

ПАСПОРТ

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

Серия..... **66/800223** Дата выпуска... **02.2023** Годен до... **02.2025**
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 **66/800223** требованиям НТД предприятия соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.

«10» февраля 2023г.




МП



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

**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ**

от 11 января 2017 года № ФСР 2010/08997

Лист 1

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 рН»;
- комплект 3 «БМ-контроль-ССК с калибратором»;
- комплект 4 «БМ-контроль-ССК + глюкоза и рН с калибратором»;
- комплект 5 «БМ-контроль-ПГК»;
- комплект 6 «БМ-контроль-ПГК + глюкоза и рН» .

7



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

Обществу 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 ABO,
Rезус и Kell (Цоликлоны анти-A, анти-B, анти-AB, анти-A1, анти-Асл,
анти-D супер, анти-D (IgG), анти-C супер, анти-с супер, анти-E супер,
анти-е супер, анти-Kell супер) по ТУ 9398-101-51203590-2009
производства

Обществу 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-A - моноклональные антитела (IgM) к антигену А;
- цоликлон анти-B - моноклональные антитела (IgM) к антигену В;
- цоликлон анти-AB - моноклональные антитела (IgM) к антигенам А и В;
- цоликлон анти-A1 - фитогемагглютинин к антигену А1;
- цоликлон анти-Асл - 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-C супер - моноклональные антитела (IgM) к антигену С;
- цоликлон анти-с супер - моноклональные антитела (IgM) к антигену с;
- цоликлон анти-E 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 досье допущено к обращению на
территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

М.А. Мурашко

05 ноября 2009 года

0001890





CERTIFICATE OF COMPLIANCE

It is confirmed that its management system

Mediclone LLC

127276, 35, Botanicheskaya, Moscow, Russian Federation

It has been evaluated and complies with the requirements of the standard

ISO 13485:2016

Medical Devices Quality Management System

This certificate is valid for the following activities

Production and sale of medical devices: reagents and reagent kits for determining human blood groups of the ABO Rhesus and Kell systems, as well as antigens and antibodies of the Rhesus system

Certificate Number: SISTEMA-RUS/0223/RMM16244

Issue date: 04.02.2023

Expiry date: 03.02.2024

Date of First Surveillance: 04.01.2024

Date of second surveillance: 04.01.2025

Recertification date: 04.01.2026


Managing Director



Verify the certificate:- www.sistemacerts.com



The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope and also responsible for maintaining the responsibilities of the relevant standard rules. If any changes in the Activities of the Company, this certificate invalid. The validity of certificate is subject to Successfully Completion of surveillance audit on before due dates and its only valid after successful surveillance with continuation letter issued by us. QUALITY SISTEMA Certifications and Inspections Pvt Ltd., Head-quarters: FF, SS-1914, Sector -H, LDA Colony, Kanpur Road, Lucknow-226012.



ООО «Медиклон»

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: 239504

Единица: 100 мл

Изготовлен: 24.04.2023

Количество единиц: 80

Годен до: 24.04.2025

Объем серии: 10000 мл.

Паспорт: А239504 от 24.04.2023

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(II) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(I) 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 А(II) – 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) – 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(I) и В(II) – 1:32 - 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



ООО "Медиклон"

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: 239604

Единица: 100 мл

Изготовлен: 23.04.2023

Количество единиц: 80

Годен до: 23.04.2025

Объем серии: 10000 мл.

Паспорт: В239604 от 23.04.2023

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 2.2 Гемагглютинирующая способность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(II) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и O(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы O(I) Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует Соответствует Соответствует Соответствует 10сек.
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) - 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) - 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 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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ООО "Медиклон"

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

Серия: 037805

Единица: 100 мл

Изготовлен: 29.05.2023

Количество единиц 10

Годен до: 29.05.2025

Объем серии: 10000 мл.

Паспорт: АВ037805 от 29.05.2023

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(II) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(I) 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 А(II) – 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(II) – 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) – 1:32 - 1:64 и В(II) – 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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127276 Москва, Ботаническая ул. 35, т/ф +7495 231-2272 +7499 502-1214

ООО "Медиклон"

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: 236105

Единица: 100 мл

Изготовлен: 15.05.2023

Количество единиц: 50

Годен до: 15.05.2025

Объем серии: 10000 мл.

