



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

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

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17

Телефон: 8 (800) 1000-730, e-mail: info@cacaudit.ru



№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



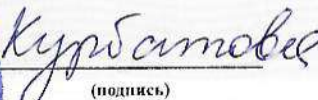
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.

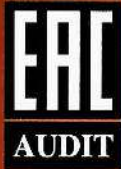




(подпись)

Е. Д. Курбатова

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



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

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

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



РАЗРЕШЕНИЕ на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

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

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

РАЗРЕШАЕТ

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

Руководитель органа
по сертификации:

(подпись)

В. И. Погдин

Председатель
экспертной комиссии:

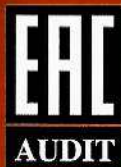
М.П.



(подпись)

Е. Д. Курбатова

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



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«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028

ИНН 7717616798 ОГРН 1087746489060

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Телефон: 8 (800) 1000-730, e-mail: info@cacaudit.ru



СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.СМ.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

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



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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



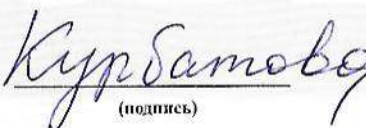
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

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

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор контрольных растворов белков мочи «БМ-контроль-ССК + глюкоза и рН»

Код ОКП 93 9816

Регистрационное удостоверение № ФСР 2010/08997

ТУ 9398-269-52208224-2010

Кат № 04.01.04

Номер серии ПВ 14 - 21

Срок годности до: 07.12.2022 г.

НАЗНАЧЕНИЕ

Набор «БМ-контроль-ССК + глюкоза и рН» предназначен для контроля правильности и воспроизводимости результатов определения в моче

- | | |
|----------------|--|
| белков | - по их реакции с сульфосалициловой кислотой |
| | - с помощью диагностических полосок |
| глюкозы | - ферментативным методом (глюкозооксидазным) |
| | - качественным по реакции Бенедикта |
| | - с помощью диагностических полосок |
| рН | - с помощью диагностических полосок |

СОСТАВ НАБОРА

Набор «БМ-контроль-ССК + глюкоза и рН» содержит 8 флаконов контрольных растворов:

- 4 флакона уровень №1 по 10 мл
- 4 флакона уровень №2 по 10 мл

В паспорте набора указывается среднее значение концентрации белка мочи и глюкозы с контрольными пределами ($X \pm 2S$).

Технические характеристики набора:

- | | | |
|---|---------|---------------|
| - коэффициент вариации результатов измерения концентрации белков, %, не более | 10 | Соответствует |
| - коэффициент вариации результатов измерения концентрации глюкозы, %, не более | 5 | Соответствует |
| - межфлаконная вариация, %, не более | 5 | Соответствует |
| - допустимый разброс результатов определения концентрации белков в разных наборах одной серии, %, не более | 10 | Соответствует |
| - допустимый разброс результатов определения концентрации глюкозы в разных наборах одной серии, %, не более | 5 | Соответствует |
| - срок хранения набора, мес | 12 | |
| - температура хранения, °С | 2 - 8°С | |
| - после вскрытия флакона раствор можно хранить, дней, не более | 14 | |

Начальник отдела
Технического контроля



Краснопольская Е.В.

« 07 » __ноября__ 2021г



Клиническая
биохимия

Agat

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

ПАСПОРТ

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

Серия..... 66/770421 Дата выпуска... 04.2021 Годен до... 05.2023
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 66/770421 требованиям НТД предприятия соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«19» апреля 2021г.



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



SYSTEM OF
INTERNATIONAL
CERTIFICATION

СЕРТИФИКАТ

на систему менеджмента качества

SIC.MS.094.ISO13485.1332 от 11.03.2020 до 10.03.2023

Орган сертификации "Международное Агентство Сертификации"
настоящим сертификатом подтверждает, что система менеджмента
качества

«Медиклон»

Общество с ограниченной ответственностью

127276 Российская Федерация, Москва, ул. Ботаническая, дом 35

Применительно к

производству изделий медицинского назначения, а
именно: «Реагентов и наборов реагентов для
определения групп крови человека систем АВО Резус и
Келл, а также антигенов и антител системы Резус»

соответствует требованиям международного стандарта

EN ISO 13485:2016

**"Изделия медицинские. Системы менеджмента качества.
Системные требования для целей регулирования"**

Дата сертификации:

11.03.2020 г.

