative control.
Reactive: any degree of agglutination visible macroscopically.

Semiquantitative tests: same as Qualitative test. The titer is defined as the highest dilution showing reactivity. The next higher dilution should be negative.

10 – QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. All result different from the negative control result, will be considered as a positive.

11- EXPECTED VALUES

A positive result indicates the level of anti-deoxyribonucleoprotein antibodies (DNP) is in the range commonly found in systemic lupus erythematosus.

12 – CHARACTERISTICS

Analytical performance. Serum samples were tested with L.E.S. LATEX : 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were clinically normal or had some nonrelated diseases (anemia, infectious mononucleosis and rheumatic diseases). Results were compared with a standard LE Cell preparation assay and a fluorescent ANA method.

	Found	L.E.S. TEST Mascia Brunelli	LE Cell Preparation	F-ANA Test	Total
Active SLE	Positive	24 83%	25 86%	24 83%	29
Inactive SLE	Positive	4 17.4%	4 17.4%	16 70%	23
Connective tissue diseases	Positive	0 0%	1 12.5%	4 50%	8
Clinically normal/non related diseases	Positive	1 1%	1 1%	6 6%	95

13 – LIMITATIONS OF THE METHOD

- Serum from patients with scleroma, rheumatoid arthritis, dermatomyositis and a variety of connective tissue diseases may elicit agglutination in the L.E.S. Test.
- As high levels of antibodies might affect the degree of agglutination, positive samples should be re-assayed using semi-quantitative procedure.
- Plasma samples should not be used because of the possibility of non-specific results.
- Bacterial contamination of controls and specimens as well as freezing and thawing of the L.E.S. TEST reagent may lead to false positive results.
- Drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.
- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test and must be supported by other clinical and laboratory data.
- The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

14 – REFERENCES

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TABLE OF APPLICABLE SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Manufacturer		Keep dry	UDI	Unique device identifier
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 3	Updated layout and content	2022/10

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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Hb FECALE

For in *Vitro* diagnostic use only

A visual one-step immunoassay for the qualitative detection of human blood haemoglobin in human fecal samples

I. INTENDED USE

Hb Fecale is a rapid, visual immuno-chromatographic test for the qualitative detection of human blood haemoglobin in fecal samples. This test is intended as an aid in the diagnosis of lower gastrointestinal (g.i.) disorders. The principal use of the test is to screen for lower g.i. pathologies, such as colorectal cancers and large adenomas that bleed. Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer death in the United States (Lieberman, 1994; MMWP, 1995). Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality (Dam et. al., 1995; Miller, 1995; and Lang, 1996).Earlier commercially available FOB tests utilized the guaiac test, which requires special dietary restriction to minimize false positive and false negative results. Hb Fecale is specially designed to detect human haemoglobin in fecal samples using Immunochemical methods, which improved specificity for the detection of lower g.i. disorders, including colorectal cancers and adenomas (Frommer et. al., 1988; St. John et. al., 1993).

II. PRINCIPLE

Hb Fecale has been designed to detect human haemoglobin in fecal samples through visual interpretation of color development in the test device. The test device contains a membrane strip, which is pre-coated with anti-human haemoglobin antibody on the test line region (T) and goat anti-mouse antibody on the control line region (C).An anti-human haemoglobin antibody-colloidal gold conjugate pad is placed at the end of the membrane. When human haemoglobin is present in the patient fecal sample dissolved in buffered saline, the mixture of colloidal gold conjugate and extracted sample moves along the membrane chromatographically by capillary action. This mixture then migrates to the test region (T) and forms a visible line as the antibodies complex with the human haemoglobin.When human haemoglobin is absent in the extracted sample, no visible color band will form on the test region (T). Therefore, the presence of a color band in the test region (T) indicates a positive result.A colored band will always appear at the control region (C) to serve as a procedural indicator for the proper performance of the test and the device.

III. STORAGE AND STABILITY

The test kit is to be stored at refrigerated (2-8°C) or at RT (up to 30°C) in the sealed pouch for the duration of the shelf-life.