Паспорт: Дс236105 от 15.05.2023

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 прекасти 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





МЕДИКЛОН

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

ООО "Медиклон"

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: 133204

Единица: 100 мл

Изготовлен: 17.04.2023

Количество единиц 5

Годен до: 17.04.2025

Объем серии: 10000 мл.

Паспорт: K133204 от 17.04.2023

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 K(-)	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 микротитре не ниже 1:16	Соответствует 1:16

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

Заведующая
ОТК ООО «Медиклон»



К.В. Ющенко



EDAN

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



START OF CE-MARKING: 2020-12-18

PLACE, DATE OF ISSUE: SHENZHEN, 2020.12.18

SIGNATURE:

NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE



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



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 03 2015

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V6
July 6, 2015

Effective (Date or Lot Number):

DEC 03 2015



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

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

A handwritten signature in blue ink that reads 'Anna Szuba'.

Anna Szuba
Quality Director

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
	3970	10 L
	3970-00	10 L
CyMet™ 610 CN free	3977	5 L
	3431.1000	1 L
	3431-00	1 L
CyMet™ Abacus CN free	3479.1000PE	1 L
CyMet™ APR Baso II	3417.0500PE	500 ml
CyMet™ APR CN free	3478.1000PE	1 L
CyMet™ APR EO	2950.2500PE	2.5 L
CyMet™ ASA	2951.0500PE	500 ml
CyMet™ ASB	2952.9010PC	10 L
CyMet™ AS CN free	2982.0500PE	500 ml
CyMet™ BS3 CN free	3968	1 L
CyMet™ III Diff	3968-00	500 ml
	3511.1000	1 L
CyMet™ III Diff CN free	3511-00	5 L
	3416-00	500 ml
CyMet™ Erma	3416.0500	500 ml
	3853.1000	1 L
CyMet™ H20	3425-00	500 ml
CyMet™ KX CN Free	3425.0500	500 ml
	3852.1000	1 L
CyMet™ Micro	3863.1000	1 L micros
CyMet™ Micro CN free	3863-00	1 L micros
	3441-00	500 ml
CyMet™ Mindray	3440.0500PE	500 ml
CyMet™ Mindray CN Free		

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 extended 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

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

Page: 1 of 2



...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

Effective Date: 2024-04-14

Latest Revision Date: 2024-03-26

Expiry Date: 2027-04-13

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Declaration of Conformity

helena
Biosciences Europe

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.

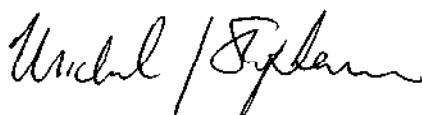
Product Code	Description	GMDN Classification Code
5392	Thrombin Time	55987

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

helena
Biosciences Europe

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.

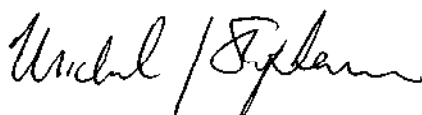
Product Code	Description	GMDN Classification Code
5556	Clauss Fibrinogen 50	55997

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

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

helena
Biosciences Europe

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.

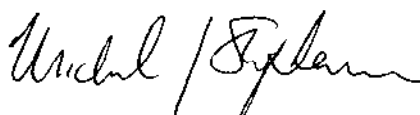
Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

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

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
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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

helena
Biosciences Europe

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
Tel +44 (0)191 482 8440

info@helena-biosciences.com

www.helena-biosciences.com

EC REP

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

Declaration of Conformity

helena
Biosciences Europe

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.

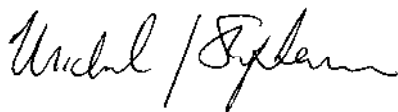
Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

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

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

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.

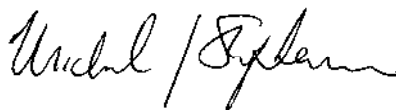
Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

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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United Kingdom

Declaration of Conformity

helena
Biosciences Europe

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.

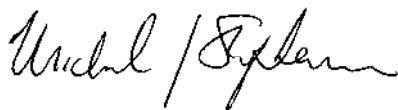
Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

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

Tel +44 (0)191 482 8440
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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

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>

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

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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>



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](http://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

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.



