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

№ 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

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.21 16:19:56 EET
Reason: MoldSign Signature
Location: Moldova

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

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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ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
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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

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(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, исключающей 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. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

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.03842-02

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: _____ (подпись) **Е. Д. Курбатова**

М.П.

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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»

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Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

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

APTACA S.p.A.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
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www.aptaca.com - www.vacuaptaca.it
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI ISO 9001 & UNI CEI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE

CE *DECLARATION OF CONFORMITY*

DECLARAÇÃO CE CONFORMIDADE

Aptaca S.p.A.

DICHIARA / *DECLARES / DECLARA*

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:
Que os dispositivos medicos de diagnóstico in vitro a seguir descriminados como:

PROVETTE CON ANTICOAGULANTE, SEPARATORI DI SIERO

BLOOD COLLECTIONS TUBES AND SERUM SEPARATORS

TUBOS PARA COLHEITA DE SANGUE COM ADITIVO

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)
(cujas referencias estão descritos no anexo 1)

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

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

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

Rilasciato / *Released*
Canelli, 03.08.2021

Duilio BUONO
Quality Assurance Manager

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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
10110/16	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
10110/PR	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
2000	Provette fondo piatto PP Ø12x56 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø12x56 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2000/1	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, tappo verde chiaro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light green cap, for paediatric use.*
2000/1/L	Volume pediatrico ridotto - K2 EDTA in provette 12 x 56 fondo piatto per 1 ml di sangue - rack da 50 pezzi - Tappo lavanda	*K2 EDTA in test tubes 12x56 for 1 ml of blood, lavender cap*
2000/1/V	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, con tappo, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light with cap, for paediatric use.*
2000/L	K2 EDTA coloro lavanda (viola chiaro), in provette 12 x 56 fondo piatto per 2,5 ml di sangue	*K2 EDTA in test tubes 12x56 for 2.5 ml of blood, lavender cap*
2001	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2002	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2003	Provette PP Ø12x86 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2003/L	K2 EDTA coloro lavanda (viola chiaro), in provette 12 x 86 cilindriche per 2,5 ml di sangue	*K2 EDTA in test tubes 12x86 for 2.5 ml of blood, lavender cap*
2004	Provette PP Ø12x86 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2004/L	K2 EDTA coloro lavanda (viola chiaro), in provette 12 x 86 cilindriche per 5 ml di sangue	*K2 EDTA in test tubes 12x86 for 5 ml of blood, lavender cap*
2005	Provette PP Ø13x75 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2005/L	K2 EDTA coloro lavanda (viola chiaro), in provette 13 x 75 cilindriche per 2,5 ml di sangue	*K2 EDTA in test tubes 13x75 for 2.5 ml of blood, lavender cap*
2007	Provette PP Ø16x100 mm., con K_2EDTA per 10 ml di sangue, tappo verde chiaro.	*PP test tubes Ø16x100 mm., with K_2EDTA for 10 ml of blood, light green cap.*
2008	Provette PP Ø13x75 mm., con K_2EDTA per 4 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 4 ml of blood, light green cap.*
2008/L	K2 EDTA coloro lavanda (viola chiaro), in provette 13 x 75 cilindriche per 4 ml di sangue	*K2 EDTA in test tubes 13x75 for 4 ml of blood, lavender cap*
2100	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2100/1	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo verde scuro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark green cap, for paediatric use.*
2100/1/V	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo viola, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark violet cap, for paediatric use.*
2100/1/V	Volume pediatrico ridotto - K3 EDTA in provette 12 x 56 fondo piatto per 1 ml di sangue - rack da 50 pezzi - Tappo viola	*K3 EDTA in test tubes 12x56 for 1 ml of blood, violet cap*
2100/TM	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, con tappo	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, with cap*
2100/V	K3 EDTA tappo VIOLA in provette 12 x 56 fondo piatto per 2,5 ml di sangue	*K3 EDTA in test tubes 12x56 for 2.5 ml of blood, violet cap*
2101	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2101/V	K3 EDTA tappo VIOLA in provette 16 x 60 fondo piatto per 2,5 ml di sangue	*K3 EDTA in test tubes 16x60 for 2.5 ml of blood, violet cap*
2102	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2102/V	K3 EDTA tappo VIOLA in provette 16 x 60 fondo piatto per 5 ml di sangue	*K3 EDTA in test tubes 16x60 for 5 ml of blood, violet cap*
2103	Provette PP Ø12x86 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2103/V	K3 EDTA tappo VIOLA in provette 12 x 86 cilindriche per 2,5 ml di sangue	*K3 EDTA in test tubes 12x86 for 2.5 ml of blood, violet cap*
2104	Provette PP Ø12x86 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2104/V	K3 EDTA tappo VIOLA in provette 12 x 86 cilindriche per 5 ml di sangue	*K3 EDTA in test tubes 12x86 for 5 ml of blood, violet cap*
2105	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, dark green cap. Quantity for box 1,000 pieces*
2105/TM	Provetta PP Ø13x75 mm, con K_3EDTA per 2,5ml di sangue, tappo viola.	*PP test tubes Ø13x75 mm, with K_3EDTA for 2,5ml of blood, violet cap.*
2105/V	K3 EDTA tappo VIOLA in provette 13 x 75 cilindriche per 2,5 ml di sangue	*K3 EDTA in test tubes 13x75 for 2.5 ml of blood, violet cap*
2105/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo viola	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, violet cap.*

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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
2107	Provette PP Ø16x100 mm., con K_3EDTA per 10 ml di sangue, tappo verde scuro.	*PP test tubes Ø16x100 mm., with K_3EDTA for 10 ml of blood, dark green cap.*
2107/V	K3 EDTA tappo VIOLA in provette 16 x 100 cilindriche per 10 ml di sangue	*K3 EDTA in test tubes 16x100 for 10 ml of blood, violet cap*
2108	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood, dark green cap.*
2108/5	Provette PP Ø13x75 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2108/TM	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2108/V	K3 EDTA tappo VIOLA in provette 13 x 75 cilindriche per 4 ml di sangue	*K3 EDTA in test tubes 13x75 for 4 ml of blood, violet cap*
2108/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2200	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2200/G	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo giallo.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, yellow cap.*
2200/G	KF+NA2 EDTA, tappo grigio, in provette 12 x 56 fondo piatto per 2,5 ml di sangue - rack da 50 pezzi	*KF+NA2 EDTA in test tubes 12x56 for 2.5 ml of blood*
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, tappo giallo.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 5 ml of blood, 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.*
2203/G	KF+NA2 EDTA, tappo grigio, in provette 12 x 86 cilindriche per 2,5 ml di sangue	*KF+NA2 EDTA in test tubes 12x86 for 2.5 ml of blood*
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.*
2204/G	KF+NA2 EDTA, tappo grigio, in provette 12 x 86 cilindriche per 5 ml di sangue	*KF+NA2 EDTA in test tubes 12x86 for 2.5 ml of blood*
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/G	KF+NA2 EDTA, tappo grigio, in provette 13 x 75 cilindriche per 2,5 ml di sangue - rack da 50 pezzi	*KF+NA2 EDTA in test tubes 13x75 for 2.5 ml of blood*
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.*
2208/G	KF+NA2 EDTA, tappo grigio, in provette 13 x 75 cilindriche per 4 ml di sangue	*KF+NA2 EDTA in test tubes 13x75 for 4 ml of blood*
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.*