IV. PRECAUTIONS

- For in-vitro diagnostic use only and for professional use only.
- Do not use test kit beyond expiration date.
- Do not mix sample collection tubes from different lots.
- Do not open the test cassette foil pouch until you are ready to perform the test.
- The control of human origin is obtained using only blood donors tested negative by tests approved by the FDA for the detection of HBsAg, HCV, and anti-HIV 1 and 2. However, since no test is able to ensure that products derived from human blood will not pose a risk of transmitting infectious agents, you should consider the product still potentially at risk and therefore handled with the same precautions that are used for the samples taken by patients.
- All patient samples should be treated as if capable of transmitting disease.
- Buffered saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Patients should closely follow the specimen collection procedures.
- Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.

V. REAGENTS AND MATERIALS SUPPLIED

- ***Test Membrane - Hb Fecal:*** Individually wrapped test devices ***(CASSETTE)***. Each test device ***(CASSETTE)*** contains one test strip with anti-human haemoglobin monoclonal antibody coated membrane and colored anti-human haemoglobin monoclonal antibody pad.
- ***Extraction Liquid Tubes - FOB Collection Tube:*** Sample collection tubes. Each contains 2 mL of 0.1 M Tris-HCl buffered saline, with Bovine Albumin (BSA) and 0.05 % sodium azide.
- **Positive Control:** H. haemoglobin (Sigma Ref. H7379), for Ref. VT81520 and UD80010.To be dispensed directly into the well S.
- **Negative Control:** (only for Ref. UD80010). Solution containing biological additives and bacteriostatic agents. To be dispensed directly into the well S.
- **Instruction for use.**

MATERIAL REQUIRED BUT NOT PROVIDED

- A clean dry container or receptacle for the collection of fecal sample.
- A piece of tissue paper to prevent solution from splashing.

VII. SPECIMEN COLLECTION AND PREPARATION

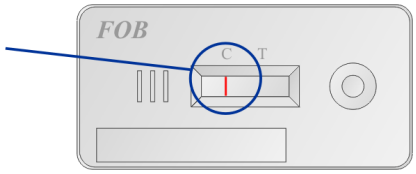
1. Collect a random sample of faeces in a clean dry container or receptacle.
2. Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.
3. Collect random sample by using the applicator stick. Take sample from various surfaces of the faeces specimen
4. Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the sample collection tube.
5. The specimen is now ready to be stored at 2-30°C, transported or tested. Faecal samples in the buffered saline are stable for up to 15 days at room temperature (up to 30°C).

For liquid or semi-solid stools using a separate pipette, draw stool of the sample itself. Dispense 150 µL of each stool into a extraction tube. Mix carefully, then vortex 15 seconds.Then proceed as above from the point forward 4.

VIII. TEST PROCEDURE

Quality Control / Internal Procedural Control

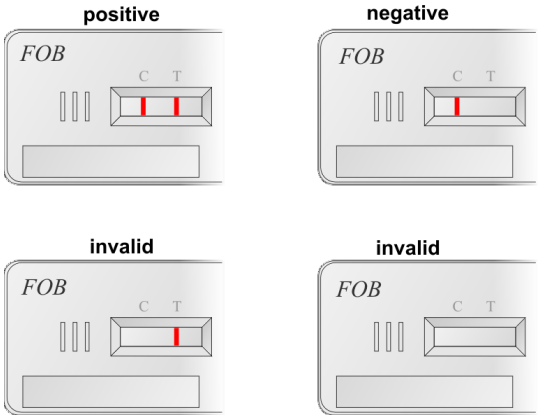
A procedural control is included in the test. A coloured band appearing on the control region (C) of the membrane indicates proper performance of the test and the device.
A clear background in the observation window is considered an internal negative control. However, when the faecal samples are tested, the background may appear slightly yellowish due to the original colour of the faecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.



IX. ASSAY PROCEDURE

1. Test device, patient's samples, (extracted sample) should be brought to room temperature (20°C to 30°C) prior to testing.
2. Remove the test device from its pouch when ready to perform the test. Bring the device to room temperature to avoid condensation of moisture in the membrane. Label the device with patient or control identification.
3. Shake the collection tube thoroughly to ensure proper mixing of the faecal sample with the extraction solution.
4. Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Hold the collection tube vertically and dispense 3-4 drops (app. 120 µL) of solution into the sample well of the test device.
5. For testing control, dispense 3-4 drops directly into the well S.
6. Observe the result in 5 minutes. Strong positive results may be observed sooner. Do not interpret results after 8 minutes.

X. INTERPRETATION OF RESULTS



Positive
Two pink-red colored bands appear. One in the control region (C) and one in the test region (T). When testing with strong positive samples, the intensity of the control band may be lighter than expected. Comparison of the line intensities is not recommended.

