Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

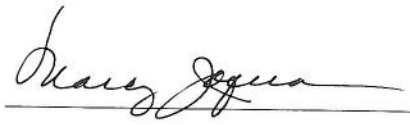
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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

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

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

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

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

Digitally signed by Ceaicovschi Tudor
Date: 2021.11.13 11:47:05 EET
Reason: MoldSign Signature
Location: Moldova

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 31 декабря 2015 года № ФСР 2010/08734

На медицинское изделие
Набор реагентов для исследования фекалий по методу Като («Диахим-КАТО») по ТУ 9398-042-27428909-2010

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

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

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

Номер регистрационного досье **№ РД-9559/60784 от 14.12.2015**

Вид медицинского изделия **139290**

Класс потенциального риска применения медицинского изделия **2а**

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

приказом Росздравнадзора от 31 декабря 2015 года № 10009
допущено к обращению на территории Российской Федерации.

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

0016928

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2016 года № ФСР 2012/14183

На медицинское изделие
Набор реагентов для клинического анализа спинномозговой жидкости («ДИАХИМ-ЛИКВОР») по ТУ 9398-056-27428909-2012

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

Производитель
Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия,

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

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

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия **1**

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

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 22 января 2016 года № 341
допущено к обращению на территории Российской Федерации.

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

0017000

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2016 года **№ ФСР 2012/14183**

На медицинское изделие
Набор реагентов для клинического анализа спинномозговой жидкости («ДИАХИМ-ЛИКВОР») по ТУ 9398-056-27428909-2012:
- Реактив Самсона - готов к применению - 1 флакон 10 мл.
- Карболовая кислота - готов к применению - 1 флакон 2,5 г.
- Аммоний сернокислый - готов к применению - 1 флакон (пакет) 85 г.

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

0014999

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

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

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

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

Регистрационный номер № 04EAC1.CM.03842

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

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, 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

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

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.

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

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

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

Председатель экспертной комиссии: 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

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

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

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacucheck.com - www.vacuaptaca.it

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

DECLARATION OF CONFORMITY FOR MATERIALS

Hereby we declare that Nuova Aptaca Srl In Vitro Medical Diagnostic Devices (Directive 98/79/CE) and Medical Device (93/42/CE):

1. During devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex). The statement is formulated on the basis of information and statements provided by the producers of the raw materials used.

2. Devices are produced with materials that do not contain substances submitted to restrictions provided by 10/2001/EU Regulation and respect the global and specific migration limits in accordance with the following conditions:
   - Simulant A (distilled water) -40°C for 10 days
   - Simulant B (acetic acid solution 3% p/v) – 40°C for 10 days
   - Simulant C (Ethyl alcohol solution 10% v/v) - 40°C for 10 days
   - Simulant D1 (ethyl alcohol solution at 50% v/v) - 40°C for 10 days
   - Simulant D2 (Vegetable oil - Try substitute made with 95% ethyl alcohol as indicated by the Italian Ministerial Decree 34 of 21.03.1973) - 40°C for 10 days

   The global migration limit, together with all other specific restrictions which monomers and/or additives present in the material can be exposed to, are respected in the use conditions here above. Notes and/or simulant used for migration tests allow to fix the food or the group of food, admitted to the contact with food.
   The statement is formulated on the basis of analytical tests made by our qualified Laboratory and information and statements provided by the producers of the raw materials used

3. Devices are produced with materials that satisfy the follow requirements:
   - Directive (UE) 2015/863 (substances use restriction – phthalates, sulphates) and following updates and changes
   - 1272/2008 Regulation (labeling and use of dangerous substances) and following updates and changes
   - 10/2011 Regulation (specific migration limits) and following updates and changes 1895/2005/CE Rule (substances use restriction for food contact) and following updates and changes
   - 2011/65/UE Directive (heavy metals, RoHS) and following updating and changes
   - 1895/2005/UE Regulation (objects intended to come in contact with food) and following updates and changes

   The use in an industrial or commercial venue of the material indicated in this statement does not exclude the determination of its compliance with applicable rules of competence as well as the technological suitability for the purpose which it is intended by the user.

