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

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

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

Digitally signed by Ceaicovschi Tudor
Date: 2022.02.08 15:52:43 EET
Reason: MoldSign Signature
Location: Moldova

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

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

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

М.П.

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

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«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
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этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

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

Регистрационный номер № 04EAC1.CM.03842

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

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

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

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(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

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

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

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

М.П.

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

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

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

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

М.П.

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

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

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

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

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

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

М.П.

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

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

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

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

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

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

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

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

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.

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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

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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
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CERTIFICATO N° 505DM07

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nella Sede Operativa di
Operative Unit

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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.

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MINISTERUL SĂNĂTĂȚII
AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ МОЛДОВА
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, muh. Chișinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: office@ansp.gov.md

DOCUMENTAȚIE MEDICALĂ / Медицинская документация
FORMULAR / Форма Nr. 303-2/e
APROBAT DE MS al RM / Утверждена МЗ РМ 31.10.11 Nr. 828

Centrul de Încercări de laborator acreditat de către
Centrul Național de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный
Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LI-044 din 17.02.2018 valabil până la 16.02.2022

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. 5033

Санитарное заключение для пищевых и непищевых продуктов

din/от " 20. " 12. a./г. 2021

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Cutii din carton

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

Regulamentului sanitar privind materialele şi obiectele destinate să vină în contact cu produsele alimentare aprobat prin HG nr.308 din 29.04.2011, GOST 7376-89, GOST 9142-90, GOST 13512-91, GOST 13511-2006, GOST 13516-86, GOST 13513-86

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

„ATGAIA-SU" SRL , Republica Moldova; ООО "ДУНАПАК ТАВРИЯ", Ucraina – furnizor materie primă

Destinatarul avizului sanitar / *получатель санитарного заключения*

„ATGAIA-SU" SRL, Moldova, Chișinău, bd. Dacia, 19, ap.11

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr.201 din 20.11.2020, facturi, certificate de calitate, declarație de conformitate, aviz sanitar nr.P-2363/2019 din 31.07.2019, raport a încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

(a enumera documentele anexate / Inscrie, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)*	**Normativul sanitar /** *санитарный норматив*

conform raportului încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

Domeniu de utilizare / *Область применения:* ambalaj, inclusiv produse alimentare

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
producerea, plasarea pe piață în condițiile respectării legislației în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 31 decembrie 2024

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ
Nicolae JELAMSCHI
(numele, prenumele/ Ф.И.О.)

L.Ș. (semnătura / подпись)

SP 10-XVI-09

ANSP/HAO3

0004158 O3

ex:Șt.Constantinovici
tel: 574 679

BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

ALCOHOL ETHANOL

Reagent for quantitative determination of alcohol in human serum, plasma, whole blood or urines.

REF 99029 **R1** 10 x 10 mL **R2** 1 x 5 mL
REF 99059 **R1** 2 x 100 mL **R2** 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax: (33) 03 23 256 256

CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1)

Most toxicologists consider ethanol to be the most often used and abused chemical substance. Consequently, the measurement of ethanol is one of the more frequently performed tests in toxicology laboratory. Although less frequently encountered, it is important to include methanol, isopropanol and acetone (a metabolite of isopropanol) in a test battery for alcohols for proper evaluation (gas chromatography analysis) of the acutely intoxicated patient.

PRINCIPLE (4)

Enzymatic method described by Gadsen R. H. and al. Reaction scheme is as follows:

$$\text{Ethanol} + NAD^+ \xrightarrow{ADH} \text{Acetaldehyde} + NADH + H^+$$

The ratio of ADH and NAD^+/ Alcohol is maintained elevated so that equilibrium is reached relatively quickly. The conversion of ethanol to acetaldehyde proceeds rapidly. A “trapping agent” is used to drive the reaction to the right by complexion of acetaldehyde as it is formed.
The absorbance of NADH, proportional to alcohol concentration in the specimen, is measured by end-point reading at 340 nm.

REAGENTS COMPOSITION

Vial R1 **ENZYME COENZYME**

NAD^+ (Nicotinamine adenine dinucleotide phosphate)	≥ 2.4	mmol/L
ADH (Alcohol dehydrogenase)	≥ 25 000	IU/L
TRIS Buffer	pH 8.65 ± 0.1 at 25° C	
Stabiliser		
Preservatives		

Before reconstitution:
Xn, R22-32: Harmful if swallowed, Contact with acids liberates very toxic gas
S22-38: Do not breathe dust. In case of insufficient ventilation, wear suitable respiratory equipment

Once reconstituted: None

Vial R2 **STANDARD**

Ethanol: approximately 100 mg/dL (21.7 mmol/L)
The exact concentration is printed on the label of the vial R2.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.
- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENT PREPARATION

REF 99029 (vial R1): Use a non-sharp instrument to remove aluminium cap.
Add promptly to the contents of the vial R1 the volume of demineralised water stated on the label.
Mix gently and wait for complete dissolution before using reagent (approximately 10 minutes).

STABILITY AND STORAGE

Store at 2-8°C well capped in the original vial and away from light.
- Standard (vial R2): transfer the requested quantity, well recap the vial and store at 2-8°C.
- When stored and used as described, unopened reagent (vial R1) and standard (vial R2) are stable upon expiry date stated on the label.
- Once reconstituted and free from contamination:
  Working reagent (vial R1) is stable for 7 days Discard any reagent (vial R1) if cloudy or if absorbance at 340 nm is > 0.500.