**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



Date: Jul/29/2020

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



**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



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

**СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»**

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ



ИСО 13485

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС33.17919

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»
141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

ВЫДАН

Общество с ограниченной ответственностью «МИНИМЕД»

ИНН: 3234007127 ОГРН: 1023202138332

Адрес: 241520, Брянская обл, Брянский р-н, село Супонево, ул Шоссейная, зд 17А

**НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО
СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА**

применительно к видам работ согласно приложению №1 к настоящему
сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

ГОСТ ISO 13485-2017(ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС33.17919П от 21.03.2022



Проверка
подлинности
сертификата
соответствия



Руководитель органа

Эксперт

[Handwritten signature]
подпись

[Handwritten signature]
подпись

К.Р. Василенко
инициалы, фамилия

М.Т. Антипин
инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

**СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»**

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ



ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.32001.04ИБФ1.ОС33.17919
(является неотъемлемой частью сертификата соответствия)

ИСО 13485

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»
141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

Применительно к видам работ: Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.



Руководитель органа

подпись

К.Р. Василенко

инициалы, фамилия

Эксперт

подпись

М.Т. Антипин

инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля.



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

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор реактивов для предстерилизационного контроля

Азопирам Ст

ОКП 32.50.50.000

МАЙ 2024

СЕРИЯ -- 0 5 2 4

Дата изготовления

Изготовитель НИИ ИТМ, г. Санкт-Петербург

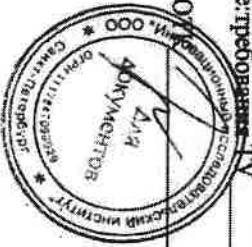
Метка	Требования по ТУ	Результаты анализа
1. Внешний вид 1.1. Реактив А амидопирин	Порошок белого цвета	00ТВЕТСТ8121
1.2. Реактив СА Сольнокислый ангидрин	Порошок белого (от серого до светло-зеленого) цвета	00ТВЕТСТ8111
1.3. Гидроксиламин солянокислый С	Порошок белого цвета	00ТВЕТСТ8121
2. Технические характеристики 2.1. Чувствительность Азопирамовой пробы из ливневых реагентов	1:100000	00ТВЕТСТ8121
Положительная реакция при разведении крови не менее		00ТВЕТСТ8121

Заключение: соответствует ТУ

00ТВЕТСТ8121

Начальник ОИ

Гавриков К.Е.



СЕРТИФИКАТ КАЧЕСТВА

Настоящим удостоверяется, что товар, идентифицированный как суше компоненты реактива для определения скрытой крови при предстерилизационном контроле Азопирам Ст код:382200000 ТНВЭД

Страна происхождения: Россия

Изготовитель: НИИ ИТМ МАЙ 2024

Дата изготовления:

Годеи до: МАЙ 2026

№ партии: -- 0 5 2 4

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



Регистрационное удостоверение № ФСР 2009/05559 от 04.12.2015 г.

Паспорт

Набор реагентов «Масло иммерсионное» по ТУ 9398-011-29508133-2009

Серия	179	Дата изготовления	12.09.2024
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1. Назначение

Используется для апохроматических и ахроматических объективов микроскопов всех видов, кроме люминесцентных, предназначенных для работы в видимой области спектра.

2. Технические требования

Наименование показателя	Характеристика и норма по ТУ	Результаты анализа
Внешний вид	Прозрачная бесцветная жидкость со слабым желтоватым оттенком	соответствует
Вязкость кинематическая при температуре 20°C, мм ² /с	От 220	1376
Показатель преломления при температуре 20°C	От 1,5150 до 1,5180	1,5156
Коэффициент пропускания масла, %	Не менее 70	440 нм – 99,7 540 нм – 100,0

Иммерсионное масло легко удаляется с поверхности препарата, фронтальной линзы и оправы объектива; инертно к окрашенным и неокрашенным препаратам.

Упаковка – флакон-капельница вместимостью 100,0 мл обеспечивает аккуратное и экономичное нанесение масла на препарат.

Срок годности – 1,5 года с даты изготовления.

3. Транспортирование и хранение

Транспортирование должно проводиться всеми видами крытого транспорта в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Хранение - в упаковке предприятия-изготовителя в прохладном месте при относительной влажности воздуха не более 80% в местах, защищенных от воздействия прямых солнечных лучей, атмосферных осадков и агрессивных сред в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие качества набора реагентов «Масло иммерсионное» требованиям ТУ 9398-011-29508133-2009 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО



Бабич В.А.

