



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@cacaudit.ru



№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



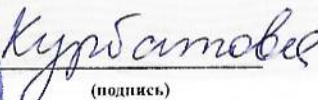
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.

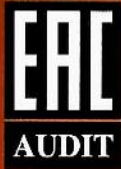




(подпись)

Е. Д. Курбатова

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



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«EAC AUDIT»

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

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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)

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(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

РАЗРЕШАЕТ

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

Руководитель органа
по сертификации:

(подпись)

В. И. Погдин

Председатель
экспертной комиссии:

М.П.



(подпись)

Е. Д. Курбатова

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



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РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.СМ.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:



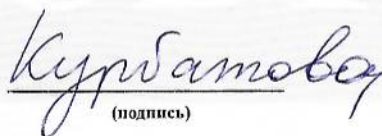
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

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



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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«ЕАС AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04ЕАС1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028

ИНН 7717616798 ОГРН 1087746489060

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04ЕАС1.СМ.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

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

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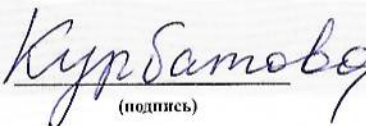
(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.





(подпись)

Е. Д. Курбатова

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



Азопирам д/предстер.контроля на 100 мл, 1компл.

Реактив предназначен для контроля качества предстерилизационной очистки изделий. Применяется для выявления следов крови, которые могли остаться на подготовленных к стерилизации медицинских изделиях в результате недостаточно тщательной предстерилизационной очистки.

Хранить в сухом защищенном от света месте

ПАСПОРТ № 1515**Антиген кардиолипиновый для реакции микропреципитации
Сифилис-АгКЛ-РМП
Комплект №2 (2000 опр.)**

ТУ 9398-016-70423725-2010

РУ № ФСР 2011/09957 от 25.07.2018

Каталожный № 03.07.3

Номер серии 33/21Дата выпуска **2021.09.02**Срок годности **2023.03.02**

Условия хранения: Хранить в сухом, защищенном от прямых солнечных лучей месте, при температуре от 2 до 8 °С.

№ п/п	Показатель	Характеристика и нормы	Результаты анализов
1.	Внешний вид		
1.1.	Взвесь АгКЛ в 10%растворе холин-хлорида, содержащая кардиолипина (0,33 г/л), лецитина (2,7 г/л), холестерина (9 г/л), ЭДТА(стабилизатор) в конечной концентрации 0,0125 моль/л и тимеросал (консервант) в конечной концентрации 0,1% 10 мл (7 фл.)	Суспензия молочно-белого цвета, при отстаивании разделяющаяся на опалесцирующую бесцветную жидкость и плотный осадок белого цвета	Соответствует
2	Специфическая активность	При исследовании плазмы, инактивированной сыворотки крови и СМЖ от больных сифилисом должна наблюдаться положительная реакция-осадок в виде хлопьев разной величины, а при исследовании плазмы, инактивированной сыворотки крови и СМЖ здоровых лиц отрицательная реакция в виде опалесценции.	Соответствует

Транспортируют при температуре от 2 до 8 °С. Допускается транспортирование при температуре от 9 до 25 °С не более 10 сут. Замораживание не допускается.

Заключение: Набор «Сифилис-АгКЛ-РМП» соответствует требованиям ТУ 9398-016-70423725-2010.

Дата выдачи паспорта 02.09.2021

Начальник ОБТК



Юрина Т.В.



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
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2020-10-30

Data di Scadenza
Expiration Date
2023-10-29



SGQ N° 023A

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

SCHEDA TECNICA PRODOTTO TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
14.09.2015



CODICE ARTICOLO: **4878/E**
ITEM CODE:

DESCRIZIONE / DESCRIPTION



Provetta cilindrica Ø12x86 mm prodotta in Polipropilene (PP) particolarmente trasparente ed inerte. Le provette contengono granuli separatori in polistirolo (inerti, tondeggianti e privi di asperità al fine di evitare la rottura delle cellule durante la centrifugazione) per 5,0ml di sangue i quali formano una sufficiente barriera (non totalmente ermetica) tra plasma e siero in seguito alla centrifugazione (raccomandiamo di non superare i 1.500g). Le provette inoltre contengono un acceleratore della coagulazione (inerte) il quale consente una separazione decisamente più rapida. Corredate di tappo in polietilene (PE) di colore azzurro a perfetta tenuta. Con etichetta. R.P.M. max 5.000

