CERTIFICATO N° 505SGQ05

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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

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CERTIFICATO N° 505DM07

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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.

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2007-10-30	2011-10-30	2020-10-30	2023-10-29

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

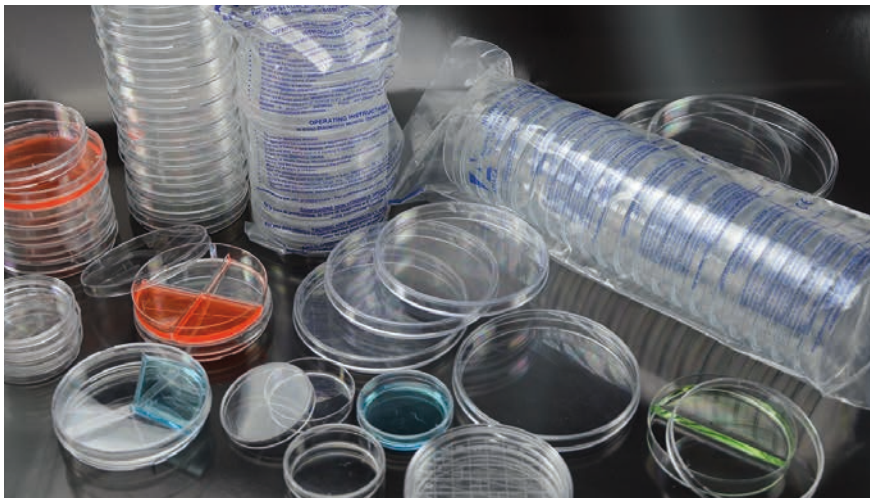
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

Data emissione / Date of issue
19.02.2021

MADE IN ITALY

Articolo: **Piastre di Petri Ø 90 mm**
Item: **Petri dishes Ø 90 mm**

DESCRIZIONE / *DESCRIPTION*



Le Piastre di Petri sono prodotte con un elevato standard di qualità garantito da un processo produttivo completamente automatizzato, in condizioni di asetticità controllata. Ideali per lavori di routine, ricerca batteriologica e per l'utilizzo in riempitori automatici. Le piastre sono **conformi allo standard UNI EN ISO 24998**. Il processo produttivo e il controllo qualità sono eseguiti in base a specifiche procedure ed istruzioni come richiesto dal Sistema Qualità conforme alle Norme UNI EN ISO 9001 e UNI EN ISO 13485 (Conformità a tali Norme rilasciata da Ente notificato esterno).

*Petri Dishes are produced with a high quality standard guaranteed by a fully automated production process, under controlled aseptic conditions. Ideal for routine use, bacteriuria screening and for their use in automatic filling machines. Petri dishes are **conform to UNI EN ISO 24998 standard**. The production process and the quality controls are executed in accordance with specific procedures and instructions as required by the Quality System in compliance with UNI EN ISO 9001 and UNI EN ISO 13485 Rules (Conformity issued by external Notified Body).*

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

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" Dispositivo atto a contenere terreni di coltura idonei ad essere inoculati con campioni biologici umani (per esempio urina, saliva, espettorato, pus, etc) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale dei Dispositivi Medici (CND) > W0503030101 (Capsule di Petri)
Classificazione EDMA > 14909090 - Other Other Microbiology

*Intended purpose is "IN VITRO MEDICAL DEVICE" Device suitable to contain culture media suitable to be inoculated with human biological samples (for example, urine, saliva, sputum, pus, etc) in order to carry out diagnostic laboratory analysis. **For professional use only.***
National classification of medical devices (CND - For Italian law) > W0503030101 (Petri dishes)
EDMA > *14909090 - Other Other Microbiology*

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PRODUCT IDENTIFICATION / *IDENTIFICAZIONE DEL PRODOTTO*

COD.	Descrizione *Description*	Confezionamento *Packaging*	RDM[1]
91	Piastre di petri Ø 90 mm, ventilate, asettiche *Petri dishes Ø 90 mm, with triple vents, aseptic*	500 pcs (25 x 20 pcs)	1898166/R
91/AN	Piastre di petri Ø 90 mm, ventilate, asettiche, anonime *Petri dishes Ø 90 mm, with triple vents, aseptic, anonymous*	500 pcs (25 x 20 pcs)	1898169/R
91*	Piastre di petri Ø 90 mm, ventilate, asettiche *Petri dishes Ø 90 mm, with triple vents, aseptic*	480 pcs (24 x 20 pcs)	1898167/R
91/SG	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated***	500 pcs (25 x 20 pcs)	1898211/R
91/SG/AN	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate**, anonime *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated**, anonymous*	500 pcs (25 x 20 pcs)	1898213/R
91/SG*	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated***	480 pcs (24 x 20 pcs)	1898212/R
101	Piastre di petri Ø 90 mm, non ventilate, asettiche *Petri dishes Ø 90 mm, without triple vents, aseptic*	500 pcs (25 x 20 pcs)	1898143/R
101/AN	Piastre di petri Ø 90 mm, non ventilate, asettiche, anonime *Petri dishes Ø 90 mm, without triple vents, aseptic, anonymous*	500 pcs (25 x 20 pcs)	1898149/R
101/SG	Piastre di petri Ø 90 mm, non ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, without triple vents, **sterile irradiated***	500 pcs (25 x 20 pcs)	1898182/R
101/SG/AN	Piastre di petri Ø 90 mm, non ventilate, **sterili irraggiate,** anonime *Petri dishes Ø 90 mm, without triple vents, **sterile irradiated,** anonymous*	500 pcs (25 x 20 pcs)	1898184/R

COD.	Descrizione *Description*	Confezionamento *Packaging*	RDM[1]
251	Petri dishes Ø 90 mm, with 2 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 2 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898157/R
251/SG	Petri dishes Ø 90 mm, with 2 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 2 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898198/R
261	Petri dishes Ø 90 mm, with 3 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 3 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898160/R
261/SG	Petri dishes Ø 90 mm, with 3 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 3 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898201/R
271	Petri dishes Ø 90 mm, with 4 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 4 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898163/R
271/SG	Petri dishes Ø 90 mm, with 4 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 4 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898204/R

[1] Repertorio Nazionale dei Dispositivi Medici

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MATERIALE DI PRODUZIONE / *MANUFACTURING MATERIAL*

Le piastre di petri sono otticamente trasparenti, atossiche, biologicamente inerti, prodotte in polistirolo cristallo antigraffio (PS - Numero CAS: 9003-53-6 - Numero CE: 500-008-9) unicamente di prima scelta.
La materia prima utilizzata è conforme ed idonea per il contatto alimentare in base a:

- ITALIA: Decreto Ministeriale 21/03/1973 e successivi aggiornamenti e modifiche; DPR 777/82 e successivi aggiornamenti e modifiche
- UE: Regolamento 1935/2004/CE (oggetti destinati a contatto con alimenti) e s.m.i.; Regolamento 10/2011 (limiti di migrazione) e s.m.i.; Regolamento 1895/2005/CE (restrizione d'uso sostanze per contatto con alimenti) e s.m.i.; Direttiva 2002/72/CE e successivi aggiornamenti e modifiche (contatto alimenti) e s.m.i.
- USA: Approvazione del Food and Drug Administration (FDA) - Title 21 §177 1640 (Styrene polymers).