Действителен до:

10.03.2023 г.

при условии ежегодного подтверждения

2021 г. - до 11.02.2021

2022 г. - до 11.02.2022

Руководитель органа



Т.Р. Погребная



SIC.MS.094.ISO13485.1332

ОС «Международное Агентство Сертификации», свидетельство Нотификации:

SIC.СВ.643.094 от 21.03.2019 г., 109444, Российская Федерация, г. Москва, б-р Самаркандский, д.10,

корпус 1, кв. 62, Тел./Факс: +7(903) 223-25-69, выданный S.I.C. Global Inc., 346 WIGSTON DR, Suite 4, NORTH BAY, ONTARIO, P1A 1X3, CANADA

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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-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: 212108

Единица: 100 мл

Изготовлен: 30.08.2021

Количество единиц: 40

Годен до: 30.08.2023

Объем серии: 10000 мл.

Паспорт: Дс212108 от 30.08.2021

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

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

Заведующая
ОТК ООО «Медиклон»

К.В. Ющенко





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 Келл» 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: 018809

Единица: 100 мл

Изготовлен: 06.09.2021

Количество единиц: 40

Годен до: 06.09.2023

Объем серии: 10000 мл.

Паспорт: В018809 от 06.09.2021

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



ООО «Медиклон»

127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, 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: 115709

Единица: 100 мл

Изготовлен: 13.09.2021

Количество единиц: 4

Годен до: 13.09.2023

Объем серии: 10000 мл.

Паспорт: K115709 от 13.09.2021

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная желтоватая или розоватая 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
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микроплате не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009
Заведующая ОТК ООО «Медиклон»



М.С. Орлова



МЕДИКЛОН

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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: 013309

Единица: 100 мл

Изготовлен: 27.09.2021

Количество единиц: 10

Годен до: 27.09.2023

Объем серии: 10000 мл.

Паспорт: АВ013309 от 27.09.2021

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная или слегка окрашенная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и 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)	Соответствует Соответствует Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов АI 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(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



МЕДИКЛОН

ООО "Медиклон"

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

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

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

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

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

Серия: 018709

Единица: 100 мл

Изготовлен: 06.09.2021

Количество единиц: 40

Годен до: 06.09.2023

Объем серии: 10000 мл.

Паспорт: А018709 от 06.09.2021

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная или слегка окрашенная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и 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)	Соответствует Соответствует Соответствует
2.2 Гематглютинирующая 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(II) и В(III) - 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



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



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
	3430.9020	20 L
Diluid™ Abacus	3430.9010	10 L
	3430-00	20 L
	3996	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
CyMet™ Abacus CN free	3431-00	1 L
	3479.1000PE	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768.1000	1 L micros
ProClean™ Abacus	3432.5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862.5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control 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
	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

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 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.

22 November 2011



Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	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
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml

3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
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
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
Cleaners		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	1liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
Reagents for 5-part WBC diff. on STKS and MaxM.		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	RetiCount™	30 ml
3777	RetiCount CD	15 x 3.5 ml

Hematology Controls		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L, 1 x N, 1 x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L,N,H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers.		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline.		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
Stains and Dyes		
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
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5 liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5 liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2.5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2.5 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
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

22 November 2011



This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

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

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

ISO 9001:2015

For and on behalf of NQA, USA

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





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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number:

FM 743464

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

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

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2018-10-12

Effective Date: 2021-10-13

Latest Revision Date: 2021-10-12

Expiry Date: 2022-04-12

Page: 1 of 2



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Certificate No: FM 743464

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

Original Registration Date: 2018-10-12

Latest Revision Date: 2021-10-12

Effective Date: 2021-10-13

Expiry Date: 2022-04-12

Page: 2 of 2

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

Certificate of Registration

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

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number:

MD 743461

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

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

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-06-01

Latest Revision Date: 2021-10-05

Effective Date: 2021-10-13

Expiry Date: 2022-04-12

Page: 1 of 2



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Certificate No: **MD 743461**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	Distribution of In Vitro Diagnostics Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

Original Registration Date: 2021-06-01

Latest Revision Date: 2021-10-05

Effective Date: 2021-10-13

Expiry Date: 2022-04-12

Page: 2 of 2

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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Facility ID Number: F004943

Holds Certificate No:

MDSAP 743463

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-12-07

Effective Date: 2021-10-13

Expiry Date: 2022-10-12



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 3

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Certificate No: **MDSAP 743463**

Registered Scope:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring.

Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.



Original Registration Date: 2017-12-07

Effective Date: 2021-10-13

Expiry Date: 2022-10-12

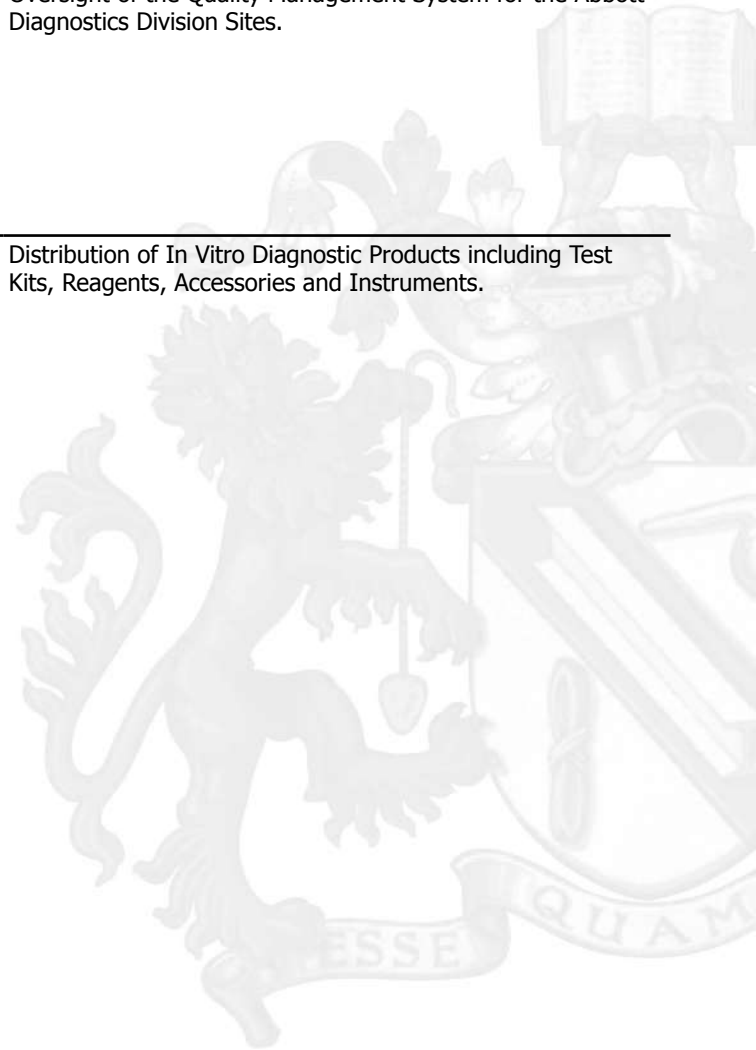
Page: 2 of 3

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 743463**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA Facility ID Number: F004943	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA Facility ID Number: F004943	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA Facility ID Number: F004943	Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



Original Registration Date: 2017-12-07

Effective Date: 2021-10-13

Expiry Date: 2022-10-12

Page: 3 of 3

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
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.