Cylindrical test tube Ø 12x86 mm in medical Polypropylene (PP), very transparent and inert. Test tubes contain PS separating granules (inert and smoothly rounded to avoid cells breakage during centrifugation) for 5.0 ml of blood, forming a sufficient barrier (not totally hermetic) between plasma and serum following to centrifugation (it is recommended not to centrifuge at more than 1,500 g). Tubes also contain an inert coagulation accelerator to facilitate a quick separation. Supplied with Polyethylene (PE) cap, light blue colour, perfectly tight and label. R.P.M. max 5,000

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	NON STERILE / NOT STERILE	<i>Microbiological status</i>
Materiale impiegato provetta	POLIPROPILENE / POLYPROPYLENE	<i>Raw material – test tube</i>
Materiale impiegato tappo	POLIETILENE / POLYETHYLENE	<i>Raw material – cap</i>
Temperature tollerate provetta	MIN -10°C MAX +121°C	<i>Temperature range - test tube</i>
Temperature tollerate tappo	MIN -50°C MAX +75°C	<i>Temperature range - cap</i>
Volume nominale (ml)	5 ML	<i>Nominal volume (ml)</i>
Dimensioni provetta (mm)	Ø 12 x 86	<i>Dimensions – test tube (mm)</i>
Taratura provetta (ml)	2,5 – 5	<i>Calibration – test tube (ml)</i>
Validità del prodotto	2 ANNI / YEARS	<i>Shelf life</i>

DESTINAZIONE D'USO / INTENDED PURPOSE

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (sangue) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**

Classificazione Nazionale dei Dispositivi Medici (CND) > W050101010201 (Provette con additivi o separatori di siero per raccolta di sangue).

Repertorio Nazionale dei Dispositivi Medici (RDM) > 1246091/R

Classificazione EDMA > 51011001 - Tubes for serum (without anticoagulant)

Intended purpose is "IN VITRO MEDICAL DEVICE" adapted to contain a human biological sample (blood) in order to perform diagnostic analysis laboratory. For professional use only.

National classification of medical devices (CND - For Italian law) > W050101010201 (Blood collection, tubes with additives or serum separator).

EDMA code > 51011001 - Tubes for serum (without anticoagulant)

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 -0°C max +40°C

Store in dry place, Temperature range: min -0°C max +40°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 substance check the resistance / compatibility chart on our catalogue

L'uso in centrifuga non deve superare la velocità massima di 5.000 r.p.m. per un massimo di 20 min.

For a maximum centrifuge speed of 5,000 r.p.m to be kept for 20" max

IMBALLO / PACKING

Quantità (pz): 1.000	Confezione interna (pz): 50 pezzi in rack polistirolo espanso	QUANTITÀ MINIMA VENDIBILE
Quantity (pcs): 1.000	Internal packing (pcs): 50 pieces in styrofoam racks	MINIMUM SALEABLE QUANTITY

Misura esterna scatola (cm): 47 x 23 x 37	Peso (Kg): 5,0	Volume (m ³): 0,039
External box dimensions (cm): 47 x 23 x 37	Weight (Kg): 5,0	Volume (m ³): 0,039

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS



Data di fabbricazione
Manufacturing date



Data di scadenza
Expiry date



Consultare i documenti accompagnatori
Please consult accompanying documents



Numero di lotto
Lot number



Monouso
Disposable

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.

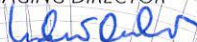
Commercializzazione di articoli da laboratorio

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

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2020-10-30

Data di Scadenza
Expiration Date

2023-10-29

Settore IAF 14 - 29



SGQ N° 023A

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

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

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

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: / **Microscope Slide**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

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

Suzhou, 201.05.26

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

CE

General Manager

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



Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 69326

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

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

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 69326**

Location

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

Registered Activities

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

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

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



Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

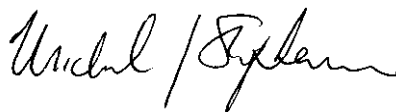
Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

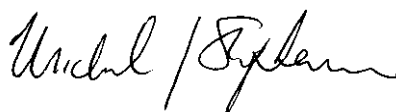
Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

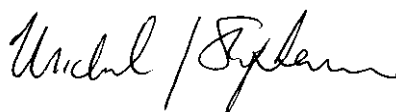
Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

Declaration of Conformity

helena
Biosciences Europe

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

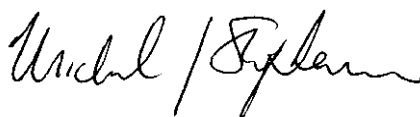
Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
TPHA Microtitre plate kit	043100A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.