Altresì il polistirolo da noi utilizzato non contiene metalli pesanti, è conforme alla Direttiva RoHS (2011/65/UE), alla Direttiva 2005/84/CE (restrizione d'uso sostanze - ftalati, solfati)

Nella fabbricazione dei Dispositivi non sono state usati materiale che contengono gomma naturale, latex, gomme sintetiche che contengono gomme naturali (ad esclusione degli articoli in lattice)
Le piastre in oggetto sono apirogene, non contenendo endotossine batteriche.

Petri dishes have high optical clarity and are atoxic, biologically inert, made in crystal Polystyrene non-scratch (PS – CAS number: 9003-53-6 - CE number: 500-008-9) of top quality only.
Raw material used is conform and idoneous to foodstuff contact according to:

- *Italy: 21/03/1973 Ministerial Decree and following updating and changes; 777/82 DPR and following updating and changes*
- *European Union: 1935/2004/CE Rule (objects intended to come in contact with food) 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; 2002/72/CE Directive and following updating and changes (food contact) and following updates and changes*
- *USA: FDA's approval – Title 21 § 177 1640 (Styrene Polymers).*

Moreover the polystyrene we use does not contain heavy metals and is conform to RoHS Directive (2011/65/UE), Directive 2005/84/CE (substances use restriction – phthalates, sulphates).

During Devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex) Dishes in object are pyrogen-free as do not contain bacterial endotoxins.

STATO MICROBIOLOGICO / *MICROBIOLOGICAL STATUS*

Tutte le piastre in oggetto sono prodotte in condizioni di asetticità controllata tali da garantire una contaminazione microbiologica ad un livello trascurabile, garantendo un SAL[2] di 1 x 10^{-3} in accordo, ove applicabile, con la British Standard BS-EN 556-2. Sempre in base alla citata BS, le piastre sono libere da contaminazione di particelle sparse, maggiori di 100 micrometri di diametro, individuate da un esame visivo. Lo stato microbiologico delle piastre, in base alle prove di invecchiamento effettuate e alla validazione del confezionamento, è garantito 5 (cinque) anni dalla data di fabbricazione.

Verifica dell'asetticità
Gli ambienti di produzione sono verificati ed igienizzati periodicamente in base alle procedure interne, in particolare le presse di produzione e gli automatismi di assemblaggio sono igienizzati ad ogni inizio turno di lavoro.
Ogni confezione (20 piastre) viene ispezionata visivamente dagli operatori a bordo macchina al fine di garantire l'assenza di eventuali particelle sparse. Con cadenza settimanale viene prelevata una confezione da 20 petri da ogni macchina e viene testata l'asetticità (carica microbica, muffe, lieviti, funghi) da un laboratorio esterno certificato ed accreditato. Per la verifica dell'asetticità sono utilizzati protocolli ufficiali, incubando per 5 giorni le piastre con terreni Plate Count Agar (PCA) e Malt Extract Agar (MEA). Nel caso di esito positivo delle analisi (presenza di UFC[3]) l'intero lotto di produzione viene segregato ed inviato in sterilizzazione.

Sterilizzazione
Le piastre di petri vendute "sterili" sono sterilizzate per irraggiamento tramite radiazioni ionizzanti raggi Beta (Dose di sterilizzazione: 21,6 kGy - Energia del fascio: 10 MeV). Il processo di sterilizzazione è validato e verificato con cadenza trimestrale tramite audit esterno. **Per le piastre "sterili" è garantito un SAL di 1 x 10^{-6}.**

[2] Sterilty Assurrance Level (SAL)
[3] Unità Formanti Colonie (UFC)

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All dishes in object are manufactured under controlled aseptic conditions so as to grant a negligible microbiological contamination, assuring a SAL[4] of 1x10^{-3} in accordance, where applicable, with the British Standard BS-EN 556-2:2003. Always in accordance with the said BS, dishes are free from contamination of scattered particles, with a diameter bigger than 100 micrometers, identified by a visual examination. The microbiological status of dishes, according to the executed ageing proofs and packing validation, is granted for 5 (five) years from manufacturing date.

Aseptic Conditions Control
Manufacturing rooms are periodically verified and hygienized according to internal procedures, in particular moulding machines and assembling automatisms are hygienized at each shift change.
Each pack (20 dishes) is visually examined by workers by machine's side in order to grant the absence of possible scattered particles. Every week a pack of 20 dishes is drawn out of each machine and aseptic conditions (microbical charge, molds, leavens, fungus) are tested by an external certified and accredited laboratory. Official protocols are used for the aseptic conditions control, incubating dishes with Plate Count Agar and Malt Extract Agar transport media for 5 days. If analysis have a positive result (presence of UFC[5]) the whole production lot is segregated and sent to sterilization.

Sterilization
Petri dishes sold in sterile version are sterilized by ionizing radiations (Beta Rays - Applied dose: 21.6 kGy – Bundle energy: 10 MeV). Sterilization process is validated and verified every three months by external audit. ***A SAL of 1x10^{-6} is granted for "sterile" dishes.***

CARATTERISTICHE FISICHE / *PHYSICAL FEATURES*

L'elevato peso, l'ottima planarità e le dimensioni altamente standard, in accordo con la Normativa UNI EN ISO 24998, rende le piastre in oggetto prodotte dall'Aptaca particolarmente idonee per l'utilizzo in riempitrici e macchinari automatizzati:

- Gli spigoli della base e del coperchio sono paralleli, entro 5°, con la superficie piana della base;
- Né la base né il coperchio hanno sporgenze pungenti che potrebbero causare tagli accidentali, punture o abrasioni sulla pelle degli utilizzatori o compromettere il corretto utilizzo nei macchinari automatizzati;
- Nel caso di piastre a comparti separati (settori), l'altezza dei divisori è superiore al 50% dell'altezza della base tali da non permettere perdite tra i comparti. L'altezza dei comparti è di 7,5 ±0,5 mm;
- Nel caso di piastre ventilate, vi sono n°3 protuberanze, di 0,25 mm di altezza, uniformemente distribuite sulla circonferenza del coperchio, tali da consentire una idonea ventilazione della piastra;
- La particolare conformazione della base rende le piastre facilmente impilabili; è possibile inclinare una pila di 10 piastre per un angolo di 12° dalla verticale senza che la pila crolli.

Ogni confezione di piastre viene esaminata visivamente dal controllo qualità al fine di garantire l'assenza di imperfezioni estetiche e/o funzionali delle piastre. Altresì è verificata l'integrità del sacchetto e la sua corretta chiusura (termosaldatura).

Con cadenza settimanale è prelevata una campionatura di piastre da ogni pressa di produzione e sono verificati i seguenti aspetti:

- Rigidità;
- Resistenza alla distorsione termica (testato con soluzione acquosa 1,5% di agar a 60°C) in accordo ISO 24998;
- Resistenza alla rottura;
- Stabilità nell'impilaggio;
- Controlli dimensionali.