Negative
Only one pink-red colored band appears in the control region (C). No apparent faint pink to red colored band in the test region (T).

Invalid
A total absence of pink colored bands in both regions is an indication of procedural error or that test reagents may have deteriorated. Repeat the test with a new test device and if condition persists, contact the manufacturer for technical assistance.
The test lines may get darker after some time. This does not have any affect on the result.

XI. PERFORMANCE CHARACTERISTICS

A. Analytical Sensitivity

A sample containing human haemoglobin at concentration equal to or higher than 40 ng/mL produces a positive result.
Prozone effect: sample containing as high as 0.5 mg/ml haemoglobin can still test positive.

B. Test Specificity

Hb Fecale is specific for human haemoglobin and does not show any cross-reaction with the haemoglobin from bovine, pig, rabbit, horse,chiken and sheep.
Hb Fecale also does not show any cross reaction with bilirubin, vitamin C, ampicillin, caffeine, atropine, glucose, human albumin, urea, uric acid and horse radish peroxidase.

Attached HOW TO TAKE A FAECAL SAMPLE, to photocopy and distribute.

XII. BIBLIOGRAPHY

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IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT	VT81500A 50 cards	VT81500B 50 tubes	VT81510 50 tests	VT81520 100 tests+control	UD80010 Controls
Test Membrane – Hb Fecale (cassette)	50 items		50 items	100 items	
Extraction Liquid Tubes–FOB Collection Tube		50 items	50 items	100 items	
Positive Control				1 x 0,5 mL	1 x 1 mL
Negative Control					1 x 1 mL
Instruction for use	1 item	1 item	1 item	1 item	1 item

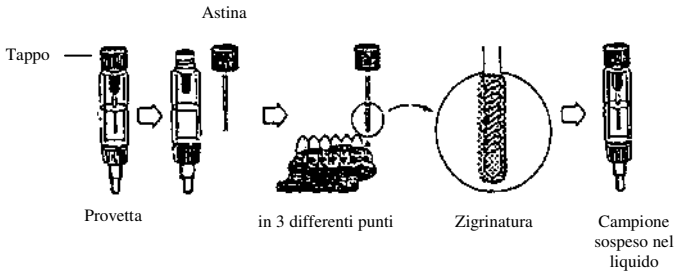
EDMA Code 13 01 70 01 00

CE IVD

ALLEGATO ALLE ISTRUZIONI PER L'USO

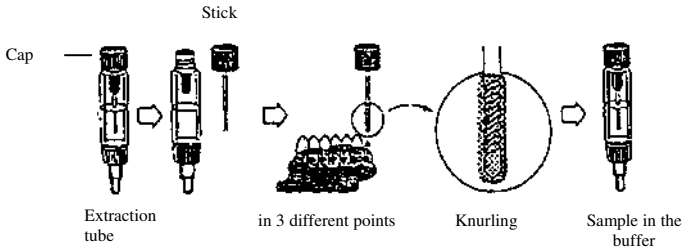
ISTRUZIONI PER IL PRELIEVO DEL CAMPIONE DI FECI

1. Raccogliere le feci in un contenitore piano asciutto.
2. Aprire il flacone del liquido di estrazione svitando il tappo ed estraendo l'astina di prelievo attaccata allo stesso.
3. Immergere in **3 punti diversi** delle feci raccolte l'astina di prelievo (**solo l'estremità zigrinata**).
4. Estrarre l'astina di prelievo dalle feci.
5. Immergere l'astina di prelievo utilizzata nel flacone del liquido di estrazione.
6. Riavvitare il tappo, serrare con forza e agitare delicatamente.



ANNEX TO THE INSTRUCTION FOR USE
HOW TO TAKE A FAECAL SAMPLE

1. Take faeces in a plane dry container.
2. Open the extraction buffer tube and take out the stick attached at the cap.
3. Dip in **3 different points** of faeces the stick (**only the knurling end**).
4. Take out the stick from the faeces.
5. Dip the stick in the extraction buffer tube.
6. Screw the cap, close and shake gently.