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

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2023-10-24

Data di Scadenza
Expiration Date

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
2007-10-30

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

Data di Rinnovo
Renewal Date
2023-10-24

Data di Scadenza
Expiration Date
2026-10-29



SGQ N° 023A

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

CERTIFIED COMPANY UNI EN ISO 9001:2008 & 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 BEONO
Responsabile Assicurazione Qualità

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	<i>Faeces containers 18ml, PS, with pressure cap and spoon</i>
1011/E	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	<i>Faeces containers 18ml, PS, with pressure cap and spoon, with label</i>
1011/E/50	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta, in confezioni da 50 pezzi	<i>Faeces containers 18ml, PS, with pressure cap and spoon, with label, in bags of 50 pieces</i>
1011/E/AST	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	<i>Faeces containers 18ml, PS, with pressure cap and spoon, with label</i>
1012	Contenitori per campioni biologici 18ml, PS, con tappo a pressione	<i>Specimen containers 18ml, PS, with pressure cap</i>
1013	Contenitori da 18ml, PS, senza tappo	<i>Containers 18ml, PS, without cap</i>
1030	Contenitori per urine 130ml, PS, graduati, tappo a pressione	<i>Graduated urine containers 130ml, PS, pressure cap</i>
1030/E	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta	<i>Graduated urine containers 130ml, PS, pressure cap, with label</i>
1030/E/CS	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta, confezione singola	<i>Graduated urine containers 130ml, PS, pressure cap, with label, individually wrapped</i>
1030/MO	Contenitori per urine 130ml, PP, graduati, tappo a pressione	<i>Graduated urine containers 130ml, PP, pressure cap</i>
1030/MO/E	Contenitori urina 130ml, in PP tappo a pressione, graduati, etichetta	<i>Graduated urine containers 130ml, PP, pressure cap, label</i>
1030/MO/T	Contenitori urina 130ml, in PP tappo a pressione inserito, graduati	<i>Graduated urine containers 130ml, PP, pressure cap</i>
1030/R	Contenitori per urine 130ml, PS, graduati, tappo a pressione rosso	<i>Graduated urine containers 130ml, PS, red pressure cap</i>
1030/S	Contenitori per urine 130ml, PS, graduati, senza tappo	<i>Graduated urine containers 130ml, PS, without cap</i>
1030/T	Contenitori per urine 130ml, PS, graduati, tappo a pressione inserito	<i>Graduated urine containers 130ml, PS, with inserted pressure cap</i>
1040	Contenitori per urina 120ml, PP, con coperchio autoadesivo	<i>Graduated urine containers 120ml, PP, with self-adhesive cap</i>
1040/P	Contenitori per urina 120ml, PS, con coperchio autoadesivo	<i>Graduated urine containers 120ml, PS, with self-adhesive cap</i>
1040/P/S	Contenitori per urina 120ml, PS, senza coperchio autoadesivo	<i>Graduated urine containers 120ml, PS, without self-adhesive cap</i>
1040/S	Contenitori per urina 120ml, PP, senza coperchio autoadesivo	<i>Graduated urine containers 120ml, PP, without self-adhesive cap</i>
1041	Contenitori per campioni biologici 30ml, PS, con tappo a pressione	<i>Specimen containers 30ml, PS, with pressure cap</i>
1041/E	Contenitori per campioni biologici 30ml, PS, con tappo a pressione, con etichetta	<i>Specimen containers 30ml, PS, with pressure cap, with label</i>
1041/S	Contenitori per campioni biologici 30ml, PS, senza tappo	<i>Specimen containers 30ml, PS, without cap</i>
1041/T	Contenitori per campioni biologici 30ml, PS, con tappo a pressione inserito	<i>Specimen containers 30ml, PS, with inserted pressure cap</i>
1050	Contenitori per urine 150ml, PS, graduati, tappo a pressione	<i>Graduated urine containers 150ml, PS, pressure cap</i>
1050/E	Contenitori per urine 150ml, PS, graduati, tappo a pressione, con etichetta	<i>Graduated urine containers 150ml, PS, pressure cap, with label</i>
1050/S	Contenitori per urine 150ml, PS, graduati, senza tappo	<i>Graduated urine containers 150ml, PS, without cap</i>
1050/T	Contenitori per urine 150ml, PS, graduati, tappo a pressione inserito	<i>Graduated urine containers 150ml, PS, with inserted pressure cap</i>
1051	Contenitori per espettorato 60ml, PS, con tappo a pressione	<i>Sputum containers 60ml, PS, with pressure cap</i>
1051/E	Contenitori per espettorato 60ml, PS, con tappo a pressione, con etichetta	<i>Sputum containers 60ml, PS, with pressure cap, with label</i>
1051/S	Contenitori per espettorato 60ml, PS, senza tappo a pressione	<i>Sputum containers 60ml, PS, without pressure cap</i>
1051/S/CS	Contenitori per espettorato 60ml, PS, senza tappo a pressione, in confezione singola	<i>Sputum containers 60ml, PS, without pressure cap, individually wrapped</i>
1051/T	Contenitori per espettorato 60ml, PS, con tappo a pressione inserito	<i>Sputum containers 60ml, PS, with inserted pressure cap</i>
1061	Contenitori per campioni biologici 35ml, PS, con tappo a pressione	<i>Specimen containers 35ml, PS, with pressure cap</i>
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	<i>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</i>
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	<i>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</i>
10631	Contenitori da 5ml, PE, tappo a vite	<i>Containers 5ml, PE, screw cap</i>
10632	Contenitori da 30ml, PE, tappo a vite	<i>Containers 30ml, PE, screw cap</i>
10633	Contenitori da 90ml, PE, tappo a vite	<i>Containers 90ml, PE, screw cap</i>