The high weight, the excellent steadiness and the highly standard dimensions, in accordance with the Standard UNI EN ISO 24998, make dishes produced by Aptaca particularly appropriate for the use with automatic filling machines:

- *Plate and lid edges are parallel, within 5°, to the flat bottom surface;*
- *Neither plate nor lid have thorny protrusions that could cause accidental cuts, punctures or abrasions on the users' skin or compromise the correct use in automatic machines;*
- *In case of dishes with sectors, divisors height is higher than 50% of bottom height as not to permit leaking among sectors. Sectors height is 7.5 ±0.5 mm;*
- *In case of dishes with triple vent, there are three protuberances, of a height of 0.25mm, uniformly distributed on the cover circumference, as to allow an appropriate dish ventilation;*
- *The particular plate shape makes dishes easily stackable; it's possible to incline a pile of 10 dishes to a 12° angle from the vertical line without pile falling.*

Each pack of dishes is visually examined by quality control in order to grant the absence of aesthetic and/or functional imperfections of dishes. Moreover, the pack completeness and its correct closing (welding) is verified.

[4] Sterilty Assurance Level (SAL)
[5] Unit Forming Colonies (UFC)

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Every week a dishes sampling is drawn from every production press and the following features are verified:

- *Stiffness*
- *Thermal distortion resistance (tested in aqueous solution containing 1,5% Agar at +60°C according to ISO 24998)*
- *Breaking resistance*
- *Stacking stability*
- *Dimensional controls*

DIMENSIONI / *DIMENSIONS*

Codice *Code*	Base *Base*			Coperchio *Lid*		Base + Coperchio (assemblati) *Base + Lid (assembled)*				
	Diametro interno *Internal diameter*	Diametro esterno *External diameter*	Altezza esterna *External height*	Diametro esterno *External diameter*	Altezza esterna *External height*	Altezza *Height*	Spazio laterale tra il coperchio e la base *Side space between lid and plate*	Altezza tra la base della piastra e il piano di appoggio *Height between dish plate and support level*	Peso *Weight*	Superficie interna utilizzabile *Internal usable surface*
91	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.809 ±35
101	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.809 ±35
251	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.800 ±35
261	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15,02 ±1	mm^2 5.795 ±35
271	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15,05 ±1	mm^2 5.790 ±35

IMBALLAGGIO ED IDENTIFICAZIONE / *PACKING AND IDENTIFICATION*

Le piastre sono confezionate in sacchetti di LDPE contenenti ognuno 20 pezzi. La chiusura del sacchetto avviene tramite termosaldatura. Sia la consistenza del sacchetto che la qualità della chiusura garantiscono lo stato microbiologico del prodotto per 5 (cinque) anni dalla data di fabbricazione.
Su ogni sacchetto sono serigrafate (in lingua italiana, inglese e francese) le istruzioni d'uso per un utilizzo corretto e sicuro del dispositivo (ad esclusione delle piastre cod. 91/AN, 91/SG/AN, 101/AN e 101/SG/AN).

L'unità di vendita è rappresentata dall'imballaggio secondario composto dalla scatola di cartone (con rivestimento kraft) contenente:

- 500 piastre (25 sacchetti da 20 pezzi). Il volume della scatola è di 0,078 m^3 (dimensioni 48,5 x 48,5 x 33 cm) – Peso 9,200 Kg. circa

Per i codici 91* e 91/SG*:

- 480 piastre (24 sacchetti da 20 pezzi). Il volume della scatola è di 0,077 m^3 (dimensioni 58,5 x 38,5 x 34 cm) – Peso 8,7 Kg. circa

Su ogni scatola è apposta l'etichetta identificativa del prodotto riportante:

- Codice articolo;
- Quantità;
- Descrizione articolo;
- Lotto di produzione;
- Data di produzione e data di scadenza;
- Codice a barre;
- Indicazione di conformità CE;
- Indicazione del produttore Aptaca;
- Simbologia conforme alla UNI CEI EN ISO 15223-1

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Dishes are packed in LDPE bags each containing 20 pieces. Bag closing is made by heat welding. Both bag consistency and closing quality grant the microbiological status of the product for 5 (five) years from manufacturing date. Use instructions for a correct and safe utilization of the device are silk-screen printed on each bag in Italian, English and French (excluding codes 91/AN, 91/SG/AN, 101/SG and 101/SG/AN).

Sale unit is represented by the secondary packing made of cardboard box (with kraft lining) which contains:

- *500 dishes (25 bags of 20 pieces). The box volume is 0.078 m^3 (dimensions 48.5 x 48.5 x 33 cm) – Weight about 9.2 Kg.*

For codes 91 e 91/SG*:*

- *480 dishes (24 bags of 20 pieces). The box volume is 0.077 m^3 (dimensions 58,5 x 38,5 x 34 cm) – Weight about 8.7 Kg.*

On each box is put a label identifying the product and indicating:

- *Item code;*
- *Quantity;*
- *Item description;*
- *Production lot;*
- *Manufacturing and expiry date;*
- *Bar code;*
- *CE Conformity indication;*
- *Aptaca Manufacturer indication;*
- *Symbology conform to UNI CEI EN ISO 15223-1*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

- Utilizzare esclusivamente per effettuare analisi di laboratorio
- In caso di fuoriuscita del contenuto usare dispositivi di protezione individuale: PERICOLO DI CONTAMINAZIONE
- Non avvicinare il Dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare
- Non utilizzare il prodotto scaduto o con la confezione aperta
- Non riutilizzare: Dispositivo monouso
- Nel caso di prodotto sterile o asettico: stato microbiologico garantito a confezione integra
- Non variare la destinazione d'uso
- Prodotto non adatto ai bambini
- Utilizzare il Dispositivo unicamente con accessori in dotazione
- Non esporre direttamente ai raggi solari; proteggere dall'umidità
- Conservare in luogo asciutto, temperatura min. -10°C (14°F) – max +50°C (122°F)
- Per lo smaltimento utilizzare gli appositi D.P.I. e smaltire secondo le normative vigenti
- Materiale di produzione: polistirolo. Prima dell'utilizzo con sostanze particolari verificare la resistenza/compatibilità del materiale.

- *Use only for laboratory analysis*
- *Use appropriate personal protective equipment: contamination risk if contents leak*
- *Keep out of flame or heat sources which might damage the product*
- *Do not use after expiry date or if packing is opened*
- *Do not re-use: Disposable Device*
- *If sterile or aseptic Device: Microbiological status in undamaged pack*
- *Do not vary the intended purpose of the product*
- *Keep out of reach of children*
- *Use with provided accessories only*
- *Do not put under direct sun rays; store in a dry, cool place*
- *Store in dry place, temperature range: min. -10°C (14°F) – max +50°C (122°F)*
- *Disposal: use appropriate personal protective equipment and act according to applicable regulations*
- *Raw material: polystyrene. Before use with particular substances check the resistance/compatibility*

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

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

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.

DRG Instruments GmbH • Frauenbergstraße 18 • 35039 Marburg

DRG Instruments GmbH
Frauenbergstraße 18
D-35039 Marburg
Telefon +49(0) 64 21/17 00-0
Telefax +49(0) 64 21/17 00-50
e-mail: drg@drg-diagnostics.de
Internet: www.drg-diagnostics.de

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EC) of the Medical Devices Act (MPG)

We, DRG Instruments GmbH, Frauenbergstr. 18, 35039 Marburg, Germany

Herewith declare under our own responsibility that the products of the attached list which are classified under **Annex II list B of the European Directive 98/79/EC** are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament in regard to the in vitro diagnostic medical devices (IVDs) and therefore are allowed to be CE signed.