Don’t use working reagent (vial R1) after expiry date stated on the label of the kit.

SPECIMEN COLLECTION AND HANDLING (1) (2)

Urines. Serum, plasma, whole blood (alcohol swabs should not be used during blood specimen collection). Use heparin, Potassium oxalate, E.D.T.A., Sodium citrate or fluoride as anticoagulant.
- Stability in whole blood (without sodium fluoride as preservative): at 18-25° C up to 2 days, at 2-8° C up to 2 weeks, at –15° C up to 4 weeks.
- Stability in whole blood (with Sodium fluoride as preservative): at 18-25° C up to 2 weeks, at 2-8° C up to 3 months, at –15° C up to 6 months.

Specimens must be kept capped to avoid evaporative loss to the atmosphere.

INTERFERENCES (3)

Interferences studies performed on sera show no interference with Proceduren°1:

Interferent	Alcohol in (mg/dL)	Results
Ascorbic Acid	95	No interference up to 25 mg/dL
Total Bilirubin	96	No interference up to 418 µmol/L
Hemoglobin	90	No interference up to 189 µmol/L
Glucose	50.7	No interference up to 1000 mg/dL
Turbidity	90	No interference up to 0.308 abs (lactescence)

Higher icteric, hemolysed or cloudy plasmas or sera may be deproteinised before performing the assay (§ **MANUAL PROCEDURE**).
Several alcohols interfere with the determination but react more slowly than ethanol (respect incubation time stated in the procedure):

Substance	approximate % of reactivity
Ethanol	100
n-Butanol	28
Isopropanol	4
Methanol	0.3
Ethylene glycol	1.6
Acetone	0

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Normal and pathological control.
3. Demineralised water for the reconstitution of the reagent.
4. TCA (Trichloro-acetic acid) 62.5 g/L.

CALIBRATION

- Standard provided in the kit (vial R2) measured in standardized conditions with enzymatic method and aqueous standard traceable to NERL Standard
- Or any calibrator traceable to a reference method or material.

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

To ensure good results, it is recommended to calibrate in the following cases:

1. When changing reagent batch.
2. After maintenance operations on the instrument.
3. When control values are out of range, even after using a new vial of fresh control.

QUALITY CONTROL

- Normal Control Ethanol/Ammonia/Bicarbonate REF 95013
- Pathological Control Ethanol/Ammonia/Bicarbonate REF 95023
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control and repeat the test.
3. If control is still out of range, use a new vial of calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

CLINICAL SIGNS (1) (2)

Ethanol concentration in WHOLE BLOOD:		States of alcoholic influence
mg/dL	**mmol/L**	
50-100	10.9-21.7	Flushing, slowing of reflexes, impaired visual activity
> 100	> 21.7	Central nervous system depression (CNS)
> 400	> 86.8	Fatalities reported (i.e.respiratory failure)
URINES:		Values in post-absorbtive state are similar to those of serum
SERUM:		Multiply by 1.2 to 1.3 the whole blood values.

Alcohol level is virtually no detectable in abstaining subjects.
Not all individuals experience the same degree of CNS dysfunction at similar blood alcohol levels. The statutory limit of blood alcohol concentration for driving a motor vehicle is different in function of the considered country.

PERFORMANCES CHARACTERISTICS (4)

Within run N = 20	*Low level*	*High level*	*Between run N = 20*	*Low level*	*High level*
Mean mg/dL	41.2	108.3	**Mean mg/dL**	41.6	109.5
S.D. mg/dL	0.87	1.41	**S.D. mg/dL**	1.6	1.3
C.V. %	2.1	1.3	**C.V. %**	3.97	1.23

Detection limit: approximately 10 mg/dL.

Sensitivity for 100 mg/dL: approximately 0.430 Abs at 340 nm.

Comparison studies with a commercially available reagent (enzymatic method):

40 sera within 40 and 280 mg/dL have been evaluated with both reagents (linear regression):

y = 1.0069 x – 0.21 r = 0.9987

X (mg/dL)	Acceptable Inaccuracy (4)	Y calculated value	Observed Inaccuracy	Conclusion
100	+/-5	100	0	Passed
300	+/-9	302	2	Passed

LINEARITY

The assay is linear up to 300 mg/dL (65 mmol/L).

Above, dilute the specimen (1 + 4) with saline solution and re-assay taking into account dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagent and specimens at room temperature.

Procedure n°1: Sera, plasmas, Urines (Without deproteinisation)

Pipette into 5 mL test tubes:	Blank	Standard	Assay
Working Reagent (vial R1)	3 mL	3 mL	3 mL
Demineralised water	10 µL		
Standard (vial R2)		10 µL	
Specimen			10 µL
Mix. Incubate for 10 minutes at 37° C or 15 minutes at 30° C or 30 minutes at room temperature. Read absorbance at 340 nm (or Hg 334) against reagent blank. The reaction is stable for 2 hours (see **§ INTERFERENCES**).			

Note:

Urines: It is recommended to perform a specimen blank (10 µL specimen + 3 mL water, read against water). Then deduct the absorbance of specimen blank from the absorbance of assay (read against reagent blank).