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

Contenitori per campioni biologici – Prodotti non Sterili

Specimen Containers – Not Sterile products

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

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

Contenitori per campioni biologici – Prodotti non Sterili
Specimen Containers – Not Sterile products

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

Contenitori per campioni biologici – Prodotti non Sterili
Specimen Containers – Not Sterile products

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

Contenitori per campioni biologici – Prodotti non Sterili
Specimen Containers – Not Sterile products

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 aluminium 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 aluminium 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 BEONO
 Responsabile Assicurazione Qualità

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 (Citrato, Heparin etc.)
EDMA code: 1302808000 Coated tubes (Citrato, 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 BEONO
Responsabile Assicurazione Qualità

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 ₂ EDTA per 2,5 ml di sangue, tappo verde chiaro.	PP flat bottom test tubes Ø12x56 mm., with K ₂ EDTA for 2,5 ml of blood, light green cap.
2000/1	Provette PP Ø12x56 mm., con K ₂ EDTA per 1 ml di sangue, tappo verde chiaro, per uso pediatrico.	PP test tubes Ø12x56 mm., with K ₂ EDTA for 1 ml of blood, light green cap, for paediatric use.
2000/1/V	Provette PP Ø12x56 mm., con K ₂ EDTA per 1 ml di sangue, con tappo, per uso pediatrico.	PP test tubes Ø12x56 mm., with K ₂ EDTA for 1 ml of blood, light with cap, for paediatric use.
2001	Provette fondo piatto PP Ø16x60 mm., con K ₂ EDTA per 2,5 ml di sangue, tappo verde chiaro.	PP flat bottom test tubes Ø16x60 mm., with K ₂ EDTA for 2,5 ml of blood, light green cap.
2002	Provette fondo piatto PP Ø16x60 mm., con K ₂ EDTA per 5 ml di sangue, tappo verde chiaro.	PP flat bottom test tubes Ø16x60 mm., with K ₂ EDTA for 5 ml of blood, light green cap.
2003	Provette PP Ø12x86 mm., con K ₂ EDTA per 2,5 ml di sangue, tappo verde chiaro.	PP test tubes Ø12x86 mm., with K ₂ EDTA for 2,5 ml of blood, light green cap.
2004	Provette PP Ø12x86 mm., con K ₂ EDTA per 5 ml di sangue, tappo verde chiaro.	PP test tubes Ø12x86 mm., with K ₂ EDTA for 5 ml of blood, light green cap.
2005	Provette PP Ø13x75 mm., con K ₂ EDTA per 2,5 ml di sangue, tappo verde chiaro.	PP test tubes Ø13x75 mm., with K ₂ EDTA for 2,5 ml of blood, light green cap.
2007	Provette PP Ø16x100 mm., con K ₂ EDTA per 10 ml di sangue, tappo verde chiaro.	PP test tubes Ø16x100 mm., with K ₂ EDTA for 10 ml of blood, light green cap.