Canelli, lì 21 May 2019

Buono Duilio
Quality and Regulatory Affairs Manager

APTACA
PLASTIC DISPOSABLE ITEMS FOR LABORATORIES OF ANALYSIS

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
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P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

DICHIARAZIONE DI CONFORMITA' DEI MATERIALI

Con la presente si dichiara che i Dispositivi Medico Diagnostici in Vitro (Direttiva 98/79/CE e s.m.i.) e i Dispositivi Medici (93/42/CE e s.m.i.) della Nuova Aptaca Srl:

1. sono stati prodotti utilizzando materiali che non contengono gomma naturale, latex, gomme sintetiche che contengono gomme naturali (ad esclusione degli articoli in lattice). L'affermazione è formulata sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

2. sono realizzati con materiali che non contengono sostanze sottoposte a restrizioni secondo il Regolamento 10/2011 (limiti di migrazione) e s.m.i. e rispettano i limiti di migrazione globale e specifica (ove applicabile) alle seguenti condizioni:
   - simulante **A** (acqua distillata) - 40°C per 10 giorni
   - simulante **B** (soluzione di acido acetico al 3% p/v) - 40°C per 10 giorni
   - simulante **C** (soluzione di alcool etilico al 10% v/v) - 40°C per 10 giorni
   - simulante **D1** (soluzione di alcool etilico al 50% v/v) - 40°C per 10 giorni
   - simulante **D2** (Olio vegetale - Prova sostitutiva effettuata con alcool etilico al 95% secondo quanto indicato dal DM 34 del 21.03.1973) - 40°C per 10 giorni

   Il limite di migrazione globale, unitamente alle altre restrizioni specifiche alle quali possono essere sottoposti i monomeri e/o gli additivi presenti nel materiale, sono rispettati nelle condizioni d'uso sopra menzionate. Le note e/o i simulanti impiegati per le prove di migrazione consentono di determinare il prodotto alimentare o il gruppo di prodotti alimentari, ammessi al contatto con alimenti.
   L'affermazione è supportata da prove analitiche da noi condotte presso Laboratori qualificati in accordo con il Regolamento citato e sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

3. sono realizzati con materiali che soddisfano i seguenti dettati legislativi:
   - Direttiva Delegata (UE) 2015/863 (restrizione d'uso sostanze - ftalati, sulfati,) e s.m.i.
   - Regolamento 1272/2008 (etichettatura e uso sostanze pericolose) e s.m.i.
   - Direttiva 2011/65/UE (metalli pesanti, RoHS) e s.m.i.
   - Regolamento 1895/2005/CE (restrizione d'uso sostanze per contatto con alimenti) e s.m.i.
   - Regolamento 10/2011 (limiti di migrazione) e s.m.i.

   L'utilizzazione in sede industriale o commerciale del materiale indicato nella presente dichiarazione non esclude l'accertamento della sua conformità alle norme vigenti di competenza nonché della idoneità tecnologica allo scopo cui è destinato da parte dell'utilizzatore.

Canelli, lì 21.05.2019

Buono Duilio
Quality and Regulatory Manager

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO

DGDMF/III/P/I.5.1.e.1/2020/78

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;

HAVING REGARD *to the 93/42/EEC Directive concerning medical devices;*

VISTO il Decreto Legislativo n. 46/97 e successive modifiche recante l'attuazione della direttiva 93/42/CEE;

HAVING REGARD *to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;*

VISTA la richiesta con prot. 2843 – A-17/01/2020, presentata dalla Ditta **APTACA S.p.A.**, con sede in Via Monte Bianco 4, 20900 Monza (MB), Italia, P. Iva 00862050960;

HAVING REGARD *to the request with ref. 2843 – A-17/01/2020, submitted by the Company* ***APTACA S.p.A.****, located in Via Monte Bianco 4, 20900 Monza (MB), Italy, VAT number 00862050960;*

CONSIDERATO che la ditta richiedente ha effettuato i versamenti richiesti dal D.M. 16 Gennaio 2019;

WHEREAS *this Company paid the fees required by Ministerial Decree (D.M.) January 16, 2019;*

VISTI gli atti d'ufficio;

HAVING REGARD *to the official deeds;*

SI ATTESTA
IT IS ATTESTED

che, la Ditta **APTACA S.p.A.,** con sede produttiva in Regione Monforte 30, 14053 Canelli (AT), Italia, è il fabbricante e ha marcato CE come dispositivi medici, secondo le procedure previste dalla direttiva 93/42 CEE, i prodotti:

that, according to Directive 93/42/EEC, the Company ***APTACA S.p.A.****, with manufacturing plant in Regione Monforte 30, 14053 Canelli (AT), Italy, is the manufacturer and has marked CE as medical devices the following products:*

ITEM CODE and DESCRIPTION
4002/SG/CS/L Tongue depressor in wood, 150 x 17 mm, sterile individually wrapped
4002/L Tongue depressor in wood 150 x 17 mm
4002/SG/CS Tongue depressor in PS, 150x20mm, sterile individually wrapped, box of 1000 pcs
4002 Plastic tongue depressor, non sterile
5601/SG/L Pap-Test cervical spatula in wood, lenght 175 mm, sterile individually wrapped
5601/L Pap-Test cervical spatula in wood, lenght 175 mm
5601/SG Pap-Test cervical spatula in high impact PS, lenght 175 mm, sterile individually wrapped