Procedure n°2: whole blood, very icteric, hemolysed or cloudy sera or plasmas (With deproteinisation)

1-Supernatant preparation

Pipette in centrifuge tube:	Standard	Specimen
TCA Solution 62,5 g/L	1.8 mL	1.8 mL
Standard (vial R2)	200 µL	
Specimen		200 µL
Cap tubes. Mix vigorously. Let stand for 5 minutes. Centrifuge for 5 minutes at 2000-3000 RPM. (Do not centrifuge Standard).		

2- Assay

Then, pipette into 5 mL test tubes:	Blank	Standard	Assay
Working Reagent (vial R1)	3 mL	3 mL	3 mL
Demineralised water	100 µL		
TCA diluted Standard		100 µL	
Supernatant			100 µL
Mix. Incubate for 10 minutes at 37° C or 15 minutes at 30° C or 30 minutes at room temperature. Read absorbance at 340 nm (or Hg 334) against reagent blank. The reaction is stable for 2 hours (see **§ INTERFERENCES**).			

Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

CALCULATION

Calculate the result as follows:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 922-927.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 1344-1347.*

(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-251-to 3-253*

(4) *GADSDEN R.H., TAYLOR E.H., STEINDEL S.J. et al: Ethanol in Biological Fluids by Enzymic Analysis. In: Selected Methods of Emergency Toxicology. C.S. Frings, W.R. Faulkner, Eds. Vol 11. Selected Methods of Clinical Chemistry, Washington DC, AACC Press, 1986, p. 63-65*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with

REPUBLIQUE FRANCAISE

CCI PARIS ILE-DE-FRANCE

Direction Générale Adjointe - Services aux Entreprises et Développement International
Direction des réseaux et partenariats internationaux
Service CLV

Certificat de Libre Vente pour l'exportation vers les pays non membres de l'Union Européenne

Free sale certificate for exportation to the non-EC Member States

dispositifs médicaux de diagnostic in vitro relevant de la directive n°98/79/CE

in vitro diagnostic medical devices covered by Directive 98/79/EC

PARTIE A COMPLETER PAR LE DEMANDEUR

Section to be completed by the applicant

Catégorie(s) du(des) dispositif(s) : Réactifs et instruments de laboratoires pour la Biologie Médicale

Device(s) category: Reagents § Instruments for Medical Biology

Nombre de page en annexe : 7

Page in annex : 7

La désignation du(des) dispositif(s) apparaît sur la déclaration(s) CE de conformité du fabricant ou du mandataire

The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative

Classification du(des) dispositif(s) :

Classification of the device(s) :

☐ **dispositif de l'annexe II liste A**
device of list A annex II

☐ **dispositif de l'annexe II liste B**
device of list B annex II

☐ **autotest hors annexe II**
device for self-testing not listed in annex II

☒ **autre dispositif (tous les dispositifs sauf dispositifs de l'annexe II et autotests)**
other device (all devices except annex II and self-testing devices

Nom et adresse du fabricant ou du mandataire :

Name and address of the manufacturer or the authorized representative:

BIOLABO SAS / Mr Jean François CHARPENTIER, Les Hautes Rives 02160 MAIZY

Nom et adresse du site de production (facultatif):

Name and address of Production site (optional):

BIOLABO SAS, Les Hautes Rives 02160 MAIZY

Je soussigné Antoine Bianchi, Directeur des méthodes certifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux de diagnostic in vitro figurant sur la(les) déclaration(s) CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°98/79/CE et répondent aux exigences essentielles de santé et de sécurité.

I the undersigned Antoine Bianchi, Director of methods declare that the information above-mentioned is correct and the in vitro diagnostic medical devices on the EC declaration(s) of conformity are CE marked under my responsibility within the meaning of the European directive n°98/79/EC and fulfil the essential requirements of health and safety.

Date :12/02/2021

Signature : P.O

BIOLABO S.A.S.
Les Hautes Rives
02160 MAIZY FRANCE
Phone : +33 (0)3 23 25 15 50
Fax : +33 (0)3 23 25 62 56
Siret 317 398 832 00038
TVA FR 82 317 398 832

PARTIE RESERVEE A LA CCIR PARIS IDF

Section reserved for the administration

Les dispositifs médicaux de diagnostic in vitro marqués CE en conformité avec la directive 98/79/CE peuvent être mis sur le marché en France et dans les autres Etats membres de l'Union Européenne et parties à l'accord sur l'espace économique européen, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant des dispositifs concernés, d'une déclaration de conformité (autre dispositifs), accompagnée le cas échéant, des certificats nécessaires délivrés par un organisme notifié (dispositif de l'annexe II liste A et liste B, autotests hors annexe II). Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

CCIR Paris IDF / DGA-SEDI
Service des CLV
9, rue Coquillière
75001 PARIS

Le Responsable du département des Facilitations du Commerce Extérieur
CCI PARIS ILE-DE-FRANCE
CCIR Paris IDF

Pour le président, Diemaba SOW-DIAGNE

The in vitro diagnostic medical devices CE marked in conformity with the directive 98/79/EC can be placed on the French market and in the other Member states of the European Union and part of the European Free Trade Association, and be exported in the non-EC Member States. This free sale certificate is valid until the maintenance, by the manufacturer of the concerned devices, of an CE declaration of conformity (other devices) together with when appropriate, the certificates delivered by a notified body (devices of list A and B, annex II, devices for self-testing not listed in annex II). This free sale certificate can only be used for exportation outside European Union.