Conformity assessment procedure in accordance with Annex IV excluding (4) and (6) by the notified body:
TÜV Rheinland, LGA Products GmbH, Tillystr.2, 90431 Nürnberg (0197)

This statement of conformity is valid in connection with the release document for the respective batch of produced devices.

Quality Management and Norms

DRG Instruments GmbH has established a Quality Management System for the design/development, production and distribution of in vitro diagnostic according to DIN EN **ISO 13485:2016**.

Marburg, 2019-04-30

Wilhelm Sänger
General Manager

Dr. Bernd Röder
Head of Regulatory Affairs

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

DRG International., Inc.
841 Mountain Avenue
Springfield NJ 07081
USA

has established and applies a quality management system for medical devices for the following scope:

Scope see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-11-25
Certificate Registration No.:	SX 60153210 0001
An audit was performed. Report No.:	21238159 006
This Certificate is valid until:	2023-11-22

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2020-11-25

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60153210 0001
Report No.: 21238159 006

Organization:
DRG International., Inc.
841 Mountain Avenue
Springfield NJ 07081
USA

Scope:

Manufacturing and distribution of in vitro diagnostic reagents used in the diagnosis of autoimmune status, cancer, cardiac markers, disease status, fertility testing, pregnancy testing, diabetes and immune status.
Installation and service of in vitro diagnostic analyzers.

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2020-11-25

Dipl.-Ing. Sven Hoffmann

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

от 30 октября 2012 года

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
и подтверждает, что медицинское изделие
Набор реагентов "Антиген кардиолипиновый для реакции микропреципитации "Сифилис-АгКЛ-РМП"
по ТУ 9398-016-70423725-2010 в следующей комплектации
производства
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
место производства:
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1

класс потенциального риска **2б** ОКП **93 9817**

вид медицинского изделия –

соответствующее регистрационному досье № 33508 от 26.09.2012

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

Приложение: на 1 листе

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

0001831

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

Комплект № 1 включает в составе:
- антиген кардиолипиновый (АгКЛ);
- раствор холин-хлорида в 0,9 % растворе натрия хлорида.

Комплект № 2 в составе:
- взвесь АгКЛ.

2

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

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

30 октября 2012 года

0001854

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.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
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

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

0860CM_03_IT

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

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СВИДЕТЕЛЬСТВО

об утверждении типа средств измерений

PATTERN APPROVAL CERTIFICATE OF MEASURING INSTRUMENTS

RU.C.29.001.A **№ 36987**

Действительно до
"01" декабря 2014 г.

Настоящее свидетельство удостоверяет, что на основании положительных результатов испытаний утвержден тип **дозаторов пипеточных одно- и многоканальных "Блэк"**,
наименование средства измерений

ЗАО "Термо Фишер Сайентифик", г.Санкт-Петербург,
наименование предприятия-изготовителя

,

который зарегистрирован в Государственном реестре средств измерений под № **41939-09** и допущен к применению в Российской Федерации.

Описание типа средства измерений приведено в приложении к настоящему свидетельству.

Заместитель Руководителя **В.Н.Крутиков**

"02" 12 2009 г.

Продлено до
"....." ..... г.

Заместитель Руководителя

"....." ..... 20 г.

360987

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2009/05681

от **15 сентября 2009 года** Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Дозаторы пипеточные, одно- и многоканальные, "Блэк"
по ТУ 9443-008-33189998-2009

производства

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

класс потенциального риска **2а** ОКП **94 4370**

соответствующее комплекту регистрационной документации

КРД № 33014 от 09.07.2009

приказом Росздравнадзора **от 15 сентября 2009 года № 7252-Пр/09**

разрешено к производству, продаже и применению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Н.В. Юргель**

006376

Бланк изготовлен ЗАО «ОПЦИОН» (лицензия № 05-05-09/003 ФНС РФ, уровень В), договор РД № 08/63, тел. (495) 648 6068, 608 7617, г. Москва, 2008 г.

Дозаторы пипеточные
Ленпипет Блэк

Стиль и надежность в Вашей лаборатории

Part of Thermo Fisher Scientific

Thermo
SCIENTIFIC

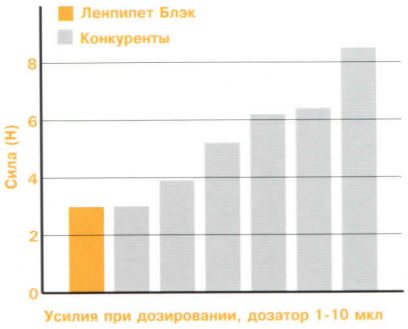
Дозаторы пипеточные Ленпипет Блэк

Усовершенствованный механизм установки объема дозировнания (AVG)

Поскольку точность и воспроизводимость - самые важные свойства любого дозатора, Ленпипет Блэк обладает специально разработанным механизмом регулировки объема, выполненным в виде автономного модуля. Поскольку механизм регулировки объема отделен от корпуса дозатора, он обладает существенно большей точностью, воспроизводимостью и прочностью. Кроме того, чтобы исключить возможное влияние тепла руки на точность измерений, механизм регулировки объема дозирования изолирован от корпуса дозатора.

Большой дисплей

Ленпипет Блэк имеет большой, легко читаемый дисплей, позволяющий легко и четко задавать объем. Кроме того, новый механизм установки объема позволяет легко устанавливать объем до сотых долей мкл, который виден на фоне. Точность обеспечивается также благодаря прецизионной регулировке объема, где каждый шаг при установке объема сопровождается щелчком. Это позволяет регулировать объем с шагом от 0,01 мкл до 20 мкл в зависимости от модели дозатора. Возле дисплея предусмотрено удобное место для идентификационных ярлычков пользователя. Такие ярлычки нужны, чтобы не перепутать дозаторы и чтобы они не затерялись в лаборатории.



Легкость дозирования

Как и у всех дозаторов Ленпипет, усилия, необходимые при дозировании, минимизированы. Конструкция Ленпипет Блэк позволяет пользователю нажимать кнопку дозирования очень легко, что обеспечивает легкость, ровность и стабильность дозирования. Это, в свою очередь, позволяет получать лучшие результаты дозирования в течение более длительных периодов работы. Кроме того, запатентованный механизм "супервыталкивания" жидкости позволяет точно дозировать даже микрообъемы. Такой механизм есть в дозаторах объемом 50 мкл и меньше.

Новая конструкция операционнной кнопки

Ленпипет Блэк имеет новую конструкцию операционной кнопки с вращающейся верхней частью, позволяющую исключительно легко устанавливать объем. Дополнительное преимущество заключается в том, что вращающаяся верхняя часть кнопки движется независимо от механизма регулировки объема, что предотвращает случайное изменение объема. Как и нижняя часть операционной кнопки, она выполнена из мягкого пластика, обеспечивающего отличный захват при регулировке объема без приложения усилий.

Полная автоклавируемость

Высокое качество результатов зависит от абсолютной стерильности. Чтобы обеспечить ее и предотвратить перекрестное загрязнение, Ленпипет Блэк может стерилизоваться в автоклаве при 121°C. Стерилизовать дозатор можно целиком в сборе или отдельными деталями в стерилизационном мешке. Дозатор выполнен из материалов, обладающих высокой стойкостью к реактивам, УФ свету и влаге.