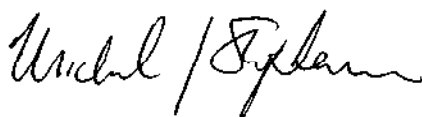
Product Code	Description	GMDN Classification Code
5392	Thrombin Time	55987

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

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 69326**

Location

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Sunderland Enterprise Park
Colima Avenue
Sunderland
SR5 3XB
United Kingdom

Registered Activities

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

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

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



Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

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-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.

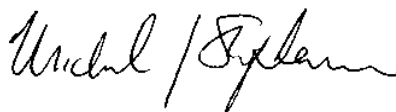
Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

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
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- 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.

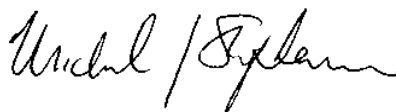
Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

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

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- 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.

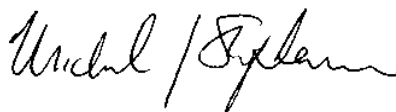
Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

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
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- 0511 DC DOI 2013/08 (3)

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.

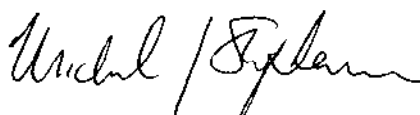
Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

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: 05 Aug 2013

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.

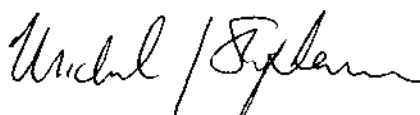
Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

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
info@helena-biosciences.com
www.helena-biosciences.com

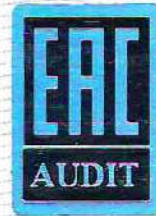
Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom



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

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

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



№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 3234007127

ОГРН: 1023202138332

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

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

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа
по сертификации:

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:



(подпись)

Е. Д. Курбатова

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

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**
manufacturer **disposable labware**

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

telefono **+39-049-9720624** fax **+39-049-9720182** posta elettronica **info@vacutestkima.it**
phone e-mail

identificazione dei prodotti
product identification

**Sistema di prelievo di sangue e altri liquidi biologici
mediante provette con vuoto predeterminato in plastica
"VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids
collection tubes in plastic.**

nome commerciale
brand name

"VACUTEST KIMA"

classificazione dei prodotti
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

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

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Arzergrande, 01/01/2015

firma
signature

Assicuratore Qualità / Quality Manager
Giovanni Chiarin





*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

CERTIFICATO n.
CERTIFICATE No.

4265/4/C

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

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici,
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

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


Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

*For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address info@icim.it.*

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022


ICIM S.p.A.

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



SGQ N° 004 A

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



www.cisq.com

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



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n. 4264/4/C
CERTIFICATE No. _____

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

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici,
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

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

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

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

*For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address info@icim.it.*

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022


ICIM S.p.A.

Piazza Don Enrico Mapelli, 76 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004A

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



www.cisq.com

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

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Commercializzazione di articoli da laboratorio

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

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
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

2020-10-30

Data di Scadenza
Expiration Date

2023-10-29

Settore IAF 14 - 29



SGQ N° 023A

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

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,

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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.