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs de Biochimie poudre polyvalents / Versatile Biochemistry powder reagents	
80351	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80001	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
87601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
99029	ALCOOL Ethanol	ALCOHOL Ethanol
99059	ALCOOL Ethanol	ALCOHOL Ethanol
80027	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80127	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80227	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80327	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
92027	ALT / TGP Méthode Colorimétrique	ALT / GPT Colorimetric Method
99261	AMMONIAC Méthode Enzymatique	AMMONIA Enzymatic Method
99523	AMYLASE CNPG3	AMYLASE CNPG3
99123	AMYLASE CNPG3	AMYLASE CNPG3
99223	AMYLASE CNPG3	AMYLASE CNPG3
80025	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80125	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80225	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80325	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
92025	AST / TGO Méthode Colorimétrique	AST / GOT Colorimetric Method
99832	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
99852	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
80553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
97553	BILIRUBINE DIRECTE Méthode DCA	DIRECT BILIRUBIN DCA Method
97443	BILIRUBINE TOTALE Méthode DCA	TOTAL BILIRUBIN DCA Method
97408	C.L.F. Capacité Latente de Fixation du Fer	U.I.B.C Unsaturated Iron Binding Capacity
92308	C.T.F. Capacité Totale de Fixation du Fer	T.I.B.C. Total Iron Binding Capacity
80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87656	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87356	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
88656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
99656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
86536	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
86516	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
82526	CHOLINESTERASE Butyrylthiocholine	CHOLINESTERASE Butyrylthiocholine
92207	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
92307	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
80008	FER (SFBC) Bathophénanthroline	IRON (SFBC) Bathophenanthrolin
97099	G6-PDH lyophilisée Méthode cinétique U.V.	Lyophilised G6-PDH U.V. Kinetic Method
97089	G6-PDH Méthode cinétique U.V.	G6-PDH U.V. Kinetic Method
97199	G6-PDH Méthode Automatisée	G6-PDH Automated Method
81110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81210	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81310	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
80009	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87109	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87409	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
16GL8	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
82250	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
97217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
97317	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
92011	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92111	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92511	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
99881	LIPASE Méthode cinétique	LIPASE Kinetic Method
99891	LIPASE Méthode cinétique	LIPASE Kinetic Method
87212	MAGNESIUM Calmagite	MAGNESIUM Calmagite

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs de Biochimie poudre polyvalents / Versatile Biochemistry powder reagents	
82560	PHOSPHATASE ACIDE Méthode Cinétique	ACID PHOSPHATASE Kinetic Method
3300060	PHOSPHATASE ACIDE Méthode Point Final (PNPP)	ACID PHOSPHATASE End Point Method (PNPP)
92214	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE DEA Method
92314	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE DEA Method
99105	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
99110	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
80016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
92026	Solution Soude 0,4 N	NaOH Solution 0.4 N
80019	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
87319	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
80221	UREE Méthode colorimétrique	UREA Colorimetric Method
80321	UREE Méthode colorimétrique	UREA Colorimetric Method
92032	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
92132	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
99032	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
99132	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
92315	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
92330	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
	Réactifs de Biochimie liquide prêt à l'emploi polyvalents / Versatile Biochemistry ready-to-use liquid reagents	
LP80501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
80107	CREATININE Méthode cinétique	CREATININE Kinetic method
90107	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
80005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
80015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
3502200	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
LP80507	ALT TGP (IFCC)	ALT GPT (IFCC)
LP80607	ALT TGP (IFCC)	ALT GPT (IFCC)
LP99553	AMYLASE CNPG3	AMYLASE CNPG3
LP80505	AST TGO (IFCC)	AST GOT (IFCC)
LP80605	AST TGO (IFCC)	AST GOT (IFCC)
92108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
80403	BILIRUBINE TOTALE ET DIRECTE Méthode Acide Sulfanilique	TOTAL AND DIRECT BILIRUBIN Sulfanilic Acid Method
80443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
90004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
80004	CALCIUM Méthode CPC	CALCIUM CPC Method
LP80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
90206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90406	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90426	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
90816	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
LP80209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP87809	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
98212	MAGNESIUM CALMAGITE Haute Stabilité - Haute Linéarité	MAGNESIUM CALMAGITE High Stability – High Linearity
LP87016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
97016	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
LP80519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80619	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP99532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99632	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs dédiés pour KENZA One / Dedicated reagents for KENZA One	
K1501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K1002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
K1507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K1523	AMYLASE CNPG3	AMYLASE CNPG3
K1ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K1505	AST / TGO (IFCC)	AST / GOT (IFCC)
K1553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K1443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K1004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
K1005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
K1106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
K1206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K1416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
K1207	CK-NAC IFCC	CK-NAC IFCC
K1107	CREATININE Méthode cinétique	CREATININE Kinetic method
K1117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K150E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
K1210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K1RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K1108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K1508	FERRITIN	FERRITIN
K1110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K1209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
K1010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K1217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K1011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K1212	MAGNESIUM CALMAGITE	MAGNESIUM CALMAGITE
K1214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K1015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
K1084	POTASSIUM Enzymatique	POTASSIUM Enzymatic
K1016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEINS Biuret Method
K1085	SODIUM Enzymatique	SODIUM Enzymatic
K1208	TRANSFERRIN	TRANSFERRIN
K1519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
K1532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K1701	VITAMIN D	VITAMIN D
K1901	ZINC	ZINC
	Réactifs dédiés pour KENZA 240 et KENZA 450 TX/ISE / Dedicated reagents for KENZA 240 and KENZA 450 TX/ISE	
K2501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K4501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K2002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
K2507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K4507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K2523	AMYLASE CNPG3	AMYLASE CNPG3
K4523	AMYLASE CNPG3	AMYLASE CNPG3
K2ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K4ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K2505	AST / TGO (IFCC)	AST / GOT (IFCC)
K4505	AST / TGO (IFCC)	AST / GOT (IFCC)
K2553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K4553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K2443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K4443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K2004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
K2005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
K2106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
K2206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K4206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K2416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
K4416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs dédiés pour KENZA 240 et KENZA 450 TX/ISE / Dedicated reagents for KENZA 240 and KENZA 450 TX/ISE	
K2207	CK-NAC IFCC	CK-NAC IFCC
K4207	CK-NAC IFCC	CK-NAC IFCC
K2107	CREATININE Méthode cinétique	CREATININE Kinetic method
K2117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K4117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K250E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
K2210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K4210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K2RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K4RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K2108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K4108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K2508	FERRITIN	FERRITIN
K4508	FERRITIN	FERRITIN
K2110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K4110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K2209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
K2010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K4010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K2217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K4217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K2011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K4011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K2212	MAGNESIUM CALMAGITE	MAGNESIUM CALMAGITE
K2214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K4214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K2015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
K2084	POTASSIUM Enzymatique	POTASSIUM Enzymatic
K2016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEINS Biuret Method
K2017	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
K2085	SODIUM Enzymatique	SODIUM Enzymatic
K2208	TRANSFERRIN	TRANSFERRIN
K4208	TRANSFERRIN	TRANSFERRIN
K2519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
K2532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K4532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K2701	VITAMIN D	VITAMIN D
K4701	VITAMIN D	VITAMIN D
K2901	ZINC	ZINC
K4901	ZINC	ZINC

