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

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI EN ISO 13485:2012

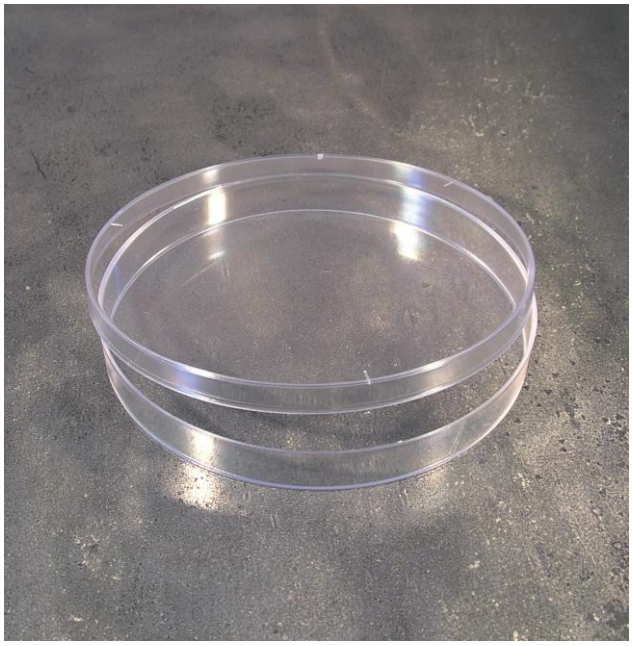
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
02.12.2014

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **231**

DESCRIZIONE / *DESCRIPTION*



Piastre di petri Ø 150 mm con ventilazione
sterili, apirogene. Prodotte in polistirolo cristallo (PS) con alta trasparenza ottica, Atossiche, antigraffio. Ideali per lavori di routine, ricerca batteriologica e per l'utilizzo in riempitori automatici. Superficie perfettamente piana per una omogenea distribuzione del terreno. Sterili in confezioni da 10 pezzi. Dispositivo latex free

Petri dishes Ø 150 mm with triple vents
Sterile, pyrogen free. Made in crystal polystyrene (PS) with high optical clarity, atoxic, non-scratch. Ideal for routine use, as well as for bacteriuria screening and for their use with automatic filling machines. Surface perfectly flat for an homogeneous distribution of the agar. Sterile in bags of 10 pieces. Latex free device

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

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

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**STERILE / *STERILE* (SAL 10^{-6})**	*Microbilogical status*
Materiale impiegato	POLISTIROLO / *POLYSTYRENE*	*Raw material*
Temperature tollerate	MIN -10°C MAX +70°C	*Temperature range*
Diametro interno base (mm)	Ø 139 ±0,5	*Base internal Ø* (mm)
Diametro esterno base (mm)	Ø 142 ±0,5	*Base external Ø* (mm)
Altezza base (mm)	17 ±1,5	*Base height (mm)*
Diametro interno coperchio (mm)	Ø 145 ±0,5	*Lid internal Ø* (MM)
Diametro esterno coperchio (mm)	Ø 149 ±0,5	*Lid external Ø* (MM)
Altezza coperchio (mm)	10 ±1,5	*Lid height (mm)*
Peso (gr.)	44,0	*Weight (gr.)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" adatte a contenere i terreni di coltura per individuare batteri ed effettuare le analisi di laboratorio
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale dei Dispositivi Medici (CND) > W0503030101 (Capsule di Petri)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1190506/R
Classificazione EDMA > 14909090 - Other Other Microbiology

Intended purpose is "IN VITRO MEDICAL DEVICE" suitable to contain culture media to identify bacteria and perform laboratory tests. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > W0503030101 (Petri dishes)
EDMA > *14909090 - Other Other Microbiology*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

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

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

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

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

Prodotto non adatto ai bambini
Keep out of reach of children

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

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

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

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	180	Confezione interna (pz): *Internal packing (pcs):*	10	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	46,5 x 46,5 x 38,5	Peso (Kg): *Weight (Kg):*	10,0	Volume (m^3): *Volume (m^3):*	0,081

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*

Data di fabbricazione *Manufacturing date*	Data di scadenza *Expiry date*	Consultare i documenti accompagnatori *Please consult accompanying documents*
LOT Numero di lotto *Lot number*	Monouso *Disposable*	STERILE R Sterilizzazione con radiazioni ionizzanti *Sterilization by ionizer rays*

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
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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

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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.