2008	Provette PP Ø13x75 mm., con K ₂ EDTA per 4 ml di sangue, tappo verde chiaro.	PP test tubes Ø13x75 mm., with K ₂ EDTA for 4 ml of blood, light green cap.
2100	Provette fondo piatto PP Ø12x56 mm., con K ₃ EDTA per 2,5 ml di sangue, tappo verde scuro.	PP flat bottom test tubes Ø12x56 mm., with K ₃ EDTA for 2,5 ml of blood, dark green cap.
2100/1	Provette PP Ø12x56 mm., con K ₃ EDTA per 1 ml di sangue, tappo verde scuro, per uso pediatrico.	PP test tubes Ø12x56 mm., with K ₃ EDTA for 1 ml of blood, dark green cap, for paediatric use.
2100/1/V	Provette PP Ø12x56 mm., con K ₃ EDTA per 1 ml di sangue, tappo viola, per uso pediatrico.	PP test tubes Ø12x56 mm., with K ₃ EDTA for 1 ml of blood, dark violet cap, for paediatric use.
2100/TM	Provette fondo piatto PP Ø12x56 mm., con K ₃ EDTA per 2,5 ml di sangue, con tappo	PP flat bottom test tubes Ø12x56 mm., with K ₃ EDTA for 2,5 ml of blood, with cap
2101	Provette fondo piatto PP Ø16x60 mm., con K ₃ EDTA per 2,5 ml di sangue, tappo verde scuro.	PP flat bottom test tubes Ø16x60 mm., with K ₃ EDTA for 2,5 ml of blood, dark green cap.
2102	Provette fondo piatto PP Ø16x60 mm., con K ₃ EDTA per 5 ml di sangue, tappo verde scuro.	PP flat bottom test tubes Ø16x60 mm., with K ₃ EDTA for 5 ml of blood, dark green cap.
2103	Provette PP Ø12x86 mm., con K ₃ EDTA per 2,5 ml di sangue, tappo verde scuro.	PP test tubes Ø12x86 mm., with K ₃ EDTA for 2,5 ml of blood, dark green cap.
2104	Provette PP Ø12x86 mm., con K ₃ EDTA per 5 ml di sangue, tappo verde scuro.	PP test tubes Ø12x86 mm., with K ₃ EDTA for 5 ml of blood, dark green cap.
2105	Provette PP Ø13x75 mm., con K ₃ EDTA per 2,5 ml di sangue, tappo verde scuro.	PP test tubes Ø13x75 mm., with K ₃ EDTA for 2,5 ml of blood, dark green cap. Quantity for box 1,000 pieces
2105/TM	Provetta PP Ø13x75 mm, con K ₃ EDTA per 2,5ml di sangue, tappo viola.	PP test tubes Ø13x75 mm, with K ₃ EDTA for 2,5ml of blood, violet cap.
2105/VIOLA	Provette PP Ø13x75 mm., con K ₃ EDTA per 2,5 ml di sangue, tappo viola	PP test tubes Ø13x75 mm., with K ₃ EDTA for 2,5 ml of blood, violet cap.
2107	Provette PP Ø16x100 mm., con K ₃ EDTA per 10 ml di sangue, tappo verde scuro.	PP test tubes Ø16x100 mm., with K ₃ EDTA for 10 ml of blood, dark green cap.
2108	Provette PP Ø13x75 mm., con K ₃ EDTA per 4 ml di sangue, tappo verde scuro.	PP test tubes Ø13x75 mm., with K ₃ EDTA for 4 ml of blood, dark green cap.
2108/5	Provette PP Ø13x75 mm., con K ₃ EDTA per 5 ml di sangue, tappo verde scuro.	PP test tubes Ø13x75 mm., with K ₃ EDTA for 5 ml of blood, dark green cap.
2108/TM	Provette PP Ø13x75 mm., con K ₃ EDTA per 4 ml di sangue	PP test tubes Ø13x75 mm., with K ₃ EDTA for 4 ml of blood
2108/VIOLA	Provette PP Ø13x75 mm., con K ₃ EDTA per 4 ml di sangue	PP test tubes Ø13x75 mm., with K ₃ EDTA 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,