	Calibrants et contrôles de biochimie / Biochemistry calibrators and controls	
95010	EXATROL-N Taux 1	EXATROL-N Level 1
95110	EXATROL-N Taux 1	EXATROL-N Level 1
95011	EXATROL-P Taux 2	EXATROL-P Level 2
95111	EXATROL-P Taux 2	EXATROL-P Level 2
95015	MULTICALIBRATOR Calibrateur Multiparamétrique	MULTICALIBRATOR Multiparametric calibrator
95115	MULTICALIBRATOR Calibrateur Multiparamétrique	MULTICALIBRATOR Multiparametric calibrator
95801	Calibrant LIPASE	LIPASE Calibrator
95406	CALIBRATEUR CHOLESTEROL HDL	HDL-CHOLESTEROL CALIBRATOR
95806	CALIBRATEUR CHOLESTEROL LDL	LDL-CHOLESTEROL CALIBRATOR
95506	CALIBRATEUR HDL LDL CK-MB	HDL LDL CK-MB CALIBRATOR
95013	Contrôle Normal AMMONIAC ALCOOL BICARBONATE	Normal Control AMMONIA ALCOHOL BICARBONATE
95023	Contrôle Pathologique AMMONIAC ALCOOL BICARBONATE	Pathological Control AMMONIA ALCOHOL BICARBONATE
95012	Contrôle urinaire Taux 1 et Taux 2	Urinary Control Level 1 and Level 2
95289	G6-PDH Contrôle Déficient (hémolysat humain lyophilisé)	G6-PDH Deficient control (Lyophilised human hemolysed blood)
95089	G6-PDH Contrôle normal (hémolysat humain lyophilisé)	G6-PDH Normal control (Lyophilised human hemolysed blood)
97599	G6-PDH Control Set	G6-PDH Control Set
95315	KIT CALCULS URINAIRES Contrôles Positifs et Négatifs	STONE ANALYSIS SET Positive and Negative Controls
95516	Sérum de contrôle HDL LDL CK-MB Lipides Taux 1	Control serum HDL LDL CK-MB Lipids Level 1
95526	Sérum de contrôle HDL LDL CK-MB Lipides Taux 2	Control serum HDL LDL CK-MB Lipids Level 2

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs d'hémostase / Haemostasis reagents	
13560	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13570	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13450	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13451	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13660	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13670	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13702	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13704	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13712	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13880	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13885	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13881	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13980	BIO-TT Temps de Thrombine	BIO-TT Thrombin Time
13565	CHLORURE DE CALCIUM 0,025M	CALCIUM CHLORIDE 0.025M
13302	FACTOR II Plasma Déficient	FACTOR II Deficient plasma
13309	FACTOR IX Plasma Déficient	FACTOR IX Deficient plasma
13305	FACTOR V Plasma Déficient	FACTOR V Deficient plasma
13307	FACTOR VII Plasma Déficient	FACTOR VII Deficient plasma
13308	FACTOR VIII Plasma Déficient	FACTOR VIII Deficient plasma
13310	FACTOR X Plasma Déficient	FACTOR X Deficient plasma
13311	FACTOR XI Plasma Déficient	FACTOR XI Deficient plasma
13312	FACTOR XII Plasma Déficient	FACTOR XII Deficient plasma
13883	TAMPON OWREN KOLLER	OWREN KOLLER BUFFER
	Calibrants et contrôles d'hémostase / Haemostasis calibrators and controls	
13965	TP-CALSET Set de Plasmas de Référence	TP-CALSET Standard Set
13970	BIO-CAL Plasma de référence	BIO-CAL Reference Plasma
13961	PLASMA CONTRÔLE Taux 1	CONTROL PLASMA Level 1
13962	PLASMA CONTRÔLE Taux 2	CONTROL PLASMA Level 2
13963	PLASMA CONTRÔLE Taux 3	CONTROL PLASMA Level 3
13210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
13211	D-DIMER Control 1	D-DIMER Control 1
13212	D-DIMER Control 2	D-DIMER Control 2
13971	COATROL 1 Taux 1	COATROL 1 Level 1
13972	COATROL 2 Taux 2	COATROL 2 Level 2