Eddy Velthuis
Technical Director



CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

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

ISO 13485:2016

EN ISO 13485:2016

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

Authorized by



Michael J. Windler, P.E.

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



Check Certificate
Status: [here](#)

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

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



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



ООО «МиниМед», ИНН 3234007127
241520, Российская Федерация, Брянская область
Брянский район, с. Супонево, ул. Шоссейная, 17 а
Телефон (4832)92-97-97, 92-54-52, факс (4832) 92-24-54
Многоканальный телефон 8-800-100-48-32
www.minimed.ru e-mail: info@minimed.ru

исх. №190 от 26.06.2018г.

Информационное письмо.

В соответствии с действующим Постановлением Правительства РФ от 01.12.2009г. №982 «Об утверждении единого перечня продукции, подлежащей обязательной сертификации, и единого перечня продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии», Набор реагентов "Масло иммерсионное" по ТУ 9398 -011-29508133-2009, изготовитель ООО «МиниМед», ОКП 939816 «Наборы реагентов для клинической лабораторной диагностики», ОКПД2 21.20.23.110 «Реагенты диагностические», обязательной сертификации и декларированию не подлежит.

Начальник ОТК



Грузинцев С.А.



NSAI

Quality System Approval Certificate

In Vitro Diagnostic Medical Devices Directive 98/79/EC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(In Vitro Diagnostics Medical Devices) Regulations (S.I. No. 304 of 2001)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Monobind Inc.

**100 North Pointe Drive
Lake Forest
CA 92630
USA**

For the Product Family

**Total and Free Prostate Specific Antigen (PSA and Free PSA) IVD,
kit, chemiluminescent immunoassay (CLIA) and enzyme
immunoassay (ELISA) and control.**

GMDN Code: 54664, 54669

*On the basis of examination under the requirements of Annex IV, Section 3 of Directive 98/79/EC,
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product is hereby authorized.*

Registration Number:	304.1006
Original Approval:	28 October 2011
Last Amended on:	25 August 2021
Remains valid until:	12 July 2023

Signed:

(Signature)
Approved by
Dr Caroline Dore Geraghty
Director, Medical Devices

(Signature)
Approved by
Dr Elaine Darcy
European Medical Device Operations
Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI**

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

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:

<u>Document No.</u>	<u>Title</u>
98/79/EC	<i>In vitro</i> 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



(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.

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
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-Thyropoxidase (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

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
(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

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
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

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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 Triiodothyronine (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 Triiodothyronine (fT3) Test System	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 Triiodothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triiodothyronine (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

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	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triiodothyronine (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 Analyzer				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

C E R T I F I C A T E



of Conformity Low Voltage Directive 2014/35/EU

Registration No.: AN 50500367 0001

Report No.: 14706948 003

Holder: Ningbo ProWay Optics & Electronics
Co., Ltd.
Room 8-1, Central Business, No.54 Dashani Street,
Ningbo
315010 Zhejiang
P.R. China

Product: Microscope
(Biological Microscope)

Identification: Type Designation: XSZ-PW104, XSZ-PW107, XSZ-PW105,
XSZ-PW109, XSZ-PW206, XSZ-PW207,
XSZ-PW208, PW-BK2000, PW-BK5000,
N-PW300Flu, N-PW300LCD, N-PW300
(Pro.Way)

Serial No.: n.a.

Remark: Refer to test report 14706948 003 for details.

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with Annex I of Council Directive 2014/35/EU, referred to as the Low Voltage Directive. This certificate does not imply assessment of the series-production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to Annex IV of the Directive.

Certification Body



Guoping Zheng

Date 12.04.2021

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Ⓒ The CE marking may be used if all relevant and effective EC Directives are complied with. Ⓒ