Provette con anticoagulante e separatori di siero

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	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 ₃ EDTA, con tappo perforabile verde, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable green cap, for 3 ml of blood.
2500*	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile verde, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable green cap, for 3 ml of blood.
2500/N	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile neutro, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable neutral cap, for 3 ml of blood.
2500/N*	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile neutro, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable neutral cap, for 3 ml of blood.
2500/SE	Provette in PP con K ₃ EDTA tappo perforabile verde, senza tappo	PP test tubes Ø13x75 mm., with K ₃ EDTA, without cap, for 3 ml of blood.
2500/SE/V	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile viola, per 3 ml di sangue, senza etichetta.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable violet cap, for 3 ml of blood, without label
2500/V	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile viola, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable violet cap, for 3 ml of blood.

Provette con anticoagulante e separatori di siero

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2500/V*	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile viola, per 3 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, with pierceable violet cap, for 3 ml of blood.
2500/V/2	Provette PP Ø13x75 mm, con K ₃ EDTA, con tappo perforabile viola, per 2 ml di sangue.	PP test tubes Ø13x75 mm., with K ₃ EDTA, 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 ₃ EDTA, 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 separating 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 separating 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

Provette con anticoagulante e separatori di siero
Blood collecting tubes and serum separators

26.07.2015

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

Cod.	DESCRIZIONE	DESCRIPTION
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 separating 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 separating 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 separating 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 BEONO
 Responsabile Assicurazione Qualità

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


Duilio BEONO
Responsabile Assicurazione Qualità

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

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

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 with screw 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

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

Cod.	DESCRIZIONE	DESCRIPTION
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 anti-evaporazione, 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 cylindrical 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 cylindrical 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 cylindrical 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+CUF	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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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, PS, 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 chiusura 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 chiusura 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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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 BEONO
Responsabile Assicurazione Qualità

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

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

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: / **Stool Container**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(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: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **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:

Suzhou, 201.05.26

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

CE

General Manager

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



SCHEDA TECNICA PRODOTTO TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
21.01.2021



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

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	Microbiological 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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E-Mail: info@aptaca.com – Website: www.aptaca.com

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): 3.000
Quantity (pcs): 3.000

Confezione interna (pz): 250
Internal packing (pcs): 250

QUANTITÀ MINIMA VENDIBILE
MINIMUM SALEABLE QUANTITY

Misura esterna scatola (cm): 60,5 x 43 x 54,5
External box dimensions (cm): 60,5 x 43 x 54,5

Peso (Kg): 18,2
Weight (Kg): 18,2

Volume (m³): 0,142
Volume (m³): 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



LORNE LABORATORIES LTD



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

Phone: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com

CERTIFICATE OF ANALYSIS

DESCRIPTION	LOT NO.	EXPIRY	PRODUCT CODE
LE Latex Kit	315040	2022-06	840050

STORAGE: Refrigerated at 2 – 8°C. Protect from light. Do not freeze.

SHIPPING: This product has data supporting stability tolerance during fluctuations in ambient shipping temperature.

This product is in compliance with **MEDICAL DEVICES REGULATIONS 2002** for Annex 3 and Self-Certification. This product was manufactured, packaged and tested in accordance with **LORNE QUALITY SYSTEMS** and meets all product specifications.

We certify that this product has been released as meeting all our acceptance criteria

If applicable:

- Components from human origin have been tested and found negative for the presence of antibody to HIV as well as HBsAg and HCV. However handle cautiously as potentially infectious.
- This product was tested by methods described in the manufacturers package insert.
- This product is intended for *In Vitro* Diagnostic use only.
- This product contains <0.1% sodium azide.

APPROVED BY:

DATE: 19 January 2021

Eddy Velthuis
Technical Director

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

Facility ID: F001410

UL Medical Regulatory Services of UL LLC® (UL Solutions) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

EN ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design and manufacture of in vitro diagnostic reagents for the detection of the blood groups.