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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 verde.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 4 ml of blood, green cap. Quantity for box 1,000 pieces*
2500	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500/1	Provette con K3 EDTA per 1,5 ml di sangue, per ematologia, tappo in gomma viola perforabile, ∅ 13 x 75 mm	*PP test tubes with K3 EDTA for 1.5ml of blood, with pierceable violet cap, Ø13 x 75 mm*
2500/N	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/N*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/SE	Provette in PP con K3 EDTA tappo perforabile verde, senza tappo	*PP test tubes Ø13x75 mm., with K_3EDTA, without cap, for 3 ml of blood.*
2500/SE/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue, senza etichetta.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood, without label*
2500/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*
2500/V*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*
2500/V/2	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 2 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood.*
2500/V/SG	Provette in PP con K3 EDTA sterili,tappo perf,viola	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood, sterile*
2501	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation.*
2501/B	Sodio Citrato 0,4ml, tappo BLU, in provette 16 x 60 fondo piatto	*Sodium citrate 0.4 ml in test tubes 16x60, blue cap*
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*
2502/B	Sodio Citrato 0,4ml, tappo BLU, in provette 12 x 86 cilindriche	*Sodium citrate 0.4 ml in test tubes 12x86, blue cap*
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.*
2505/1/B	Volume pediatrico ridotto - SODIO CITRATO 0,1 ml tappo BLU per COAGULAZIONE in provette 12 x 56 fondo piatto - rack da 50 pezzi	*Sodium citrate 0.1 ml in test tubes 12x56, blue cap*
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/B	Sodio Citrato 0,4ml, tappo BLU, in provette 13 x 75 cilindriche	*Sodium citrate 0.4 ml in test tubes 13x75, blue cap*
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.*
2511/B	Sodio Citrato 0,5 ml, tappo BLU, in provette 16 x 60 fondo piatto	*Sodium citrate 0.5 ml in test tubes 16x60, blue cap*
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/B	Sodio Citrato 0,5 ml, tappo BLU, in provette 12 x 86 cilindriche	*Sodium citrate 0.5 ml in test tubes 12x86, blue cap*
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.*

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2515/BLU	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo blu	*PP test tubes Ø113x75 mm., with Sodium Citrate 0,5 ml, blue 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/B	Sodio Citrato 0,25ml, tappo BLU, in provette 12 x 56 fondo piatto	*Sodium citrate 0.25 ml in test tubes 12x56, blue cap*
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.*
2521/B	Sodio Citrato 0,25ml, tappo BLU, in provette 16 x 60 fondo piatto	*Sodium citrate 0.25 ml in test tubes 16x60, blue cap*
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/B	Sodio Citrato 0,25ml, tappo BLU, in provette 12 x 86 cilindriche	*Sodium citrate 0.25 ml in test tubes 12x86, blue cap*
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.*
2525/B	Sodio Citrato 0,25ml, tappo BLU, in provette 13 x 75 cilindriche	*Sodium citrate 0.25 ml in test tubes 13x75, 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.*
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.*
2642	Provette con sodio citrato 0,4 ml per 1,6 ml di sangue, per VES, tappo nero, Ø13 x 75 mm	*PP test tubes with sodium citrate 0.4 ml, for 1.6 ml of blood, for ESR, black cap, Ø13x75 mm*
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/E/TBR	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso rosso	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, red low cap*

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2662/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2662/TM	in prov.16x100 in metacr. x 10 ml di sangue t/marrone	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2663/E/TB	Provette Ø13x75 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø13x75 mm, low cap*
2664/E/TB	Provette Ø12x86 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø12x86 mm, low cap*
2665/E	Provette Ø13 x 75 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm*
2665/E/TB	Provette Ø13 x 75 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2665/TB	gel separ.+acc. in prov.13x75 pmma per 5 ml sangue	*PMMA test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2666/E/TB	Provette Ø16 x 100 mm, in PP, con gel separatore + acceleratore, con etichetta, tappo basso	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2666/TB	gel separ.+acc.in prov.16x100 pp x 10 ml di sangue	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2668/E	Provette Ø12 x 86 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø12 x 86 mm*
2668/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap*
2668/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap, without label*
2678/E/TB	Provette con gel+acceleratore per 5ml di sangue, in PP,	#N/D
2700	Provette Ø13x75 mm in PP con 0,3ml di Sodio Citrato per coagulazione, tappo azzurro in gomma perforabile	*PP test tubes Ø13x75 mm with 0.3ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2700/2	Provette in PP tappo azzurro perforabile con 0,2 ml di	*PP test tubes Ø13x75 mm with 0.2ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2705	Provette in PP tappo blu con 0,35 ml di Sodio Citrato	*PP test tubes Ø13x75 mm with 0.35 ml of Sodium Citrate for coagulation, with blue cap*
2710	Provette Ø12x56 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x56 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2711	Provette Ø16x60 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø16x60 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2712	Provette Ø12x86 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x86 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2715	Provette Ø13x75 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø13x75 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
3553/E	Provette Ø16 x 100 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø16x100 mm*
3554/E	Provette Ø12 x 86 mm in PP, con acceleratore	*PP test tubes with clot accelerator, Ø12 x 86 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*
3775/E	Provette Ø13 x 75 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø13 x 75 mm*
3775/E/TB	Provetta Ø13 x 75 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separatine gel, Ø13 x 75 mm, low cap*
3776/E/TB	Provetta Ø16 x 100 mm. in PP, con gel separatore, tappo basso marrone	*PP test tubes with separatine gel Ø 16 x 100 mm, brown low cap.*
3776/TB	gel separatore in prov. 16x100 pp+etichetta x 10 ml di sangue	*PP test tubes with separatine gel Ø 16 x 100 mm, low cap.*
3778/E	Provette Ø12 x 86 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø12 x 86 mm*
3778/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separating gel, Ø12 x 86 mm, low cap*
4875/E	Provette Ø13 x 75 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E/TB	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/ETB	Provette con granuli + acc. per 5ml di sangue, in PP,	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/TR/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4878/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo azzurro	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light blue cap*
4878/TR/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo rosso	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light red cap*
4883/E	Provette Ø13 x 100 mm in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 100 mm*

APTACA S.p.A.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
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e-mail: info@aptaca.com
www.aptaca.com - www.vacuaptaca.it
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
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 Ø16 x 100 mm 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*

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

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

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

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

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

Settore IAF 14 - 29

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

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

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

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

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

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

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

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HOLTSCH 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 Counsel.

Taunusstein, November 17th , 2021

HOLTSCH Medizinprodukte GmbH

HOLTSCH
Medizinprodukte GmbH
In den Faltern 13 · 65232 Taunusstein

Malte Hertzberg
(Certified Biologist)

Zertifikat-Nr./Certificate no:
DE_SN_01_GMP_2016_0003

Aktenzeichen/Reference Number:
L24-5117/90

BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES HERSTELLERS MIT GMP

Teil 1

Ausgestellt nach einer Inspektion gemäß

• Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller
HOLTSCH Medizinprodukte GmbH

Anschrift der Betriebsstätte
HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Deutschland

• Sonstiges:
Der Hersteller wurde im Rahmen der nationalen Arzneimittelüberwachung inspiziert in Verbindung mit der Herstellungserlaubnis Nr. DE_SN_01_MIA_2012_0045 gemäß Art. 40 der Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch § 13 Abs. 1 Arzneimittelgesetz.

Aufgrund der aus der letzten Inspektion vom 27. November 2015 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

• den Grundsätzen und Leitlinien der Guten Herstellungspraxis gemäß
- Richtlinie 2003/94/EG

ergeben.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with

• Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the following:

The manufacturer
HOLTSCH Medizinprodukte GmbH

Site address
HOLTSCH Medizinprodukte GmbH
Leipziger Straße 300
01139 Dresden
Germany

• Other:
The manufacturer has been inspected under the national inspection programme in connection with manufacturing authorisation no. DE_SN_01_MIA_2012_0045 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Sec 13 para 1 Arzneimittelgesetz (German Drug Law).