Легкость обслуживания и калибровки в лаборатории

Ленпипет Блэк очень легко обслуживать: просто разберите дозатор, сняв сбрасыватель наконечника рукой, а затем с помощью удобного инструмента для обслуживания удалите конус наконечника. Тот же практичный инструмент используется для регулирования калибровки пипетки с помощью калибровочной гайки, расположенной наверху рукоятки дозатора.

Сочетание комфорта и автоклавируемости

Удобство и эргономичность

Ленпипет Блэк имеет широкий упор для пальца, который позволяет держать дозатор под идеальным для дозирования углом и дает руке расслабиться между циклами дозирования. В результате длительные циклы дозирования становятся более комфортными и менее утомительными, снижается риск развития травмы, возникающей из-за постоянной нагрузки (repetitive strain injury, RSI). Кнопка сбрасывателя наконечника закруглена и имеет эргономичную конструкцию, обеспечивающую наиболее комфортное положение большого пальца при сбрасывании.

Разнообразие типов и ассортимента объемов дозирования

Чтобы удовлетворить потребности каждой лаборатории, дозаторы Ленпипет Блэк выпускаются в одноканальных и многоканальных вариантах. Одноканальные дозаторы могут быть переменного или фиксированного объема.
По желанию заказчика поставляются штативы как для одноканальных, так и для многоканальных дозаторов.
Каждый дозатор Ленпипет Блэк имеет удобную цветовую кодировку на операционной кнопке и корпусе рукоятки, а также на многоканальных модулях, чтобы легче было находить нужный наконечник Finntip.

Многоканальные дозаторы Ленпипет Блэк

Многоканальные дозаторы Ленпипет Блэк выпускаются 8-канальными с различными диапазонами объема. Как и в одноканальных моделях Ленпипет Блэк, механизм усовершенствованной регулировки объема обеспечивает высокий уровень точности и воспроизводимости. Кроме того, в моделях малого объема функция супервыталкивания жидкости обеспечивает точное дозирование даже самых малых объемов.

Одноканальные дозаторы пипеточные Ленпипет Блэк постоянного объема

Кат. №	Объем мкл	Точность мкл	%	Воспр-мость s.d.*мкл	CV%*	Наконечник
4652002	1	±0,040	±4,00	0,040	4,00	Flex 10,10, 50
4652012	5	±0,070	±1,40	0,070	1,40	Flex 10,10, 50
4652022	10	±0,090	±0,90	0,080	0,80	Flex 200, 250 Унив., 200 Удл.
4652132	20	±0,14	±0,70	0,10	0,50	Flex 200, 250 Унив., 200 Удл.
4652032	25	±0,15	±0,60	0,13	0,50	Flex 200, 250 Унив., 200 Удл.
4652042	50	±0,30	±0,60	0,20	0,40	Flex 200, 250 Унив., 200 Удл.
4652052	100	±0,40	±0,40	0,30	0,30	Flex 200, 250 Унив., 200 Удл.
4652142	200	±0,80	±0,40	0,60	0,30	Flex 1000,1000,1000 Удл.
4652062	250	±1,0	±0,40	0,8	0,30	Flex 1000,1000,1000 Удл.
4652072	500	±1,5	±0,30	1,5	0,30	Flex 1000,1000,1000 Удл.
4652082	1000	±3,0	±0,30	3,0	0,30	Flex 1000,1000, 1000 Удл.

Одноканальные дозаторы пипеточные Ленпипет Блэк переменного объема

Кат. №	Диапазон	Шаг	Объем мкл	Точность мкл	%	Воспр-мость s.d.*мкл	CV%*	Цветов. код	Наконечник
4642022	0,5-5 мкл	0,01 мкл	5 0,5	±0,075 ±0,030	±1,50 ±6,00	0,050 0,025	1,00 5,00	Розовый	Flex 10, 10, 50
4642032	1-10 мкл	0,02 мкл	10 1	±0,100 ±0,025	±1,00 ±2,50	0,050 0,020	0,50 2,00	Розовый	Flex 10, 10, 50
4642042	1-10 мкл	0,02 мкл	10 1	±0,100 ±0,035	±1,00 ±3,50	0,080 0,030	0,80 3,00	Желтый	Flex 200, 250 Унив.
4642052	2-20 мкл	0,02 мкл	20 2	±0,20 ±0,06	±1,00 ±3,00	0,08 0,05	0,40 2,50	Бирюзовый	50
4642062	2-20 мкл	0,02 мкл	20 2	±0,20 ±0,06	±1,00 ±3,00	0,08 0,05	0,40 2,50	Желтый	Flex 200, 250 Унив.
4642132	5-50 мкл	0,1 мкл	50 5	±0,30 ±0,15	±0,60 ±3,00	0,15 0,125	0,30 2,50	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642072	10-100 мкл	0,2 мкл	100 10	±0,80 ±0,25	±0,80 ±2,50	0,20 0,10	0,20 1,00	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642082	20-200 мкл	0,2 мкл	200 20	±1,2 ±0,36	±0,60 ±1,80	0,4 0,14	0,20 0,70	Желтый	Flex 200, 250 Унив., 300, 200 Удл.
4642092	100-1000 мкл	1 мкл	1000 100	±6,0 ±1,0	±0,60 ±1,00	2,0 0,6	0,20 0,60	Синий	Flex 1000, 1000, 1000 Удл.
4642102	0,5-5 мл	0,01 мл	5000 500	±25,0 ±5,0	±0,50 ±1,00	10,0 4,0	0,20 0,80	Зеленый	5 мл
4642112	1-10 мл	0,02 мл	10 000 1000	±50,0 ±10,0	±0,50 ±1,00	20,0 8,0	0,20 0,80	Красный	10 мл

Многоканальные дозаторы пипеточные Ленпипет Блэк переменного объема

Кат. №	Кол-во каналов	Диапазон	Шаг	Объем мкл	Точность мкл	Воспр-мость %	s.d.*мкл	Цветов. код CV%*	Наконечник
4662002	8	1,0-10 мкл	0,02 мкл	10 1	±0,240 ±0,080	±2,40 ±8,00	0,160 0,070	1,60 7,00	Розовый	Flex 10, 10, 50
4662012	8	5-50 мкл	0,1 мкл	50 5	±0,75 ±0,25	±1,50 ±5,00	0,35 0,10	0,70 2,00	Желтый	Flex 200, 250 Унив., 200 Удл.
4662022	8	10-100 мкл	0,2 мкл	100 10	±1,30 ±0,25	±1,30 ±2,50	0,50 0,20	0,50 2,00	Желтый	Flex 200, 250 Унив., 200 Удл.
4662032	8	30-300 мкл	1 мкл	300 30	±3,0 ±0,6	±1,00 ±2,00	0,9 0,6	0,30 2,00	Оранжевый	Flex 300, 300

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Thermo SCIENTIFIC

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CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

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

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

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SGQ N° 005 A

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

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

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This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

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ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
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IAF: 12

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The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years.