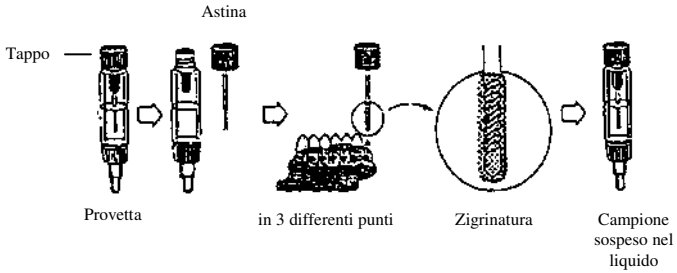
CE IVD

Mascia Brunelli S.p.A. Viale Monza 272, 20128 Milano, Tel. 02-25209.1, Fax 02-2576428,
mktg@masciabrunelli.it www.masciabrunelli.it

ALLEGATO ALLE ISTRUZIONI PER L'USO

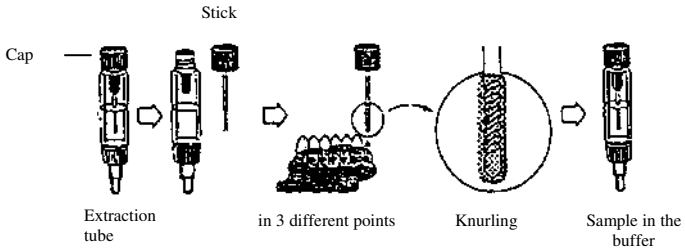
ISTRUZIONI PER IL PRELIEVO DEL CAMPIONE DI FECI

7. Raccogliere le feci in un contenitore piano asciutto.
8. Aprire il flacone del liquido di estrazione svitando il tappo ed estraendo l'astina di prelievo attaccata allo stesso.
9. Immergere in **3 punti diversi** delle feci raccolte l'astina di prelievo (**solo l'estremità zigrinata**).
10. Estrarre l'astina di prelievo dalle feci.
11. Immergere l'astina di prelievo utilizzata nel flacone del liquido di estrazione.
12. Riavvitare il tappo, serrare con forza e agitare delicatamente.



ANNEX TO THE INSTRUCTION FOR USE
HOW TO TAKE A FAECAL SAMPLE

7. Take faeces in a plane dry container.
8. Open the extraction buffer tube and take out the stick attached at the cap.
9. Dip in **3 different points** of faeces the stick (**only the knurling end**).
10. Take out the stick from the faeces.
11. Dip the stick in the extraction buffer tube.
12. Screw the cap, close and shake gently.



CE IVD

Mascia Brunelli S.p.A. Viale Monza 272, 20128 Milano, Tel. 02-25209.1, Fax 02-2576428,
mktg@masciabrunelli.it www.masciabrunelli.it

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 25 октября 2023 года № РЗН 2023/21423

На медицинское изделие
Набор реагентов для окраски по Граму (ДИАХИМ-ГРАМ) по ТУ 21.20.23-019-27428909-2022

Настоящее регистрационное удостоверение выдано
**Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ "АБРИС+"), Россия,
196006, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, этаж 2**

Производитель
**Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ "АБРИС+"), Россия,
196006, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, этаж 2**

Место производства медицинского изделия
**ООО "НПФ "АБРИС+", Россия, 192019, Санкт-Петербург,
ул. Профессора Качалова, д. 15а, лит. А**

Номер регистрационного досье **№ РД-56456/46444 от 14.06.2023**

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции по видам экономической деятельности **21.20.23.110**

Настоящее регистрационное удостоверение имеет приложение на 2 листах

Научно-производственная фирма "АБРИС" Для документов Санкт-Петербург

приказом Росздравнадзора от 25 октября 2023 года № 7538
допущено к обращению на территории Российской Федерации.

**Руководитель Федеральной службы
по надзору в сфере здравоохранения** **А.В. Самойлова**

0068089

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2016 года № ФСР 2012/14183

На медицинское изделие
Набор реагентов для клинического анализа спинномозговой жидкости («ДИАХИМ-ЛИКВОР») по ТУ 9398-067-27428909-2012

Настоящее регистрационное удостоверение выдано
**Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж**

Производитель
**Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж**

Место производства медицинского изделия
192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье **№ РД-9561/60865 от 14.12.2015**

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 22 января 2016 года № 641
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения М.А. Мурашко

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: GJEC8290C8

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
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2003 12 0393 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer*:
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas /** *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II /** *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HDV Ab ELISA cualitativo / *ELISA qualitative*

- DAB.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity*.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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