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 27 November 2015, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

• the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

Dieses Zertifikat bestätigt den Status der Betriebsstätte zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten Inspektion mehr als drei Jahre vergangen sind. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt werden.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.

Teil 2

• Humanarzneimittel

1 HERSTELLUNGSTÄTIGKEITEN

- Die erlaubten Herstellungstätigkeiten umfassen vollständige und teilweise Herstellung (einschließlich verschiedener Prozesse wie Umfüllen, Abpacken oder Kennzeichnen), Chargenfreigabe und -zertifizierung, Lagerung und Vertrieb der genannten Darreichungsformen sofern nicht anders angegeben;

- Die Qualitätskontrolle und/oder Freigabe und/oder Chargenzertifizierung ohne Herstellungsschritte sollten unter den entsprechenden Punkten spezifiziert werden;

- Unter der relevanten Produktart und Darreichungsform sollte auch angegeben werden, wenn der Hersteller Produkte mit speziellen Anforderungen herstellt, z.B. radioaktive Arzneimittel oder Arzneimittel, die Penicilline, Sulfonamide, Zytostatika, Cephalosporine, Stoffe mit hormoneller Wirkung oder andere potenziell gefährliche Wirkstoffe enthalten (anwendbar für alle Bereiche des Teils 1 mit Ausnahme 1.5.2 und 1.6).

1.1 Sterile Produkte

1.1.3 Ausschließlich Chargenfreigabe

1.2 Nichtsterile Produkte

1.2.1 Nichtsterile Produkte

1.2.1.17 Andere nichtsterile Produkte
Alkoholtupfer

Part 2

• Human Medicinal Products

1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1 Sterile Products

1.1.3 Batch certification only

1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.17 Other non-sterile medicinal product
alcoholic pads

13. Januar 2016

FREISTAAT SACHSEN
LANDESDIREKTION SACHSEN

Name und Unterschrift des Bearbeiters der zuständigen Behörde

Klaus Hartmann
Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201

13 January 2016

Name and signature of the authorised person of the Competent Authority

Klaus Hartmann
Landesdirektion Sachsen
Referat 24, Pharmazie, GMP-Inspektorat
Braustraße 2
04107 Leipzig
Deutschland

Tel.: +49(0)351 825-2411
Fax: +49(0)351 825-9201

LANDESDIREKTION SACHSEN
09105 Chemnitz

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_SN_01_MIA_2012_0045/Nr. 6 / 24-5482.11/62
2. Name of authorisation holder	HOLTSCH Medizinprodukte GmbH
3. Address(es) of manufacturing site(s)	HOLTSCH Medizinprodukte GmbH Leipziger Straße 300 01139 Dresden
4. Legally registered address of authorisation holder	In den Faltern 13 65232 Taunusstein
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Edith Detlefsen
8. Signature	
9. Date	09/27/2012
10. Annexes attached	Annex 1 Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised)

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
HOLTSCH Medizinprodukte GmbH, Leipziger Straße 300, 01139 Dresden

Human Medicinal Products

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	**Sterile Products**
	1.1.3 Batch certification only
1.2	**Non-sterile products**
	1.2.1 Non-sterile products
	1.2.1.17 Other non-sterile medicinal product alcoholic pads

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This Authorisation is according with the site plans of manufacturing rooms with list of room numbers and classification dated 16 July,2009.

Address(es) of Contract Laboratories	Li-iL GmbH Arzneimittel Arzneibäder Leipziger Strasse 300 01139 Dresden - total quality control without sterility and microbiological testing
	SGS Institut Fresenius GmbH Im Maisel 14 65232 Taunusstein - Sterility Testing in accordance with Pharm Europ. 2.6.1 - Microbiological Testing non-steril products in accordance with Pharm Europ. 2.6.12 Total viable aerobic count of non-sterile intermediate

Name(s) of Qualified Person(s)	Mrs. Dr. Karin Beck-Piotraschke
	Mr. Malte Hertzberg

Date of Inspection on which authorisation was granted	09/01/2011
Scope of last Inspection	Quality Management, Personnel, Premises and Equipment, Documentation, Contract Manufactore and Analysis, Complaints and Product Recall, Self Inspection

Annex 8

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Quickpad® Tupfer

FREISTAAT SACHSEN LANDESDIREKTION SACHSEN

***HOLTSCH* Medizinprodukte GmbH**
D 65323 Taunusstein • Germany

To whom it may concern

The product line of our swab dispenser is ruled differently according to the claim which is posted on the product. In Germany both is possible.
It depends on the claim you choose. If the claim is for **disinfecting** the skin before an injection, etc, it is ruled by the **AMG** (German Drug Law). If we sell Quickpad just for **cleaning** the skin Quickpad is ruled as a **cosmetic** (for example like make up remover).

We produce and sell „Quickpad" in Germany under the regulations of the German Drug Law (Arzneimittelgesetz **AMG**).
The European market and the European regulations (i.e. Guideline-for medical items-93/42/EWG), are converted in Germany into the Medizinproduktegesetz (**MPG**).

There is a difference between these two regulations.
The **AMG** (strictly national) covers all products which have a pharmaceutical effect.
The **MPG** covers all products which are not drugs but support drugs or have a **physical** (not a pharmaceutical) effect, like for example our tourniquet. The MPG fulfils the guideline 93/42/EWG. MPG, items have to bear the CE signet.

As mentioned before it depends on the claim you choose. If the claim is for disinfecting the skin before an injection, etc., it is a drug and ruled by the AMG. For this reason we have the permission to produce and to market this product under AMG (CE-signet is not possible in this case). The product has to be labeled strictly with the original HOLTSCH label

If your claim is for **cleaning** the skin, it is considered as a cosmetic item and is ruled by the cosmetic act and has no CE signet and no special permission as per the AMG is necessary. This is also possible in Germany.

Most of our customers do not declare Quickpad as a drug because they might run through some kind of registration with their ministry of health. They prefer to use Quickpad like a cosmetic and as explained above there is no possibility of a CE-signet on the product.
Maybe the regulations in other countries are different.

If so, please let us know.

Taunsstein, September 07, 2021

Malte Hertzberg
Qualified Person AMG

HOLTSCH MED

Quality. Safety. Trust.