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
VIA GRAMADORA 12/14 - 47122 FORLI' (FC)
has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2020 - 09 - 29**
Expires on: ***2023 - 10 - 07***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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Custom Primers and TaqMan® Probes shipped at ambient temperature reduce environmental impact and retain their quality and stability

Abstract

To minimize the adverse environmental impact of packaging and shipping products on gel or dry ice, Thermo Fisher Scientific investigated the feasibility of shipping its Custom Primers and TaqMan® Probes at ambient temperatures. This report describes stability testing of dye-labeled primers and MGB, TAMRA™, and QSY® probes after subjecting them to simulated summer shipping conditions. Analytical and stability testing demonstrated that Custom Primers and TaqMan® Probes that underwent simulated summer ambient-temperature shipping conditions maintained the same integrity and functionality as primers and probes that were kept at the recommended storage condition. By shipping at ambient temperatures, the need for expanded polystyrene (EPS) coolers and added refrigerant is eliminated and the fuel consumption and greenhouse gas emissions from transporting the product are significantly reduced.

Introduction

The adverse environmental impact of shipping refrigerated or frozen products is tremendous. The annual carbon footprint to manufacture EPS and convert it into coolers for our Custom Primers and TaqMan® Probes is approximately 6 tons CO_2-equivalents (CO_2e) [1]. Factoring in the number of shipments, the average distance traveled per package, and the fact that most packages are shipped via air, the annual total carbon footprint for transporting Custom Primers and TaqMan® Probes is 32 tons CO_2e [2].

There are other facts to consider beyond the greenhouse gas emissions. When a cooler arrives at the laboratory, the researcher is often put in the untenable position of deciding whether to burn additional fossil fuels to transport the empty cooler across country for reuse/recycling or to dispose of the cooler in a landfill. The best way to address the total environmental impact of "cold-chain" transport is to follow the hierarchy of "reduce, reuse, recycle": 1) Design the product for stability to ensure it can withstand the rigors of ambient shipping conditions without added refrigerant or insulation; 2) Design the packaging to be reusable, without increasing source material consumption; and 3) Recycle locally. We have opted to reduce whenever possible, reuse when it is an environmentally preferable option, and to encourage our customers to recycle locally.

Thermo Fisher Scientific has been systematically evaluating novel ways to minimize the impact of shipping Life Technologies™ products on gel or dry ice, and the CO_2 footprint left by these products during distribution. Here we demonstrate that selected Custom Primers and TaqMan® Probes are stable at ambient temperatures during shipping. By avoiding the cooler and refrigerant, the product can be shipped in a smaller, corrugated cardboard box, which improves the carrier's freight density (less fuel and emissions per box) and reduces the amount of packaging materials requiring disposal or recycling. By eliminating the cooler and gel or dry ice for these products, Thermo Fisher Scientific is helping to divert an annual total of nearly 1,826 kg (5,062 cubic feet)

life technologies

of EPS from landfills and incinerators by replacing it with recyclable corrugated paper packaging, and to reduce the annual total carbon footprint by 38 tons CO_2e [1,2].

In 2009, we investigated the stability of five TaqMan® Assays: TaqMan® Gene Expression, Custom TaqMan® Gene Expression, TaqMan® MicroRNA, TaqMan® Drug Metabolism Genotyping, and TaqMan® SNP Genotyping Assays [3]. These assays comprise a preformulated set of unlabeled locus-specific oligonucleotide primers and minor grove binder–nonfluorescent quencher (MGB-NFQ) probes labeled with a fluorescent dye (VIC® or FAM™ dye), and are supplied in liquid form. A total of 42 different TaqMan® Assays were selected to represent the widest range of performance as well as chemical, sequence, and structural motifs. Assays were subjected to simulated summer ambient shipping conditions and subsequently analyzed for physical integrity and functional performance. Stressed samples were compared to controls in analytical HPLC and functional real-time PCR assays. In all cases, simulated ambient shipping of the assays had no effect on their quality, integrity, or functional performance. This study provided ample evidence for the stability of a wide range of structural motifs and oligonucleotide sequences under ambient shipping conditions and also demonstrated the stability of the VIC® and FAM™ dyes and the MGB moiety at the concentrations found in the assays.

For many years, Custom Primers and TaqMan® Probes have been shipped refrigerated on gel ice (with storage after shipping at +4°C or –20°C, depending on the product). Building on our 2009 study, this paper describes results from stability testing carried out after the Custom Primers and TaqMan® Probes were exposed to established summer shipping temperature profiles. These experiments demonstrate that by shipping selected Custom Primers and TaqMan® Probes under ambient conditions, not only can we supply researchers with the same superior-quality product they are used to receiving, but we can also reduce our environmental footprint in the process. This is a win for our customers (eliminating packaging waste and extra costs associated with refrigerated shipments), a win for our planet (reducing resource consumption and total carbon footprint), and a win for our company (eliminating the need to manage cold-chain transport).

Materials and methods

Products tested. Custom Primers are 5'-labeled oligos that come with a choice of six dyes: 6-FAM™, TET™, VIC®, HEX™, NED™, or PET™ dye. The Custom Primer Pairs also come with an unlabeled oligo in a separate tube. Primers and Primer Pairs may be HPLC purified and can be ordered in two or three different quantities, with the largest having the highest concentration. For this study, four different labeled primers at the highest concentration were selected to represent the variety of primer types and dyes available (Table 1). The FAM™ and VIC® dyes were not tested with the primers because the 2009 study demonstrated the stability of these dyes in the TaqMan® Assays under ambient shipping conditions. Additionally, the Sequence Detection Primers, which are unlabeled, were not tested because the 2009 study established that unlabeled oligos are not affected by simulated ambient shipping conditions. All primers tested were formulated in Tris-EDTA (TE) buffer and were not HPLC purified. HPLC purification has no impact on the stability of the oligo or dye. Formulations in water were not evaluated because the pH of Tris buffers is known to vary inversely with temperature [4,5], something that does not occur in water, making TE a higher-risk formulation for ambient shipping.

TaqMan® MGB Probes incorporate a 5' reporter dye (FAM™, VIC®, TET™, or NED™ dye) and a 3' nonfluorescent quencher, with the MGB moiety attached to the quencher molecule. The TAMRA™ probes incorporate a 5' reporter dye (FAM™, TET™, or VIC® dye) and a 3' TAMRA™ quencher dye. The TaqMan® QSY® Probes can be ordered with a 5' reporter dye (FAM™, VIC®, ABY®, or JUN® dye) and the QSY® quencher. All TaqMan® Probes are HPLC purified and supplied at a single concentration in TE buffer. The MGB, TAMRA™, and QSY® probes were each tested with their respective dyes, with the exception of the MGB probe. This probe was not tested with VIC® dye because our own unpublished studies have shown that FAM™ is more labile than VIC® at elevated temperatures; therefore, FAM™ was used to represent a "worst-case" scenario. Because the 2009 study showed that variation in sequence and length did not affect oligo stability, a single sequence was chosen for all primers and probes:

5' - TGGACAGCCACCGACGAGAGCCTGG - 3'

Table 1. Custom Primers and TaqMan® Probes represented in this study.