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs calibrants et contrôles d'Immunoturbidimétrie / Turbidimetric Immunoassay reagents, calibrators and controls	
RF050E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF520E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF CALSET51	BIOLABO FR Kit de Calibration	BIOLABO RF Standard Set
RF CALSH1	BIOLABO FR Calibrant Super Haut	BIOLABO RF Standard Super High
RF CONT1	BIOLABO FR Contrôle	BIOLABO RF Control
RF CONT5	BIOLABO FR Contrôle	BIOLABO RF Control
CRP050E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP620E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP CALSET51	BIOLABO CRP Kit de Calibration	BIOLABO CRP Standard Set
CRP CALSH1	BIOLABO CRP Calibrant Super Haut	BIOLABO CRP Standard Super High
CRP CONTL1	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTL5	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTH1	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
CRP CONTH5	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
ASLO050E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO620E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO CALH1	BIOLABO ASLO Calibrant Haut	BIOLABO ASLO Standard High
ASLO CALSH1	BIOLABO ASLO Calibrant Super Haut	BIOLABO ASLO Standard Super High
ASLO CALSET41	BIOLABO ASLO Kit de Calibration	BIOLABO ASLO Standard Set
ASLO CONT1	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
ASLO CONT5	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
23010	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23011	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23012	MICROALBUMINE Calibrant Super Haut	MICROALBUMIN Standard Super High
23013	MICROALBUMINE Kit de calibration	MICROALBUMIN Standard Set
23014	MICROALBUMINE Contrôle	MICROALBUMIN Control
22050	HbA1c ENZYM	HbA1c ENZYM
22052	HbA1c ENZYM Kit de calibration	HbA1c ENZYM Standard Set
22010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22011	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22012	HbA1c Kit de calibration	HbA1c Standard Set
22013	HbA1c Kit de contrôle	HbA1c Control Set
	Tests sur lame / Slide tests	
9905TH	S. Typhi H (d.H)	S. Typhi H (d.H)
9905TO	S. Typhi O (9,12-O)	S. Typhi O (9,12-O)
9905AH	S. Paratyphi AH (a-H)	S. Paratyphi AH (a-H)
9905AO	S. Paratyphi AO (1,2,12-O)	S. Paratyphi AO (1,2,12-O)
9905BH	S. Paratyphi BH (b-H)	S. Paratyphi BH (b-H)
9905BO	S. Paratyphi BO (1,4,5-O)	S. Paratyphi BO (1,4,5-O)
9905CH	S. Paratyphi CH (c-H)	S. Paratyphi CH (c-H)
9905CO	S. Paratyphi CO (6,7-O)	S. Paratyphi CO (6,7-O)
9905BA	Brucella abortus	Brucella Abortus
9905PK	Proteus OXK	Proteus OXK
9905P19	Proteus OX19	Proteus OX19
9905P2	Proteus OX2	Proteus OX2
9905BM	Brucella Melitensis	Brucella Melitensis
9905RB	Rose Bengal (B. Abortus)	Rose Bengal (B. Abortus)
9901PC	Contrôle Positif Polyvalent	Positive Polyvalent Control
9901NC	Contrôle Négatif Polyvalent	Negative Polyvalent Control
99058	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
081050	ASLO-LATEX	ASLO-LATEX
097100	CRP-LATEX	CRP-LATEX
098100	FR-LATEX	FR-LATEX
3800100	RPR-CHARBON	RPR-CHARBON
3800150	RPR-CHARBON	RPR-CHARBON
4500100	TPHA	TPHA
4500200	TPHA	TPHA
085100	HCG-LATEX	HCG-LATEX