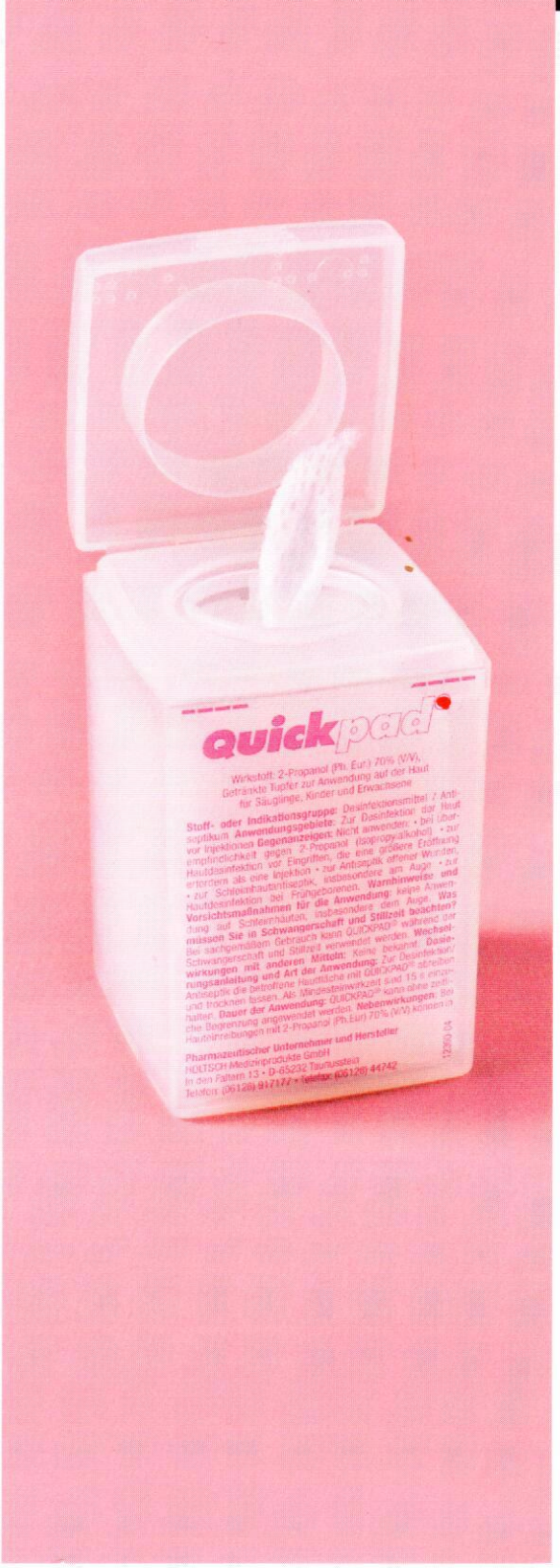
Quickpad

The Quickpad alcohol swab dispenser, being sterile and physiologically verified as harmless, is ideal for cleaning and disinfecting the skin.

The active agent 2 propanol acts as an effective, "mild on skin" disinfecting agent. The "swab tear-off" ready to use system allows for the single use of the swab. This makes Quickpad not only economical but also efficient in its use.

The lid of the Quickpad alcohol swab dispenser container seals air-tight, keeping the alcohol swabs moist and sterile. As a result, the swab dispenser has a particularly long shelf life of 24 months.

Quickpad is supplied ready for use and with its simple operation, can be used by specialists as well as patients for cleaning/ disinfecting the skin. An ideal product for diabetics and other users of self-injection syringes. Additionally, it is always possible through the transparent container to see the fill level and it is suitable for self-application by the patient.



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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

от 05 ноября 2009 года

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

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

вид медицинского изделия –

соответствующее регистрационному досье № 67875 от 22.09.2009

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

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

Приложение: на 1 листе

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

0001849

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

Лист 1

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

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

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

05 ноября 2009 года

0001890

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
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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.

4426

Authorized by

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

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

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LORNE LABORATORIES LTD.

GREAT BRITAIN

CE 1434

MONOSPECIFIC ANTI-HUMAN GLOBULIN REAGENT (RABBIT)

DIRECTIONS FOR USE

Anti-Human IgG (Clear or Green): For Antiglobulin Techniques.

SUMMARY

In 1945, Coombs, Mourant and Race described the use of anti-human globulin serum for detecting red cell-bound non-agglutinating antibodies.

INTENDED PURPOSE

These reagents are monospecific blood grouping reagents intended to be used to qualitatively detect the presence or absence of sensitising IgG antibodies (all 4 subclasses) on human red cells when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

The reagents contain antibodies against human IgG antibodies on human red cells and will cause direct agglutination (clumping) of red cells that are sensitised with human IgG antibodies. No agglutination generally indicates the absence of sensitising human IgG antibodies on human red cells (See **Limitations**).

REAGENTS

Lorne Monospecific Anti-Human IgG Clear and Anti-Human IgG Green reagents contain anti-IgG derived from rabbits. All non-specific activity is removed by adsorption. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. The reagents are supplied at optimal dilution, for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see **Vial Label**.

Reagent	Cell Line/Clone	Colour	Dye Used
Anti-Human IgG Clear	Rabbit Anti-Human IgG	Colourless	None
Anti-Human IgG Green	Rabbit Anti-Human IgG	Green	Patent Blue and Tartrazine

STORAGE

Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37ºC and –25ºC as described in document EN13640:2002.

SAMPLE COLLECTION AND PREPARATION

Samples should be drawn aseptically into EDTA and tested as soon as possible. If EDTA is unavailable, samples drawn into ACD, CPD or CPDA-1 are preferable to clotted ones. If only clotted samples are available, do not refrigerate them before testing. All blood samples should be washed at least twice with PBS or Isotonic saline before being tested.

PRECAUTIONS

1. The reagents are intended for *in vitro* diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagents past the expiration date (see **Vial Label**).
4. Do not use the reagents if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagents have been filtered through a 0.2 µm capsule to reduce the bio-burden, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagents contain < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. Materials used to produce the products were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagents and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended a positive control (weak Anti-D <0.1 IU/ml) and a negative control (an inert serum) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
3. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
4. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
5. The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
6. The user must determine the suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED BUT NOT SUPPLIED

- Coombs cell washer.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells i.e. Lorne Coombs Control Cells (Cat # 970010).
- Inert antibody i.e. Lorne Inert AB Serum (Cat # 110010).
- Low Ionic Strength Solution (LISS): Containing 0.03M NaCl, 0.003M Na_2HPO_4: NaH_2PO_4 buffer pH 6.7 at 22ºC ± 1ºC and 0.24M glycine.
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC.
- Weak anti-D i.e. Lorne Precise Weak Anti-D (Cat # 209005).

RECOMMENDED TECHNIQUES

A. Direct Antiglobulin Technique (DAT)

1. Wash test red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each cell button after each wash. Completely decant saline after last wash.
2. Add 2 volumes of Lorne Anti-IgG to each dry cell button.
3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination

B. Indirect Antiglobulin Technique (NISS IAT)

1. Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 2 volumes of test serum and 1 volume of test red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Wash test red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
5. Add 2 volumes of Lorne Anti-IgG to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination

C. LISS Indirect Antiglobulin Technique (LISS IAT)

1. Prepare a 1.5-2% suspension of washed test red cells in LISS.
2. Place in a labelled test tube: 2 volumes of test serum and 2 volumes of test red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Follow steps 4 to 7 of **NISS IAT** above.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of test red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates the presence of IgG on the test red cells.
2. **Negative:** No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of IgG on the test red cells.

STABILITY OF THE REACTIONS

1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those **recommended**.

LIMITATIONS

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the **Indirect Antiglobulin Techniques**.
2. Inadequate washing of red cells in the indirect antiglobulin technique may result in neutralisation of the anti-human globulin reagent.

3. A positive DAT due to complement sensitisation may not reflect *in vivo* complement fixation if test cells are from a refrigerated clotted sample.
4. A negative direct antiglobulin test result does not necessarily preclude clinical diagnosis of ABO Haemolytic Disease of the Newborn or Auto Immune Haemolytic Anaemia. It also does not necessarily rule out HDN, especially if ABO incompatibility is suspected.
5. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each lot of these reagents were tested using the recommended test methods listed in this IFU against red cells coated with Anti-D, Anti-K and Anti-Fy^{a} to check suitable reactivity. The tests complied with the test requirements as stated in the current version/issue of the "Guidelines for the Blood Transfusion Services in the United Kingdom".
2. The anti-IgG potency has been tested against the following minimum potency reference standard obtained from National Institute of Biological Standards and Controls (NIBSC):
   - Anti-AHG reference standard 96/666
3. The reactivity of any Anti-IgM, Anti-IgA or Anti-light chain components that might be present has not been established.
4. The Quality Control of the reagents was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use[6].