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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
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Cod.	DESCRIZIONE	DESCRIPTION
10126	Provetta cilindrica in polipropilene 31ml	Polypropylene cylindrical test tubes 31ml
10127	Provetta cilindrica in polipropilene 48ml	Polypropylene cylindrical test tubes 48ml
10128	Provetta cilindrica in polipropilene 75ml	Polypropylene cylindrical test tubes 75ml
10129	Provetta cilindrica in polipropilene 110ml	Polypropylene cylindrical test tubes 110ml
10130	Provetta cilindrica in polipropilene 160ml	Polypropylene cylindrical test tubes 160ml
10131	Provetta cilindrica in polipropilene 200ml	Polypropylene cylindrical test tubes 200ml
1014	Provetta cilindrica per RIA 4ml, PS	Cylindrical test tubes for RIA 4ml, PS
1014/C	Provetta cilindrica per RIA 3ml, PS	Cylindrical test tubes for RIA 3ml, PS
1014/C/T	Provetta cilindrica per RIA 3ml, PS, tappo	Cylindrical test tubes for RIA 3ml, PS, cap
1014/C+1008/C	Provetta cilindrica per RIA 3ml, PS + tappo cod. 1008/C non inserito	Cylindrical test tubes for RIA 3ml, PS + cap cod. 1008/C not inserted
1014+1128	Provetta cilindrica per RIA 4ml, PS + tappo cod. 1128 non inserito	Cylindrical test tubes for RIA 4ml, PS + cap cod. 1128 not inserted
10150	Provetta con tappo a vite e base appoggio 10ml, in PP, graduata, Ø16x100	Test tubes with screw cap and selfstanding base 10ml, in PP, graduated, Ø16x100
10150/E	Provetta con tappo a vite e base appoggio 10ml, in PP, graduata, Ø16x100, con etichetta	Test tubes with screw cap and selfstanding base 10ml, in PP, graduated, Ø16x100, with label
10160	Provetta con tappo a vite e base appoggio 5ml, in PP, graduata, Ø16x50	Test tubes with screw cap and selfstanding base 5ml, in PP, graduated, Ø16x50
10160/E	Provetta tappo a vite e base appoggio 5ml, in PP, graduata, Ø16x50, etichetta	Test tubes 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, label

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



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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

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

ISO 13485:2016

EN ISO 13485:2016

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

Authorized by



Michael J. Windler, P.E.

Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC



Check Certificate
Status: [here](#)

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

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



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

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany


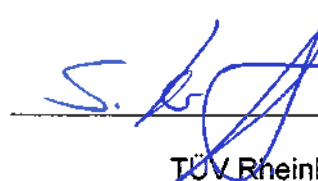
Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing as well as associated in vitro diagnostic devices for sampling and analysis systems for rapid tests.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs and lancets.

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.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29



Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1034230-1


Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Manufacture and distribution
/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development and distribution
/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development and manufacture
/04	c/o nal von minden GmbH Raseweg 4 37124 Rosdorf Germany	Administration and distribution

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29





Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131398 0001

Report No.: 21200072 015

Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products:

- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

Expiry Date: 2023-11-27

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2018-11-28

Date: 2018-11-27

Notified Body



Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60131398 0001
Report No.: 21200072 015

Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products included:

In vitro diagnostica for self-testing:

- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:

- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

Site included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Activities: Design and development

Date: 2018-11-27

Notified Body




Dipl.-Ing. Sven Hoffmann

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

Certificate Holder: **nal von minden GmbH**

Carl-Zeiss-Str. 12
47445 Moers
Germany

including the locations according to annex

Scope:

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2021-09-10 until 2024-09-09.
First certification 2018

2021-09-10



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02 c/o nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03 c/o nal von minden GmbH
Robert-Bosch-Breite 34
37079 Göttingen
Germany

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2016 года № ФСР 2009/04160

На медицинское изделие

**Набор реагентов для окраски по Граму «Диахим-Набор для окраски по Граму»
по ТУ 9398-019-27428909-2008**

Настоящее регистрационное удостоверение выдано

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

Производитель

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

Место производства медицинского изделия

192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье № РД-9488/61061 от 11.12.2015

Вид медицинского изделия 107820

Класс потенциального риска применения медицинского изделия 2а

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 11 января 2016 года № 48
допущено к обращению на территории Российской Федерации.