Product Description	Reporter dye	Cat. No.
Custom Primers		
Sequence Detection Primers, 10,000 pmol, 80,000 pmol, 130,000 pmol	None	4304970, 4304971, 4304972
Custom 5'-Labeled Primer Pair Di-Repeats, 10,000 pmol, 80,000 pmol, **300,000 pmol**	HEX™, **NED™**, PET®, 6-FAM™, VIC®, TET™	4304976, 4304977, **4304978**
Custom 5'-Labeled Primer, 10,000 pmol, 80,000 pmol, **300,000 pmol**	HEX™, NED™, **PET®,** 6-FAM™, VIC®, TET™	450007, 450006, **450017**
Custom 5'-Labeled Primer Pair, 10,000 pmol, 80,000 pmol, **300,000 pmol**	HEX™, NED™, PET®, 6-FAM™, VIC®, **TET™**	450056, 450059, **450062**
Custom 5'-Labeled Primer Pair Di-Repeat + Tail, 10,000 pmol, 80,000 pmol, **300,000 pmol**	**HEX™**, NED™, PET®, 6-FAM™, VIC®, TET™	4304979, 4304981, **4304982**
TaqMan® Custom Probes		
TaqMan® MGB Probe, 6,000 pmol, 20,000 pmol, **50,000 pmol**	**6-FAM™**, VIC®, **NED™, TET™**	4316034, 4316033, **4316032**
TaqMan® TAMRA™ Probe, 6,000 pmol, 20,000 pmol, **50,000 pmol**	**VIC®, 6-FAM™, TET™**	450025, 450024, **450003**
TaqMan® QSY® Probe, 6,000 pmol, 20,000 pmol, **50,000 pmol**	**6-FAM™, VIC®, ABY®, JUN®**	4482777, 4482778, **4482779**

Products tested are in **bold**

Creating replicates. To help eliminate manufacturing lot variability when creating the replicates, individual tubes of the primers and probes were manufactured, pooled, and aliquoted into the same packaging tube at the same fill volume as specified for the manufactured product. A total of 10 lots for each primer and probe were used to create five replicate stress tubes and five replicate control tubes. The control tubes were kept at –20°C for the duration of the study.

Simulated shipping conditions. To simulate temperatures experienced during shipping, samples were placed in a cycling environmental chamber (Thermotron® S-16) programmed to reproduce a "worst-case" 288-hour (12-day) summer temperature profile (Figure 1). This profile is adopted from one developed and validated by Amgen to simulate global ambient shipping conditions and mimics product temperature extremes encountered during transit of over 2,500 shipments during summer months between the latitudes of 59.9° N and 37.8° S [6]. Testing of winter ambient conditions was not considered, due to the low risk of exposing the Custom Primers and TaqMan® Probes to cold conditions.

Stability and integrity testing. Structural integrity changes in stressed samples compared to controls were measured by reverse-phase HPLC (RP-HPLC) and MALDI mass spectrometry. RP-HPLC samples were analyzed using an Agilent® 1200 HPLC. The HPLC column used was a Phenomenex® Clarity® 3 µm Oligo-RP, 2.0 mm ID x 50 mm. Mobile phases used were 0.1 M TEAA (triethylamine acetate) in water and 0.1 M TEAA in

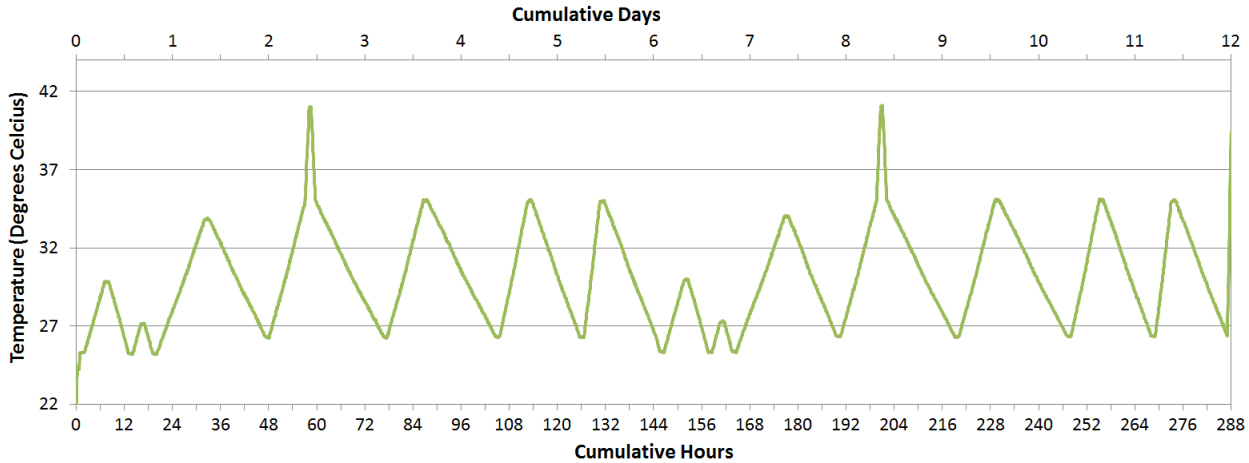

Figure 1. 288 hr summer temperature profile used to simulate shipping conditions. The summer temperature profile was used to mimic average high temperature extremes between the latitudes of 59.9° N and 37.8° S.

50% water/40% acetonitrile/10% methanol for the primers, MGB, and TAMRA™ probes, and 0.1 M TEAA in water and 2.0 M TEAA in 5% water/95% methanol for the QSY® probes. Absorbance was monitored at 260 nm for the oligonucleotide and at the maximum absorbance wavelength of the dye. Samples for MALDI mass spectrometry were analyzed on an AB Sciex® 4800 Plus MALDI TOF/TOF™ Analyzer.

Results

RP-HPLC. RP-HPLC was used to create peak profiles of the dye-labeled primers using UV/Vis absorbance detection. Matched test and control tubes from each assay were analyzed. An example of the data is shown in Figure 2. Test and control peak profiles were compared, and the purity (peak areas) were calculated (data not shown). For all samples analyzed, test samples were judged as identical to matched controls (no degradation), confirming that the simulated shipping stress did not affect product integrity.

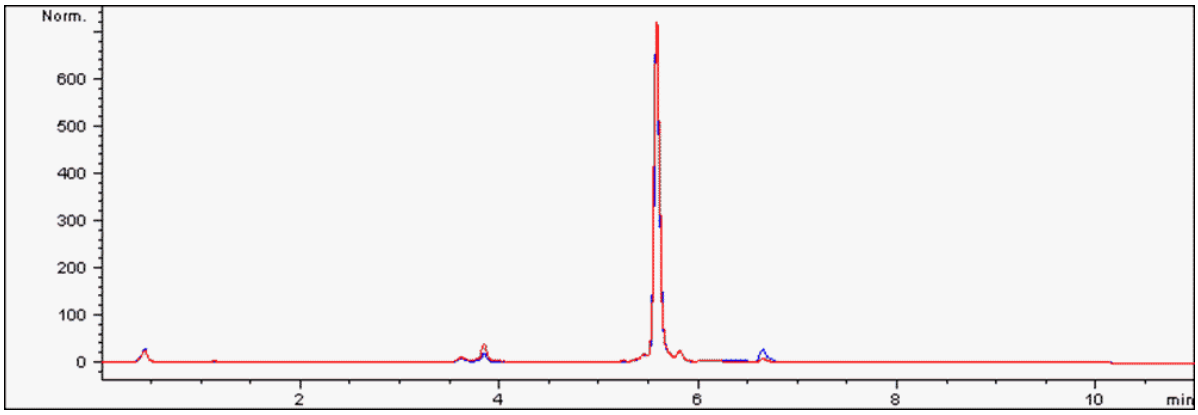

Figure 2. Simulated summer ambient shipping does not affect oligonucleotide stability—representative HPLC data. The effect of simulated summer ambient shipping on oligonucleotide integrity was measured by comparing RP-HPLC profiles of matched test and control samples. The HPLC chromatogram profiles of the test samples are comparable to the profiles of the control samples. There was no indication of probe or primer degradation in the simulated ambient-shipped 5'-Labeled Primer Pair Di-Repeats with the NED™ dye (red) compared to the matched control (blue).