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AVAILABLE REAGENT SIZES

	Vial Size	Catalogue Number	Tests per vial
Lorne Anti-Human IgG (Clear)	10 ml	401010	100
	1000 ml	401000*	10,000
Lorne Anti-Human IgG (Green)	10 ml	402010	100
	1000 ml	402000*	10,000

***This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.**

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ANTI-HUMAN GLOBULIN (AHG)

LORNE LABORATORIES

CE 1434

DIRECTIONS FOR USE

AHG Elite (Clear or Green): For Antiglobulin Techniques.

SUMMARY

In 1945, Coombs, Mourant and Race described the use of anti-human globulin serum for detecting red cell-bound non-agglutinating antibodies. In 1957, Dacie et al showed that the antibodies present in antiglobulin sera were directed against certain components of complement. Anti-human globulin reagents detect non-agglutinating antibody molecules as well as molecules of complement attached to red cells following in vivo or in vitro antigen-antibody reactions.

INTENDED PURPOSE

These reagents are polyspecific blood grouping reagents intended to be used to qualitatively detect the presence or absence of sensitising IgG antibodies (all 4 subclasses) and compliment factors C3d and C3b on human red cells when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

The reagents contain antibodies against human IgG antibodies and C3 complement factors (C3d and C3b) on human red cells and will cause direct agglutination (clumping) of red cells that are sensitised with human IgG antibodies and/or C3 complement factors (C3d and C3b). No agglutination generally indicates the absence of sensitising human IgG antibodies and C3 complement factors (C3d and C3b) on human red cells (See **Limitations**).

REAGENT

Lorne AHG Elite Clear and AHG Elite Green reagents contain anti-IgG derived from rabbits with non-specific activity removed by adsorption and mouse monoclonal IgM anti-C3d, Clone BRIC-8. The antibodies are diluted in a buffered solution containing bovine albumin. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. Each reagent is supplied at optimal dilution, for use with all the recommended techniques stated below without need for further dilution or addition. For lot reference number and expiry date see Vial Label.

Reagent	Cell Line/Clone	Colour	Dye Used
AHG Elite Clear	Rabbit Anti-Human IgG BRIC-8 (Anti-C3d)	Colourless	None
AHG Elite Green	Rabbit Anti-Human IgG BRIC-8 (Anti-C3d)	Green	Patent Blue and Tartrazine

STORAGE

Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37ºC and –25ºC as described in document BS EN ISO 23640:2015.

SAMPLE COLLECTION AND PREPARATION

Samples should be drawn aseptically into EDTA to prevent in vitro complement binding and tested as soon as possible. If EDTA is unavailable, samples drawn into ACD, CPD or CPDA-1 are preferable to clotted ones. If only clotted samples are available, do not refrigerate them before testing.

PRECAUTIONS

1. The reagents are intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagents past the expiration date (see Vial Label).
4. Do not use the reagents if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagents have been filtered through a 0.2 μm capsule to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagents contain < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. Materials used to produce the products were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagents and decontamination of a spillage site see Material Safety Data Sheets, available on request.

CONTROLS AND ADVICE

1. It is recommended a positive control (weak Anti-D <0.1 IU/ml) and a negative control (an inert serum) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
3. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
4. In the Recommended Techniques one volume is approximately 50μl when using the vial dropper provided.
5. Use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with requirements of the country where the reagents are in use. User must determine the suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Coombs cell washer.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells e.g. Lorne Coombs Control Cells (Cat # 970010).
- Inert antibody e.g. Lorne Inert AB Serum (Cat # 110010).
- Low Ionic Strength Solution (LISS): Containing 0.03M NaCl, 0.003M Na2HPO4: NaH2PO4 buffer pH 6.7 at 22ºC ± 1ºC and 0.24M glycine.
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC.
- Weak anti-D e.g. Lorne Precise Weak Anti-D (Cat # 209005).

RECOMMENDED TECHNIQUES

A. Direct Antiglobulin Technique (DAT)

1. Wash 1 volume of red cells (2–3% suspension in PBS or Isotonic saline) 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each cell button after each wash. Completely decant saline after last wash.
2. Add 2 volumes of Lorne AHG Elite to each dry cell button.
3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination

B. Indirect Antiglobulin Technique (NISS IAT)

1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 2 volumes of test serum and 1 volume of red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Wash red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
5. Add 2 volumes of Lorne AHG Elite to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination

C. LISS Indirect Antiglobulin Technique (LISS IAT)

1. Prepare a 1.5-2% suspension of red cells in LISS.
2. Place in a labelled test tube: 2 volumes of test serum and 2 volumes of red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Follow steps 4 to 7 of NISS IAT above.

INTERPRETATION OF TEST RESULTS

1. Positive: Agglutination of test red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates the presence of IgG and/or complement (C3d/C3b) on the red cells.
2. Negative: No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of IgG and complement (C3d/C3b) on the red cells.

STABILITY OF THE REACTIONS

1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the Indirect Antiglobulin Techniques.
2. A positive DAT due to complement sensitisation may not reflect in vivo complement fixation if test cells are from a refrigerated clotted specimen.
3. Inadequate washing of red cells in the indirect antiglobulin techniques may neutralise the AHG reagent.
4. Following completion of the wash phase excess residual saline may dilute the AHG Elite, reducing its potency.
5. A negative direct antiglobulin test result does not necessarily preclude clinical diagnosis of ABO Haemolytic Disease of the Newborn or Auto Immune Haemolytic Anaemia. It also does not necessarily rule out HDN, especially if ABO incompatibility is suspected.
6. False positive or false negative results may also occur due to:

- Contamination of test materials
- Improper storage, cell concentration, incubation time or temperature
- Improper or excessive centrifugation

SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each lot of the reagents were tested using the recommended test methods listed in this IFU against red cells coated with Anti-D, Anti-K and Anti-FyA to check suitable reactivity. The tests complied with the test requirements as stated in the current version/issue of the 'Guidelines for the Blood Transfusion Services in the United Kingdom'.
2. The anti-IgG and anti-C3d potencies have been tested against the following minimum potency reference standard obtained from the National Institute of Biological Standards and Controls (NIBSC): Anti-AHG reference standard 96/666
3. Anti-C3d potency is demonstrated in tests employing cells coated with C3d and C3b.
4. The presence of contaminating heterospecific agglutinins or antibodies to C4d has been excluded in tests employing red cells of all ABO groups and cells coated with C4d.
5. The reactivity of any Anti-IgM, Anti-IgA or Anti-light chain components that might be present has not been established.
6. The Quality Control of the reagents was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use[12].

BIBLIOGRAPHY

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AVAILABLE REAGENT SIZES

	Vial Size	Catalogue Number	Test Per Vial
Lorne AHG Elite	10 ml	415010	100
(Clear)	1000 ml	415000*	10,000
Lorne AHG Elite	10 ml	435010	100
(Clear)	1000 ml	435000*	10,000

*These sizes are For Further Manufacturing Use (FFMU) only and are therefore not CE marked.

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MONOCLONAL BLOOD GROUPING REAGENTS.

LORNE LABORATORIES

CE 1434

DIRECTIONS FOR USE

Anti-D Duoclone Monoclonal:

For Tube, Bio-Rad-ID, Ortho BioVue, Microplate and Slide Techniques.

SUMMARY

The Rh blood group system was discovered in 1940. The D antigen is the most clinically significant non-ABO red blood cell antigen and has been implicated in causing Haemolytic Transfusion R eactions and Haemolytic Disease of the Newborn.