**Руководитель Федеральной службы
по надзору в сфере здравоохранения**



М.А. Мурашко

0016961

HOLTSCHE Medizinprodukte GmbH

In den Faltern 13 . D – 65232 Taunusstein
Germany

Declaration of conformity

This is to confirm that

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

is

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

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

conform to

the German Medical Product Law according to

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

Taunusstein, November 17th, 2021

HOLTSCHE Medizinprodukte GmbH

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



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

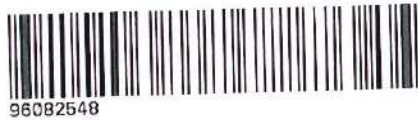
Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

Ministero della Salute

DGFDM

0043588-P-26/10/2011



Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE E DELL'ORDINAMENTO DEL SERVIZIO
SANITARIO NAZIONALE
DIREZIONE GENERALE DEI DISPOSITIVI MEDICI, DEL SERVIZIO FARMACEUTICO
E DELLA SICUREZZA DELLE CURE
UFFICIO IV ex DGFDM – DIAGNOSTICI IN VITRO

I.5.l.c.2/IV/2011/37

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;

VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;

VISTA l'istanza del 29/09/2011 presentata dalla ditta Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;

CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;

VISTI gli atti d'ufficio;

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical-devices;

HAVING REGARD to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;

HAVING REGARD to the request dated 29/09/2011 submitted by the company Dia.Pro Diagnostic Bioprobes Srl with legal site in Via Columella, 31 – 20128 Milano – C.F. and P.Iva 11924660159;

WHEREAS this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;

HAVING REGARD to the official deeds;

SI ATTESTA IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, ha prodotto e marcato CE, come dispositivo medico- diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il prodotto:

that the Company Dia.Pro Diagnostic Bioprobes Srl located in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, manufactured and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

DP-9 DIA.BLOOD INSTRUMENT

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.



Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione nei paesi extra UE.

The above mentioned product, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and to export to non-European countries

IC/CM

IL DIRETTORE DELL'UFFICIO IV
(Dott.ssa Giovanna Nisticò)
Giovanna Nisticò

Certificate

mdc medical device certification GmbH
certifies that

VECTOR



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

with the locations listed in the attachment
for the scope

**Design and development, production and distribution of
medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)**

has introduced and applies a

Quality Management System

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

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

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

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02


Head of Certification Body



Attachment of the certificate

No. D1213100019

date 2020-06-02

Page 1 of 1

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




Head of Certification Body

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
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 ITT-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 thyrot-stimulating 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.	Veddoimean - CHF - IgG		ELISA kit for determination of IgG to Crinear-Congo hemorrhagic fever virus	D-5052
39.	Veddoimean - CHF - IgM		ELISA kit for determination of IgM to Crinear-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

N° 2007/28642.5

AFNOR Certification certifies that the management system implemented by:
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ZAO "EKOLab"
ЗАО «ЭКОлаб»



for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

**РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ
ДЛЯ IN-VITRO ДИАГНОСТИКИ.**

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485:2016

and is developed on the following locations:
и действует на следующих площадках:

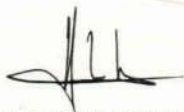
142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А

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Franck LEBEUGLE
Managing Director of AFNOR Certification
Генеральный директор AFNOR Certification



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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

от 30 октября 2012 года

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
и подтверждает, что медицинское изделие

Набор реагентов "Антиген кардиолипидный для реакции
микропреципитации "Сифилис-АгКЛ-РМП"
по ТУ 9398-016-70423725-2010 в следующей комплектации
производства

Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
место производства:

Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1

класс потенциального риска 2б

ОКП 93 9817

вид медицинского изделия –

соответствующее регистрационному досье № 33508 от 26.09.2012

В соответствии с приказом Росздравнадзора от 30 октября 2012 года № 2280-Пр/12
и приказом от 23 июля 2013 года № 3428-Пр/13 о замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения



М.А. Мурашко
0001831

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
№ ФСР 2011/09957

Лист 1

Комплект № 1 включает в составе:

- антиген кардиолипиновый (АгКЛ);
- раствор холин-хлорида в 0,9 % растворе натрия хлорида.

Комплект № 2 в составе:

- взвесь АгКЛ.

2

Приказом от 23 июля 2013 года № 3428-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения



М.А. Мурашко

30 октября 2012 года

0001854