Authorized by



Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

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

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

Facility ID: F001410

Additional Regulatory Requirements

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

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**UL Medical and Regulatory
Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

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

ПАСПОРТ

**Набор реагентов для окраски микроорганизмов по методу Грам 100 опр. х 1 мл
«Окраска по Граму-100 (фуксин)»**

Серия **19806/640824** Дата выпуска **08.2024** Годен до... **08.2025**
Количество наборов в серии. **1000**

Наименование показателя	Требования НТД предприятия	Результаты анализа
1. Внешний вид		
1.1 Раствор генциана фиолетового	Жидкость насыщенного темно-фиолетового цвета	Соответствует
1.2 Раствор Люголя	Жидкость темно-желтого цвета	Соответствует
1.3 Раствор фуксина Циля	Жидкость темно-вишневого цвета	Соответствует
2. Показатели правильности определения по результатам микроскопии окрашенных препаратов.		
2.1 «Staphylococcus epidermidis» Тест штамм № 9198	Кокковидные клетки фиолетового или синего цвета.	Соответствует
2.2 «Escherichia coli» Тест штамм № K109	Крупные палочки розового или красного цвета	Соответствует

Заключение ОКК ООО «Агат-Мед»:
Серия **19806/640824** требованиям НТД предприятия соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.

«01» августа 2024 г.






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

Localizador: GJEC8290C8

Fecha de la firma: 19/11/2018

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

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318



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 n°/Certificate no	Fecha de validez/Date of validity	ON n°/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

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. M^a Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: GJEC8290C8

Fecha de la firma: 19/11/2018

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

CORREO ELECTRÓNICO

on0318@aemps.es

Página 2 de 2

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

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2,4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section G)

Manufacturer:
ZAO "Vector-Best"
Address: AHC, Koltsovo,
Novosibirsk Region, 630559, Russia,
Tel: +7 (383) 363 20 60,
Fax: +7 (383) 363 35 55

European authorized representative:
Bioron GmbH,
Rheinhorststr. 18, D-67071
Ludwigshafen, Germany.
Tel: +49 (0) 621 5720 915,
fax: +49 (0) 621 5720 916

Date: 2013/04/12



Murat Khushainov

Murat Khushainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep ITV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1096
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1098
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectohSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectohSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2166
17.	Ureaplasma urealyticum - IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum - IGA-EIA-BEST	ELISA kit for determination of IGA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis - IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus antigens	D-3356

24.	Ascend- IgG-EIA-BEST	antigens	ELISA kit for determination of IgG to Ascends Lumbicoides	D-3452
25.	Lambia-antibodies-EIA-BEST		ELISA kit for determination of IgG, IgM and IgA to Lambia antibodies	D-3552
26.	Lambia-IgM-EIA-BEST		ELISA kit for determination of IgM to Lambia antibodies	D-3554
27.	Lambia-antigen-EIA-BEST		ELISA kit for determination of Lambia antigen	D-3556
28.	Helicobacter pylori-Caga-antigen-EIA-BEST		ELISA kit for determination of total antibodies to Caga Helicobacter pylori	D-3752
29.	TSH-EIA-BEST		ELISA kit for determination of concentration of thyrotropin releasing hormone	X-3952
30.	T3 total-EIA-BEST		ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST		ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST		ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST		ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4150
34.	Mycoplasma hominis-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST		ELISA kit for determination of IgA to Mycoplasma hominis	D-4356
36.	Mycoplasma pneumoniae-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST		ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectormean - CHF - IgG		ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectormean - CHF - IgM		ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST		ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST		ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST		ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST		ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST		ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST		ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST		ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST		ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST		ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST		ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST		ELISA kit for determination of concentration of interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST		ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST		ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST		ELISA kit for determination of concentration of interleukine 6	A-8768
56.	Interleukine-2-EIA-BEST		ELISA kit for determination of concentration of interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST		ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST		ELISA kit for determination of concentration of N-terminal prohomone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST		ELISA kit for determination of concentration of troponin I	A-9106



Certificate of Registration

This certificate has been awarded to

AO Vector-Best

3, Pasechnaya str., Novosibirsk, 630117, Russian Federation

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

**Design, Development, and Production of In Vitro Diagnostic Medical Devices
(ELISA, PCR)**

Certificate Number **209535/A/0003/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g. xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
05 October 2022	1	04 October 2025	1
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
06 October 2022	1	05 October 2022	n/a

For detailed explanation for the data fields above, refer to <http://www.urs-holdings.com/logos-and-regulations>

Issued by

On behalf of the Schemes Manager