Anti-D	Phenotype	Caucasians %[3]	Afro-Americans %[3]
+	Rh D +ve	83	92
0	Rh D -ve	17	8

INTENDED PURPOSE

The Anti-D reagents are blood grouping reagents intended to be used to qualitatively determine the presence or absence of the Rh D antigen on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

The reagents contain antibodies against the D antigen on human red cells and will cause direct agglutination (clumping) of human red cells that carry the D antigen and indirect agglutination of human red cells that are Category D^{vi} in the antiglobulin phase of testing. No agglutination (no clumping) generally indicates the absence of the D antigen on human red cells (see **Limitations**).

REAGENT

Lorne Monoclonal Anti-D Duoclone blood grouping reagent is a low protein, blended reagent containing a human monoclonal IgM and IgG anti-D, diluted in a phosphate buffer containing sodium chloride (0.9 g%), bovine albumin (2.0 g%) and macromolecular potentiators (1.5 g%). When typing patient samples, this reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{vi}) and a high proportion of weak D (D^{u}) phenotypes when using the recommended techniques. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. The reagent is supplied at optimal dilution for use on patient samples with all recommended techniques stated below without need for further dilution or addition. For lot reference number and expiry date see Vial Label.

IgM / IgG	Cell Line / Clone
IgM	RUM-1
IgG	MS-26

WEAKENED EXPRESSION OF THE RhD ANTIGEN

The collective term D^{u} is widely used to describe red cells which have a weaker expression of the D antigen than normal. The term weak D denotes individuals with a reduced number of complete D antigen sites per red cell. The term partial D denotes individuals with missing D antigen epitopes. D^{vi} is a partial D category which misses most D epitopes. Duoclone reagent will detect most examples of partial and weak D red cells by direct agglutination, but will not detect D^{vi} cells. This reagent will detect D^{vi} and partial D cells in the IAT phase.

STORAGE

Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37ºC and –25ºC as described in document BS EN ISO 23640:2015.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulant or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8ºC. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable (but not essential) to wash all blood samples with PBS or Isotonic saline before being tested.

PRECAUTIONS

1. The reagent is intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see Vial Label).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 μm capsule to reduce the bio-burden, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagent contains <0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see Material Safety Data Sheets, available on request.

CONTROLS AND ADVICE

1. It is recommended that a positive control (ideally R1r cells) and a negative control (ideally rr cells) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. When typing red cells from a patient who is diagnosed with a disease that causes the red cells to become coated with antibody or other proteins (such as HDN, AIHA), it is important to test the patient's red cells using Lorne's reagent negative control (Monoclonal D Negative Control, catalogue # 650010). Tests must be considered invalid if red cells are agglutinated using Lorne's Monoclonal D Negative Control (catalogue # 650010).
3. Test samples for category D^{vi} determination by the Indirect Antiglobulin Test, Coombs Bio-Rad-ID and Coombs Ortho BioVue Techniques only.
4. Weak and variant D antigens are poorly detected by gel card, microtitre plate and slide techniques. It is recommended that weak and partial variants are tested using the tube test technique.
5. The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
6. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
7. In the Recommended Techniques one volume is approximately 50μl when using the vial dropper provided.
8. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
9. The user must determine suitability of reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Anti-human globulin e.g. Lorne AHG Elite (Cat # 435010) or Anti-Human IgG e.g. Lorne Anti-Human IgG (Cat # 402010).
- Applicator sticks.
- Automatic plate reader.
- Coombs cell washer.
- Bio-Rad ID-Cards (LISS/Coombs) and (NaCl, enzyme test and cold agglutinins).
- Bio-Rad ID-Centrifuge.
- Bio-Rad ID-CellStab or ID-Diluent 2.
- Bio-Rad ID-Incubator equilibrated to 37ºC ± 2ºC.
- Glass microscope slides or white card tiles.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells e.g. Lorne Coombs Control Cells (Cat # 970010).
- Microplate centrifuge.
- Ortho BioVue System Cassettes (AHG/Coombs) and (Neutral).
- Ortho BioVue System Centrifuge.
- Ortho BioVue System Heat Block equilibrated to 37ºC ± 2ºC.
- Ortho 0.8% Red Cell Diluent.
- Plate shaker.
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Positive (ideally R,r) and negative (rr) control red cells.
- Test tube centrifuge.
- Validated "U" well microplates.
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC.

RECOMMENDED TECHNIQUES (NOT CATEGORY D^{vi})

A. Tube Technique

1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume of Lorne Duoclone reagent and 1 volume of red cell suspension.
3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination
5. Any tubes, which show a negative or questionable result (which can happen with D^{u} or weak D samples), should be incubated for 15 minutes at room temperature.
6. Following incubation, repeat steps 3 and 4.

B. Bio-Rad-ID Technique (NaCl, enzyme test and cold agglutinins cards)

1. Prepare a 0.8% suspension of red cells in ID-CellStab or ID-Diluent 2.
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50μl test red cell suspension and 25μl Lorne Duoclone reagent.
4. Centrifuge the ID-Card(s) in a Bio-Rad gel card centrifuge.
5. Read macroscopically for agglutination.

C. Ortho BioVue Technique (Neutral cards)
1. Prepare a 0.8% suspension of red cells in 0.8% Ortho Red Cell Diluent
2. Remove aluminium foil from as many reaction chambers as needed.
3. Place in appropriate reaction chamber: 50µl of red cell suspension and 40µl of Lorne Duoclone reagent.
4. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
5. Read macroscopically for agglutination.

D. Microplate Technique, using "U" wells
1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in the appropriate well: 1 volume of Lorne Duoclone reagent and 1 volume of red cell suspension.
3. Mix thoroughly, preferably using a microplate shaker, taking care to avoid cross-well contamination.
4. Incubate at room temperature for 15 minutes (time dependant on user).
5. Centrifuge the microplate for 1 minute at 140 rcf or for a suitable alternative time and force.
6. Resuspend the cell buttons using carefully controlled agitation on a microplate shaker
7. Read macroscopically or with a validated automatic reader.
8. Any weak reactions should be repeated by the tube technique.

E. Slide Technique
1. Prepare a 35-45% suspension of red cells in serum, plasma or PBS or Isotonic saline or use anti-coagulated whole blood (in it's own plasma).
2. Place on a labelled glass slide or card tile: 1 volume of Lorne Duoclone reagent and 1 volume of red cell suspension.
3. Using a clean applicator stick, mix reagent and cells over an area of about 20 x 40 mm.
4. Slowly tilt the slide back and forth for 30 seconds, with occasional further mixing during the 1 minute period, maintaining slide at room temperature.
5. Read macroscopically after 1 minute over a diffuse light and do not mistake fibrin strands as agglutination.
6. Any weak reactions should be repeated by the tube technique.

RECOMMENDED TECHNIQUES (TO DETECT CATEGORY DVI)

A. Indirect Antiglobulin Technique (IAT)
1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume of Lorne Duoclone and 1 volume of red cell suspension.
3. Mix thoroughly and incubate at 37ºC for 15 minutes.
4. Wash red cells at least once with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each cell button after each wash. Completely decant saline after last wash.
5. Add 2 drops of AHG or anti-IgG to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf for a suitable alternative time and force.
7. Resuspend each cell button and read macroscopically.
8. Confirm validity of all negative reactions with IgG sensitised red cells.

B. Bio-Rad-ID Technique (LISS/Coombs cards)
1. Prepare 0.8% suspension of red cells in ID-CellStab or ID-Diluent 2.
2. Remove aluminium foil from as many microtubes as needed.
3. Place in appropriate microtube: 50µl of red cell suspension and 25µl of Lorne Duoclone.
4. Incubate the ID-Card(s) for 15 minutes at 37ºC.
5. Centrifuge the ID-Card(s) in a Bio-Rad gel card centrifuge.
6. Read macroscopically for agglutination.