ITEM CODE and DESCRIPTION
5601 Pap-Test cervical spatula, in high impact PS, lenght 178 mm in bags of 500 pcs
5631/SG Cyto-Brush for endocervical cells collection, lenght 210mm sterile individually wrapped
5631 Cyto-Brush for endocervical cells collection, lenght 210mm not sterile
12790 Bed pan in PP with ergonomic handle, 2,500 ml
12791 Bed pan 2.500ml, in PP, autoclavable
12795 Bed pan lid in PP
12761 Male bed bottle 1,000ml, in PE , graduated
12762 Male bed bottle 1,000ml, in PP , graduated
12765 Male bed bottle cap in PE
12771 Female bed bottle in PE, 750 ml, graduated
12401 Irrigator in PP, graduated up to 1,000 ml
12402 Irrigator in PP, graduated up to 2,000 ml
5100 Cotton swabs with wooden stick lenght 150 mm, not sterile
6100 Rayon swabs with plastic stick lenght 150 mm, not sterile
7100 Swabs with alluminium stick, rayon tip, Ø0.9 x 145 mm, no sterile in bags of 100 pcs
301/SG Rayon swabs with clear Amies, plastic stick, in PP test tubes Ø12x150 mm, sterile
301/AL/SG Rayon swabs with clear Amies, metallic stick, in PP test tubes Ø12x150 mm, sterile
301/SG/XL Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES clear, with label, sterile individually wrapped
303/SG Rayon swabs with Amies with charcoal, plastic stick, test tubes Ø12x150 mm, sterile
303/AL/SG Rayon swabs with Amies with charcoal, metallic stick, test tubes Ø12x150 mm, sterile
303/SG/XL Rayon swabs with double Amies charcoal, plastic stick, test tubes Ø12x150 mm, sterile
305/SG Rayon swabs with clear Stuart, plastic stick, in PP test tubes Ø12x150 mm, sterile.
305/AL/SG Rayon swabs with clear Stuart, metallic stick, in PP test tubes Ø12x150 mm, sterile
307/SG Rayon swabs with Stuart with charcoal, plastic stick, test tubes Ø12x150 mm, sterile
307/AL/SG Rayon swabs with Stuart with charcoal, metallic stick, test tubes Ø12x150 mm, sterile
309/SG Rayon swabs with Cary Blair, plastic stick, in PP test tubes Ø12x150 mm, sterile
309/AL/SG Rayon swabs with Cary Blair, aluminium stick, in PP test tubes Ø12x150mm, sterile
311/SG VIRUS transport swabs plastic stick, rayon tip, in test tube Ø12x150, sterile .
313/SG VIRUS transport swabs, alluminium stick rayon tip in test tube Ø12x150, sterile
321/SG CHLAMYDIA transport swabs, plastic stick, rayon tip, in test tube Ø12x150, sterile
323/SG CHLAMYDIA transport swabs, alluminium stick rayon tip in test tube Ø12x150, sterile
430/SG/ST CliniswabLTS-Flocked standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT CliniswabLTS-Flocked fine swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/PT CliniswabLTS-Flocked paediat. swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST CliniswabLTS-Flocked standard swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/FT CliniswabLTS - Flocked fine swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/PT CliniswabLTS-Flocked paediatr. swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/ST CliniswabLTS-Flocked standard swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT CliniswabLTS-Flocked fine swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/PT CliniswabLTS-Flocked paediatr. swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST CliniswabLTS-Flocked standard swabs+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT CliniswabLTS - Flocked fine swabs+ Selenite liquid medium in tubes screw cap, sterile
445/SG/PT CliniswabLTS-Flocked paediatr. swabs+ Selenite liquid medium in tubes screw cap, sterile
450/SG/ST CliniswabLTS-Flocked standard swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT CliniswabLTS-Flocked fine swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/PT CliniswabLTS-Flocked paediatr. swabs+ Saline liquid solution in tubes screw cap, sterile
430/SG/ST/F CliniswabLTS - Foam standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/F CliniswabLTS - Foam fine tip swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/F CliniswabLTS - Foam standard swabs +Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/F CliniswabLTS - Foam fine tip swabs +Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/F CliniswabLTS - Foam standard swab+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/F CliniswabLTS - Foam fine tip swab+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/F CliniswabLTS - Foam standard swab+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/F CliniswabLTS - Foam fine tip swab+ Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/F CliniswabLTS - Foam standard swab+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT/F CliniswabLTS - Foam fine tip swab+ Saline liquid solution in tubes screw cap, sterile
430/SG/ST/D CliniswabLTS - Polyester std. swab + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/D CliniswabLTS - Polyester fine swab + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/D CliniswabLTS - Polyester std. swab + Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/D CliniswabLTS - Polyester fine swab + Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/D CliniswabLTS - Polyester std. swab+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/D CliniswabLTS - Polyester fine swab+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/D CliniswabLTS - Polyester std. swab+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/D CliniswabLTS - Polyester fine swab+Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/D CliniswabLTS - Polyester std. swab + Saline liquid solution tubes screw cap, sterile