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
Analyseurs / Analysers		
KENZA MAX	KENZA MAX BioChemisTry PHOTOMETRE	KENZA MAX BioChemisTry PHOTOMETER
KENZA ONE	KENZA ONE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA ONE - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240TX	KENZA 240TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 240TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240ISE	KENZA 240ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE avec module ISE	KENZA 240ISE - AUTOMATIC BIOCHEMISTRY ANALYSER with ISE Module
KENZA 450TX	KENZA 450TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 450TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 450ISE	KENZA 450ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 450ISE - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 120TX	KENZA 120TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 120TX - AUTOMATIC BIOCHEMISTRY ANALYSER
BIOSOLEA 2	BIO SOLEA 2 - COAGULOMETRE 2 CANAUX	BIO SOLEA 2 - COAGULOMETER 2 CHANNELS
BIOSOLEA 4	BIO SOLEA 4 - COAGULOMETRE 4 CANAUX	BIO SOLEA 4 - COAGULOMETER 4 CHANNELS
SOLEA 100	SOLEA 100 - ANALYSEUR AUTOMATIQUE D'HEMOSTASE	SOLEA 100 - FULL AUTOMATED COAGULATION ANALYSER
Consommables et solutions de nettoyage / Consumables and cleaning solutions		
SCUP120	Serum Cup K120TX	Serum Cup K120TX
CO0080	SERUM CUPS	SERUM CUPS
CO4015	EXTRA Cleaning	EXTRA Cleaning
CO4020	IPO Cleaning	IPO Cleaning
CO0058	SERUM CUPS K450	SERUM CUPS K450
K450CS	Cleaning Solution K450	Cleaning Solution K450
RP240ISE	Pack Réactifs - ISE	Reagent Pack - ISE
G2058/A	Cleaning Solution - ISE	Cleaning Solution - ISE
5202	Electrode K - ISE	Electrode K - ISE
5205	Electrode Li - ISE	Electrode Li - ISE
5207	Electrode Cl - ISE	Electrode Cl - ISE
5201	Electrode Na - ISE	Electrode Na - ISE
5204	Electrode de référence	Reference Electrode
S100CS	CLEANING SOLUTION SOLEA 100	CLEANING SOLUTION SOLEA 100

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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 N.* 0967.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

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

SITI / *SITES*

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

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

ISO 14001:2015

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 tramite processo di stampaggio. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radiofrequenza (RFID) tramite processo di stampaggio. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche canto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercia di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG tramite processi di accoppiamenti delle materie prime e taglio a misura. Gestione della produzione ed immissione in commercia di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

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*
	2019-06-05	2019-06-05	2022-06-04

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

IMQ

FEDERAZIONE CISQ

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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGA N° 006 D

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

IAF: 07, 09, 19, 12, 29

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento
Processes related to underlined IAF sectors are not yet covered by accreditation

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

Organismo di Certificazione Federato CISQ
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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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)

has implemented and maintains a

Environmental 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 by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

which fulfills the requirements of the following standard:

ISO 14001:2015

Issued on: **2019 - 06 - 05**
Expires on: ***2022 - 06 - 04***

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 - 125879

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

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

mantiene negli stabilimenti di:

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:
DM17-0017248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

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

manages in the factories of:

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

a quality assurance system ensuring the conformity of the following products:

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2017-11-18

Expiry Date: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CERACARTA® S.p.A.

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipment
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking sys
lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017

Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali

2017-11-18

EC Certificate

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

Registration No.: HL 60119814 0001

Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products:
Products for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60076687 0001

Expiry Date: 2022-05-28

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

Effective Date: 2017-05-29

Date: 2017-05-29

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60119814 0001
Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products for self-testing:
- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

Additional site for warehousing and logistics:

Bahnstr. 120
52355 Düren, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization:
MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

Scope:
Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Neumann-Neander-Str. 6-8
52355 Düren
Germany

including the locations according to annex

Scope: Design and development, production and distribution of products for filtration, rapid tests, water analysis, chromatography and bioanalysis

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

LUMED S.r.l.

Sede Operativa / *Operational Headquarter:*
Via Staffora, 18/9
20073 Opera, MI - Italia

Sede legale / *Registered Headquarter*
Via Vittor Pisani, 28
20124 Milano, MI - Italia

Sede Operativa / *Operational Headquarter*
Via Senio, 36/40
47121 Forlì, FC - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Carte di registrazione per apparecchiature elettromedicali / *Recording chart paper for medical devices*
Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*
Elettrocardiografi / *Electrocardiographs*
Elettrocardiografi di seconda generazione / *Electrocardiographs*
Holter ECG / *Holter systems*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* 12-13-14-15/01/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:11

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Carte di registrazione per apparecchiature elettromedicali / *Recording chart paper for medical devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 0104

Modello / Model:

Carte termiche prive di Bisfenoli / Phenol free chart paper

Codici / Codes:

CF αα xxx (/yyy) BF αα xxx (/yyy)

Tipologia / *Medical Devices:*
Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106

Modello / Model:

Boccagli / Mouthpieces

Codici / Codes:

TSxxxx (/yyyy); 910300

Modello / Model:

Boccagli con filtro antiparticolato / Mouthpieces with particulate filter

Codici / Codes:

TSFxxxx

Modello / Model:

Filtri B.V. (batterici - virali) / Bacterial-viral filters

Codici / Codes:

TSVBM xxx (/yyy)

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:29

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_ecg 3view; euro_ecg 6view; euro_ecg 12view;

Codici / Codes:

EP-LU30001 EP-LU30002 EP-LU30003

Tipologia / *Medical Devices:*
Elettrocardiografi di seconda generazione / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_ecg 301A; euro_ecg 301; euro_ecg 301B; euro_ecg 601A; euro_ecg 601; euro_ecg 601B; euro_ecg 1201A; euro_ecg 1201; euro_ecg 1201B

Codici / Codes:

EP-LU30111, EP-LU30101, EP-LU30121, EP-LU30112, EP-LU30102, EP-LU30122, EP-LU30113, EP-LU30103, EP-LU30123

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:06:47

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26032	Revisione / *Revision*	10
Primo rilascio / *First issue date*	2006-09-07	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Holter ECG / *Holter systems*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Modello / Model:

euro_holter 3view ; euro_holter 12view

Codici / Codes:

EP-LU20001 EP-LU20002 EP-LU20003 EP-LU20004

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:24/05/2021 17:07:17

Organismo Notificato n. 0476
Notified Body nr. 0476

DICHIARAZIONE CE DI CONFORMITÀ
CONFORMITY CE DECLARATION - DECLARATIONE CE DE CONFORMITE
KONFORMITÄTSERKLÄRUNG - DECLARATION CE DE CONFORMIDAD

Modulo: TPM999 (ref. ISO/IEC 17050-1)

Nome del rilasciante - Manufacturer's name - Nom de la Société délivrante - Name des Hersteller - Nomgre de expedidor

TECNO-GAZ S.p.A.