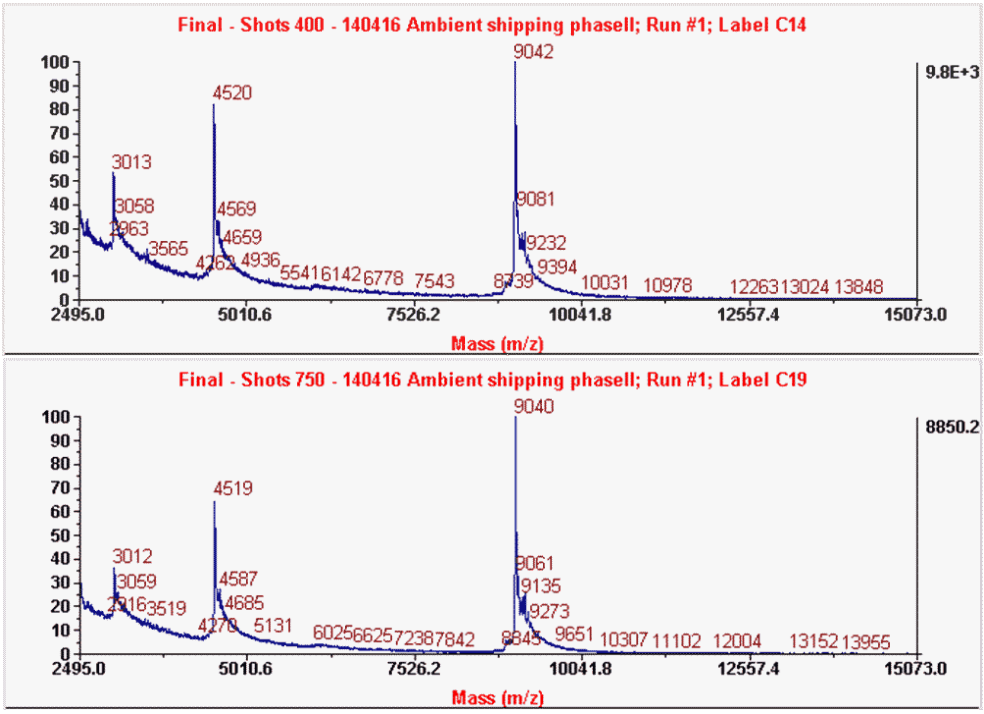

Figure 3. Simulated summer ambient shipping does not affect oligonucleotide stability—representative MALDI mass spectrometry data. The effect of simulated summer ambient shipping on oligonucleotide integrity was measured by comparing mass spectrum profiles of matched test and control samples. The profiles of the test samples are comparable to the profiles of the control samples. There was no indication of probe or primer degradation in the simulated ambient-shipped TaqMan® TAMRA™ Probe with the VIC™ dye (bottom) compared to the matched control (top).

MALDI mass spectrometry. MALDI mass spectrometry was used to generate mass profiles of the dye-labeled primers and probes. Again, matched test and control assays were analyzed and compared to each other. An example mass spectrum is shown in Figure 3. Test and control samples showed the same mass profiles, indicating that no degradation of the oligo, dye, or quencher occurred during the shipping simulation, further confirming that the simulated shipping stress did not affect product integrity.

Conclusions

The data described in this paper demonstrate that ambient shipping conditions have no effect on the quality and stability of Custom Primers and TaqMan® Probes. For each dye-labeled primer and probe tested, we were able to clearly demonstrate that ambient-temperature shipping conditions do not affect the product quality or integrity.

These results substantiate the change to ambient shipping conditions, and provide the researcher with confidence that when shipped under ambient conditions, their Custom Primers and TaqMan® Probes will exhibit no difference in function or stability compared to dry or gel ice–shipped products. In addition to ensuring our customers will continue to receive the highest quality possible, this study enables us to reduce the impact of transport of these products by 32 tons CO_2e. Our customers will see a reduction of 1,826 kg of EPS waste. Our planet will collectively see CO_2 emissions reduced by 38 tons every year.

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620802	14×14mm	0.13-0.17	0.17-0.25	100
620803	16×16mm	0.13-0.17	0.17-0.25	100
620804	18×18mm	0.13-0.17	0.17-0.25	100
620805	20×20mm	0.13-0.17	0.17-0.25	100
620806	22×22mm	0.13-0.17	0.17-0.25	100
620807	24×24mm	0.13-0.17	0.17-0.25	100
620808	24×32mm	0.13-0.17	0.17-0.25	100
620809	24×40mm	0.13-0.17	0.17-0.25	100
620810	24×50mm	0.13-0.17	0.17-0.25	100
620811	24×60mm	0.13-0.17	0.17-0.25	100

620812	ϕ 12 mm	0.13-0.17	0.17-0.25	200
620813	ϕ 13 mm	0.13-0.17	0.17-0.25	200
620814	ϕ 16 mm	0.13-0.17	0.17-0.25	200
620815	ϕ 18 mm	0.13-0.17	0.17-0.25	200
620816	ϕ 19 mm	0.13-0.17	0.17-0.25	200
620817	ϕ 20 mm	0.13-0.17	0.17-0.25	200
620818	ϕ 22 mm	0.13-0.17	0.17-0.25	200

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 529 Anti-Phospholipid Screen IgG/IgM

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH * ORGENTEC CE and ISO-approved * Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-90-00
GMDN 55085

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Geschäftsführer
Ralf Wehen

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

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Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 515 Anti-Cardiolipin IgG/IgM

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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GMDN 54870

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USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products;
AccuBind® ELISA,
AccuLite® CLIA,
QSure® Control,
Instruments
see appendix

4) The product(s) described above is in conformity with:

Document No.	Title
98/79/EC	*In vitro* Diagnostic Medical Devices Directive

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2021-09-20 — A Shatola

(Place & date of issue (yyyy-mm-dd))

Tony Shatola; QA Director, Monobind Inc.
(name, function and signature of manufacturer)

Appendix

Date: 2021-09-20

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Allergy & Anemia							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
Autoimmune							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
Bone Metabolism & Growth							
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
Diabetes							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
Endocrine							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
Fertility & Prenatal							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid -hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
Infectious Diseases							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
Neonatal							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
Steroid							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
Thyroid							
Total Triidothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triidothyronine (fT3) Test Stystem	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triidothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triidothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triidothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29
Miscellaneous Controls							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analzyer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05

Certificate of Registration of Quality Management System to ISO 13485:2016

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
United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 - Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

Facility ID: F002818
has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4585)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4585 / Rev 2
Certification Granted: 2019/09/25
Effective Date: 2022/09/25
Expiry Date: 2025/09/24

Annex to Certificate Number: MP19.4585 / Rev 2

Scope of Registration:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585 Facility ID: F002818
Manufacture, Distribution	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585/A Facility ID: F002818

Verified by:
Director of Certification