C. Ortho BioVue Technique (AHG/Coombs cards)
1. Prepare a 0.8% suspension of red cells in 0.8% Ortho Red Cell Diluent.
2. Remove aluminium foil from as many reaction chambers as needed.
3. Place in appropriate reaction chamber: 50µl of red cell suspension and 40µl of Lorne Duoclone.
4. Incubate the cassette(s) for 15 minutes at 37ºC.
5. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
6. Read macroscopically for agglutination.

INTERPRETATION OF TEST RESULTS
1. Positive: Agglutination of the red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the D antigen on the test red cells.
2. Negative: No agglutination of the red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the D antigen on the test red cells.
3. Test results of cells that are agglutinated using the reagent negative control shall be excluded, as the agglutination is most probably caused by the effect of the macromolecular potentiators in the reagent on sensitised cells.

STABILITY OF THE REACTIONS
1. Read all tube and microplate tests immediately after centrifugation.
2. Complete washing steps without interruption and centrifuge and read tests immediately after addition of anti-human globulin because delays may result in dissociation of antigen-antibody complexes, leading to false negative or weak positive reactions.
3. Slide tests should be interpreted after a maximum of 1 minute to ensure specificity and to avoid the possibility a negative result may be incorrectly interpreted as positive due to drying of the reagent.
4. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS
1. Lorne Anti-D is not suitable for use with enzyme treated cells or cells suspended in LISS.
2. The use of solutions for making red cell suspensions other than those described in the "Recommended Techniques" sections in the document must be validated prior to use. Some solutions may give rise to false positive or false negative reactions.
3. Stored blood may give weaker reactions than fresh blood.
4. False positive agglutination may be seen when testing IgG sensitised cells.
5. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS
1. Prior to release, each lot of Lorne Anti-D Duoclone monoclonal reagent was tested using the recommended test methods listed in this IFU. The tests complied with the test requirements as stated in the current version/issue of the 'Guidelines for the Blood Transfusion Services in the United Kingdom' and the 'Common Technical Specifications'.
2. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
3. The potency of the reagent has been tested against the following minimum potency reference standard obtained from National Institute of Biological Standards and Controls (NIBSC): Anti-D reference 99/836.
4. The Quality Control of the reagent was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

DISCLAIMER
1. The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use[5].

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5. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationery Office.
6. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, 5, 145-150.

AVAILABLE REAGENT SIZES

Vial Size	Catalogue Number	Tests Per Vial
10 ml	740010	200
1000 ml	740000*	20,000
5000 ml	740000X5*	100,000

*This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.

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CERTIFICATE OF REGISTRATION

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REPs Facility ID: F001410

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

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
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Certificate Number	1459.200523	Effective Date	May 23, 2020
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REPs Facility ID: **F001410**

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Brazil:
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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Зарегистрирована в едином реестре систем добровольной сертификации
Регистрационный № РОСС RU.31763.04ЖОЭ2

Рег. № VCS-IST.OS3.RU.0001.02.15
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СЕРТИФИКАТ СООТВЕТСТВИЯ

Рег. № VCS-IST.SS.RU.0215.04.20

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО
СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА
МЕДИЦИНСКИХ ИЗДЕЛИЙ
СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ

ГОСТ ISO 13485-2017 (ISO 13485:2016)

СЕРТИФИКАТ ВЫДАН

ООО «Медиклон»
Адрес: 127276 Москва, Ботаническая ул, дом 35
ИНН 7719191607 ОГРН 1027700153766

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:

Малиновский Э.Г.

Эксперт:

Анафиев А.Р.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМ СТАНДАРТОМ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «МТС» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ИНСПЕКЦИОННОГО КОНТРОЛЯ

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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Приложение № 1
к сертификату соответствия **Рег. № VCS-IST.SS.RU.0215.04.20**

Область сертификации системы менеджмента качества:

21.20.2 Производство материалов, применяемых в медицинских целях

Руководитель органа:

Малиновский Э.Г.

Эксперт:

Анафиев А.Р.

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
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Викторов Николай Александрович

Соответствует требованиям СДС «МТС» предъявляемым к

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по направлению
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Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:

Малиновский Э.Г.

Эксперт:

Анафиев А.Р.

Сертификат выдан на основании решения комиссии в системе добровольной сертификации «Международные Технологии Стандартизации» от 27.04.2020
Зарегистрирован в Реестре аудиторов внутренних проверок системы добровольной сертификации «Международные Технологии Стандартизации» Протокол № 04 от 28.04.2020

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«МЕЖДУНАРОДНЫЕ ТЕХНОЛОГИИ СТАНДАРТИЗАЦИИ»
Зарегистрирована в едином реестре систем добровольной сертификации
Регистрационный № РОСС RU.31763.04ЖОЭ2

Рег. № VCS-IST.OS3.RU.0001.02.15
Орган по сертификации ООО «Парадигма»
Адрес: 191014, г. Санкт-Петербург, Басков пер., д. 13-15, лит. А, пом. 42 Н
тел: 8 (812) 425-34-39 iso.sds@mail.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ ПЕРСОНАЛА

Рег. № VCS-IST.SS.RU.1140.04.20

Настоящий сертификат удостоверяет, что

Ерышев Роман Михайлович

Соответствует требованиям СДС «МТС» предъявляемым к

ВНУТРЕННИМ АУДИТОРАМ

по направлению
ГОСТ ISO 13485-2017 (ISO 13485:2016)
Настоящий сертификат предоставляет право на проведение внутренних проверок системы менеджмента качества продукции медицинского назначения

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:

Малиновский Э.Г.

Эксперт:

Анафиев А.Р.

Сертификат выдан на основании решения комиссии в системе добровольной сертификации «Международные Технологии Стандартизации» от 27.04.2020
Зарегистрирован в Реестре аудиторов внутренних проверок системы добровольной сертификации «Международные Технологии Стандартизации» Протокол № 04 от 28.04.2020

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«МЕЖДУНАРОДНЫЕ ТЕХНОЛОГИИ СТАНДАРТИЗАЦИИ»
Зарегистрирована в едином реестре систем добровольной сертификации
Регистрационный № РОСС RU.31763.04ЖОЭ2

Рег. № VCS-IST.OS3.RU.0001.02.15
Орган по сертификации ООО «Парадигма»
Адрес: 191014, г. Санкт-Петербург, Басков пер., д. 13-15, лит. А, пом. 42 Н
тел: 8 (812) 425-34-39 iso.sds@mail.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ ПЕРСОНАЛА

Рег. № VCS-IST.SS.RU.1141.04.20

Настоящий сертификат удостоверяет, что

Ющенко Кристина Валерьевна

Соответствует требованиям СДС «МТС» предъявляемым к

ВНУТРЕННИМ АУДИТОРАМ

по направлению
ГОСТ ISO 13485-2017 (ISO 13485:2016)
Настоящий сертификат предоставляет право на проведение внутренних проверок системы менеджмента качества продукции медицинского назначения

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Руководитель органа:

Малиновский Э.Г.

Эксперт:

Анафиев А.Р.