Strada Cavalli n. 4, 43038, Sala Baganza, Parma, ITALY

Oggetto della dicharazione - Subject of declaration - Objet de la déclaration - Betreffvon Erklärung - Objeto de la declaración

REF: CS005Z01

ROTOLI PIATTI mm 150x200 mt
confezione 4 pz
STERILIZATION PAPER REELS mm 150x200 mt
4 units box package

TECNO-GAZ dichiara sotto la propria responsabilità che l'oggetto della dichiarazione sopra descritto è conforme ai requisiti dei seguenti documenti:
TECNO-GAZ declares under its own responsability that The object of the declaration described conforms to the requirements of the following documents:
TECNO-GAZ déclare sous sa responsabilité que l'objet de la déclaration décrit ci-dessus est conforme aux exigences des documents suivants
TECNO-GAZ erklärt, dass der Gegenstand dieser Erklärung den Anforderungen folgender Unterlagen beachtet:
TECNO-GAZ declara bajo su responsabilidad que el objeto de la declaración se ha descrito anteriormente se ajusta a los requisitos de los siguientes documentos

*Direttiva 93/42/CEE e successive modifiche e integrazioni | Directive 93/42/EEC and following modifications and supplements | Directive 93/42/CEE et modifications ultérieures et supplémentaires | Richtlinie 93/42/EWG und folgendene Änderungen und Ergänzungen | Directiva 93/42/CEE e siguientes variaciones e adiciones.
Recepita in Italia dal Decreto Legislativo n.46 del 24 Febbraio 1997 e successive modifiche e integrazioni.
La procedura di valutazione della conformità è conforme all'allegato VII della direttiva 93/42/CEE | The conformity assessment procedure is in accordance with Annex VII of Directive 93/42/EEC | La procédure d'évaluation de la conformité est en conformité avec l'annexe VII de la directive 93/42 /CEE | Das Konformitätsbewertungsverfahren ist gemäß Anhang VII der Richtlinie 93/42/EWG | El proceso de evaluación de la conformidad se conforma al anexo VII de la directiva 93/42/CEE.
Classe I - Class I - classe I - Klasse I - Clase I .

EN 11607

EN ISO 868-1 5

Data di produzione | Production date | Date de fabrication | Produktionsdatum | Fecha de producción **13/06/2019**

Marchio CE è stato apposto sul prodotto in data 13/06/2019 | CE mark have been affixed to this product on 13/06/2019 | Le marquage CE a été apposée sur le produit le 13/06/2019 | Die CE Markierung wurde am 13/06/2019 angebracht | Marca CE se ha puesto sobre el producto en la fecha 13/06/2019

Luogo e data di rilascio - Place and date of issue - Lieu et date de délivrance - Ort und Datum - Lugar de producción

Sala Baganza (PR), 13/06/2019

Paolo Bertozzi

Presidente - Chairman - Président - Vorstandvorsitzender - Presidente

CE

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

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/A

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

MEUS S.r.l.

Unità Operative / *Operative Units*
Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.
Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.
Via dell'Industria 2-16 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

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 kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Design and production of moulds for plastic labware.

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	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*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.

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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.

ICIM

CERTIFICATO n.
CERTIFICATE No.

4265/5/B

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

ROLL S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

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 Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Injection moulding of thermoplastic materials for medical devices.

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.

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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.

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CISQ is the Italian Federation of management system Certification Bodies.

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G-CERTI *Certificate*

hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

has been audited and certified as meeting the requirements & Scope of registration

ISO 13485:2016
Medical Devices - Quality Management Systems

Design, Development, Manufacture and Service of Special Paper (Thermal Paper, Ink-jet Paper, Photographic Paper, Mat Sheet)

Certificate No : GK-0233-MD
Valid Period : 05 Jul 2020 ~ 04 Jul 2023
Initial Date : 05 Jul 2014 Issue Date : 01 Jul 2020
Expiry Date : 04 Jul 2023

Signed for and on behalf of GCERTI
President I.K.Choi

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F, Surveillance audits shall be conducted at least once a carlendar year, execpt in recetification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

IAS ACCREDITED
MSCB-113

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Certificate of Completion

this is to certify

Mr. Alexei Legun

has successfully completed

The technical maintenance training course

On

Urine Analysis

URYXXON 200;
URYXXON RELAX;
URYXXON 500;

Mars, 2006

President
MACHEREY-NAGEL GMBH & CO.KG

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

№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(юридический адрес лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(фактический адрес лица)

ИНН: 3234007127 **ОГРН: 1023202138332**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации: _____ **В. И. Погодин**

(подпись)

Председатель экспертной комиссии: _____ **Е. Д. Курбатова**

(подпись)

М.П.

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