ITEM CODE and DESCRIPTION
450/SG/FT/D CliniswabLTS - Polyester fine swab + Saline liquid solution tubes screw cap, sterile
430/SG/ST/R CliniswabLTS - Rayon standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/R CliniswabLTS - Rayon fine tip swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/R CliniswabLTS - Rayon standard swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/R CliniswabLTS - Rayon standard swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/R CliniswabLTS - Rayon standard swabs+Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/R CliniswabLTS - Rayon standard swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT/R CliniswabLTS - Rayon fine tip swabs+ Saline liquid solution in tubes screw cap, sterile
430/SG/AL CliniswabLTS - Aluminium std. swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/AL CliniswabLTS - Aluminium std. swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/AL CliniswabLTS - Aluminium std. swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/AL CliniswabLTS - Aluminium std. swabs + Selenite liquid medium in tubes screw cap, sterile
450/SG/AL CliniswabLTS - Aluminium swabs+ Saline liquid solution in tubes screw cap, sterile
2150/SG Cotton swabs with wooden stick in PP test tubes Ø12 x 150 mm, sterile
2150/SG/CS Cotton swabs with wooden stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2160/SG Rayon swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile
2160/SG/CS Rayon swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2170/SG Rayon swab with metallic stick in PP test tubes Ø12 x 150 mm, sterile
2170/SG/CS Rayon swab with metallic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2190/SG FOAM swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile
2190/SG/CS FOAM swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2191/SG Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2191/SG/CS Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2195/SG Swabs Plastic stick and Standard FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2195/SG/CS Swabs Plastic stick and Standard FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2196/SG Swabs Plastic stick and Fine FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2196/SG/CS Swabs Plastic stick and Fine FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2197/SG Swabs Plastic stick and Paediatric FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2197/SG/CS Swabs Plastic stick and Paediatric FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
5100/SG/CS Cotton swabs with wooden stick lenght 150 mm, sterile individually wrapped
5100/SG/2 Cotton swabs with wooden stick lenght 150 mm, sterile, pack of 2pcs
5100/SG/10 Cotton swabs with wooden stick lenght 150 mm, sterile, pack of 10pcs
6100/SG/CS Rayon swabs with plastic stick lenght 150 mm, sterile individually wrapped
7100/SG/CS Swabs with alluminium stick, rayon tip, Ø0.9 x 145 mm, sterile in individual peelpack
6200/SG/CS FOAM swabs with plastic stick and standard tip, sterile, individually wrapped.
6300/SG/CS FOAM swabs with plastic stick and fine tip, sterile, individually wrapped.
6510/SG/CS Plastic stick, flocked standard tip, sterile individually wrapped in blister
6520/SG/CS Plastic stick, flocked fine tip, sterile individually wrapped in blister
6530/SG/CS Plastic stick, flocked paediatric tip, sterile individually wrapped in blister
Swabs Plastic stick and POLYESTER tip, sterile individually wrapped
201/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile
201/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile individually wrapped
203/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES with Charcoal, with label, sterile
203/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Charcoal, with label, sterile individually wrapped
205/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile
205/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile individually wrapped
207/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART with Charcoal, with label, sterile
207/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Charcoal, with label, sterile individually wrapped
209/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile
209/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
31300 Holder in PP, disposable
020 44020 000 600 Holder in PP, disposable

The above mentioned products, according to the art. 4 of Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici **al di fuori della Unione Europea**.

This document has been issued in a unique original version upon request of the manufacturer in order to export medical devices to ***Countries outside European Union.***

Non è consentita la sua riproduzione o pubblicazione su carta, stampa, supporti elettronici o siti internet.

It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

MINISTERO DELLA SALUTE
Dispositivi Medici e Servizio Farmaceutico
DGDMF 03

Il Dirigente
The Executive Manager
Dott. Marco Musella

DP

MODULARIO
Salute - 2

MOD. 2 - U.G.

MINISTERO DELLA SALUTE

APTACA S.p.A.
Regione Monforte 30
14053 Canelli (AT)

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

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