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

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

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

Председатель экспертной комиссии: 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

Клиническая биохимия
Агат

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

ПАСПОРТ

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

Серия..... **66/770421** Дата выпуска... **04.2021** Годен до... **05.2023**
Количество наборов в серии... **500**

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

Заключение ОКК ООО «Агат-Мед»:
Набор серии **66/770421** требованиям НТД предприятия соответствует.

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

"Агат-Мед"

МП

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

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

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

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Blood Collection Needle Holder** **UMDNS-Code: [12726]**
der Klasse: / of class: / de la classe: / di classe:	**I**

nach Anhang VIII, Verordnung (EU) 2017/745 / according to annex VIII, Regulation (EU) 2017/745 /
selon l'annexe VIII, le règlement (UE) 2017/745 / secondo l'allegato VIII, regolamento (UE) 2017/745

erfüllt die Anforderungen der Medizinprodukteverordnung (EU) 2017/745 und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the requirements of Medical Device Regulation (EU) 2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

répond aux exigences du Règlement sur les dispositifs médicaux (UE) 2017/745 et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa i requisiti del Regolamento sui dispositivi medici (UE) 2017/745 e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Verordnung (EU) 2017/745 Anhang II+III** **Regulation (EU) 2017/745 Annex II+III** **Réglementation (UE) 2017/745 Annexe II+III** **Regolamento (UE) 2017/745 Allegato II+III**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	**CE**

Suzhou, 2021.05.26

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

General Manager

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

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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

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

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

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

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

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

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

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

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

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

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

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

CE

Suzhou, 201.05.26

General Manager

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

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products:
- Immuno-biochemical test systems
- Immunofluorescence test systems
- Molecular diagnostic test systems
- Test systems for the determination of pathogens

Replaces Certificate, Registration No.: HL 60139384 0001

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

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-CMV ELISA (IgG, IgM, Avidity IgG, CSF IgG, p52 IgM)
Anti-Chlamydia ELISA (IgA, IgG, IgM)
Anti-Chlamydia trachomatis ELISA (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae ELISA (IgA, IgG, IgM)
Anti-Toxoplasma gondii ELISA (IgG, IgM, Avidity IgG, CSF IgG, IgA)
Anti-Rubella Virus ELISA (IgG, Avidity IgG, CSF IgG, Glycoprotein IgM)

Anti-Toxoplasma gondii IIFT (IgG, IgM)
Anti-Toxoplasma gondii IIFT EUROPattern (IgG, IgM)

Anti-Chlamydia MIF (IgA, IgG, IgM)
Anti-Chlamydia trachomatis MIF (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF (IgA, IgG, IgM)
Anti-Chlamydia MIF EUROPattern (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF EUROPattern (IgA, IgG, IgM)

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-Rubella Virus WESTERNBLOT (IgG)
Anti-Chlamydia HP EUROLINE-WB (IgA, IgG)

Multimarker Controls for Euroimmun ELISA

EUROLINE Anti-TO.R.C.H. Profile (IgG, IgM)
EUROLINE Anti-TO.R.C.H. 10-Profile (IgG)
EUROLINE Anti-CMV (IgG, IgM)

EUROArray STI

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Manufacturer:
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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and Development, Manufacture
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design and Development, Manufacture
/03	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture

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Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Location	Scope
/04	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design and Development, Manufacture, final Quality Control
/05	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Manufacture
/06	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture

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VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

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

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

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

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

identificazione dei prodotti / *product identification*:

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

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

nome commerciale / *brand name*: **"VACUTEST KIMA"**

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

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

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

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

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4265/5/D

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

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

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

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

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

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18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

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CISQ is the Italian Federation of management system Certification Bodies.

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