Сертификат выдан на основании решения комиссии в системе добровольной сертификации «Международные Технологии Стандартизации» от 27.04.2020
Зарегистрирован в Реестре аудиторов внутренних проверок системы добровольной сертификации «Международные Технологии Стандартизации» Протокол № 04 от 28.04.2020

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«МЕЖДУНАРОДНЫЕ ТЕХНОЛОГИИ СТАНДАРТИЗАЦИИ»
Зарегистрирована в едином реестре систем добровольной сертификации
Регистрационный № РОСС RU.31763.04ЖОЭ2

Рег. № VCS-IST.OS3.RU.0001.02.15
Орган по сертификации ООО «Парадигма»
Адрес: 191014, г. Санкт-Петербург, Басков пер., д. 13-15, лит. А, пом. 42 Н
тел: 8 (812) 425-34-39 iso.sds@mail.ru

РАЗРЕШЕНИЕ

Рег. № VCS-IST.SS.RU.0215.04.20

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ
СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»

РАЗРЕШЕНИЕ ВЫДАНО

ООО «Медиклон»
Адрес: 127276 Москва, Ботаническая ул, дом 35
ИНН 7719191607 ОГРН 1027700153766

НА ОСНОВАНИИ СЕРТИФИКАТА
Рег. № VCS-IST.SS.RU.0215.04.20

Дата выдачи: 28.04.2020

Срок действия до: 28.04.2023

Условия применения Знака соответствия:
Фирменные бланки предприятия, договоры, рекламные и печатные издания

Руководитель органа _____ Малиновский Э.Г.

SYSTEM OF INTERNATIONAL CERTIFICATION

CERTIFICATE

of Quality Management System
SIC.MS.094.ISO13485.1332 dated 11.03.2020 till 10.03.2023
The Certification Center "International Agency Certification" hereby certifies that the Quality Management System of

«Mediclone»
Limited Liability Company

35, Botanicheskaya, Moscow, Russian Federation, 127276

Concerning:

production of medical devices, namely: Reagents and sets of reagents for the determination of human blood groups of ABO Rhesus and Kell systems, as well as antigens and antibodies of the Rhesus system

EN ISO 13485:2016

"Medical devices. Quality management systems. Requirements for regulatory purposes"

Date of Certification: 11.03.2020
Date of Expiry: 10.03.2023

subject to annual approval
2021 г. – till 11.02.2021
2022 г. – till 11.02.2022

Head of certification Body T. Pogrebnaya

ISO 13485 CERTIFIED

SIC.MS.094.ISO13485.1332

International Certification Agency, 109444, Russian Federation, Moscow, 10 Samarkandsky blvd., Bldg. 1, Apt. 62,
Tel./fax: +8 (903) 223-25-69, Notification letter **SIC.02.094**,
S.I.C. Global Inc., 346 WIGSTON DR, Suite 4, NORTH BAY, ONTARIO, P1A 1X3, CANADA http://sic-global.com

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

ISO 13485 CERTIFIED

SIC.MS.094.ISO13485.1332

ОС «Международное Агентство Сертификации», свидетельство Нотификации:
SIC.CB.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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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(IgM) антитела 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 2009г.

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

Серия: 221511 **Единица:** 100 мл

Изготовлен: 07.11.2022 **Количество единиц** 50

Годен до: 07.11.2024 **Объем серии:** 10000 мл.

Паспорт: А221511 от 07.11.2022

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

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

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

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

Цоликлон анти – А – моноклональные(IgM) антитела 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 2009г.

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

Серия: 221410 **Единица:** 100 мл

Изготовлен: 10.10.2022 **Количество единиц** 50

Годен до: 10.10.2024 **Объем серии:** 10000 мл.

Паспорт: В221410 от 10.10.2022

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

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

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

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

Цоликлон анти – А – моноклональные(IgM) антитела 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 2009г.

Наименование: Цоликлон Анти-АВ

Серия: 023411 **Единица:** 100 мл

Изготовлен: 21.11.2022 **Количество единиц** 19

Годен до: 21.11.2024 **Объем серии:** 10000 мл.

Паспорт: АВ023411 от 21.11.2022

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

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

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

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

(ЦОЛИКЛОН Анти-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: 228711 **Единица:** 100 мл

Изготовлен: 07.11.2022 **Количество единиц** 30

Годен до: 07.11.2024 **Объем серии:** 10000 мл.

Паспорт: Дс228711 от 07.11.2022

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

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

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

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

Наименование: Цоликлон Анти-Kell Супер

Серия: 120810 **Единица:** 100 мл

Изготовлен: 24.10.2022 **Количество единиц** 15

Годен до: 24.10.2024 **Объем серии:** 10000 мл.

Паспорт: К120810 от 24.10.2022

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

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
(ЦОЛИКЛОНЫ Анти-А I и Анти-Асл)

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

Наименование: Цоликлон Анти-А1

Серия: 329611 **Единица:** 100 мл

Изготовлен: 07.11.2022 **Количество единиц** 0,7

Годен до: 07.11.2024 **Объем серии:** 10000 мл.

Паспорт: А1-329611 от 07.11.2022

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А1	Прозрачная бесцветная или слегка окрашенная жидкость	Соответствует
1.2 Цоликлон анти-Асл	Прозрачная жидкость малинового цвета	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А1 не должен давать агглютинации с эритроцитами групп А2(II), В(III), А2В(IV) и О(I) Цоликлон анти-Асл не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов группы А(II) с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона А1 в прямой реакции агглютинации на плоскости с эритроцитами А1 – 1:64 Титр Цоликлона Асл в прямой реакции агглютинации на плоскости с эритроцитами А1 – 1:64, А2(II) – 1:32	Соответствует Соответствуе
3. Добавки	ЭДТА, БСА, Гаммин	

Цоликлоны соответствуют требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н18087

Срок действия с 18.09.2019г. **по** 18.09.2022г.

№ 0405479

ОРГАН ПО СЕРТИФИКАЦИИ № RA.RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д. 3 тел. (495) 683-97-92, факс (499) 187-89-54
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикаторы химические одноразовые воздушной стерилизации МедИС-В в исполнениях: МедИС-В-160/150, МедИС-В-160/150-1, МедИС-В-180/60, МедИС-В-180/60-1 по ТУ 9398-032-11764404-2004
Серийный выпуск.

код ОК
034-2014 (КПЕС 2008)
32.50.50.190

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

ГОСТ ISO 11140-1-2011 (класс 4),

ГОСТ Р 50444-92 (р.р. 3, 5)

код ТН ВЭД
3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII ИНН 5023001024
Место производства - 141009, Московская обл., г. Мытищи, ул. Колонцова, д. 17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ актов № 19-1550 А, № 19-1551 А и протоколов технических испытаний № 19-1550, № 19-1551 от 05.06.2019г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационные удостоверения: № ФСР 2009/04944 от 27.08.2019 г; № ФСР 2009/05017 от 27.08.2019 г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Схема сертификации – 3с

М.П.

Руководитель органа _____ (подпись) Е.И. Полянская (инициалы, фамилия)

Эксперт _____ (подпись) В.В. Русова (инициалы, фамилия)

Сертификат не применяется при обязательной сертификации

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 27 августа 2019 года № ФСР 2009/05017

На медицинское изделие
Индикаторы химические одноразовые воздушной стерилизации МедИС-В в исполнениях: МедИС-В-180/60, МедИС-В-180/60-1 по ТУ 9398-032-11764404-2004

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Научно-производственная фирма "Винар" (ООО "НПФ "ВИНАР"), Россия, 105094, Москва, ул. Госпитальный вал, д. 5, стр. 7А, помещ. VIII

Производитель
Общество с ограниченной ответственностью "Научно-производственная фирма "Винар" (ООО "НПФ "ВИНАР"), Россия, 105094, Москва, ул. Госпитальный вал, д. 5, стр. 7А, помещ. VIII

Место производства медицинского изделия
ООО "НПФ "ВИНАР", Россия, 141009, Московская область, г. Мытищи, ул. Колонцова, д. 17/2

Номер регистрационного досье **№ РД-27958/39246 от 03.07.2019**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.50.190**

приказом Росздравнадзора от 27 августа 2019 года № 6347
допущено к обращению на территории Российской Федерации.

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

0043820