



CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

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

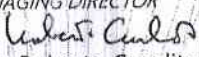
Gestione della fabbricazione ed immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici 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. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.*

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Settore IAF 14 - 29

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2017-10-30

Data di Scadenza
Expiration Date

2020-10-29



SGQ N° 023A PRD N° 123B
SGA N° 0200 ISP N° 075E
PRS N° 097C
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



articoli per laboratorio analisi
disposable labware

www.kima.it



Messrs

"GBG-MLD" SRL
STR. TIGHINA 65
2001 CHISINAU
MOLDOVA

Piove di Sacco, 25/02/2019

DISTRIBUTOR AGREEMENT

To whom it may concern, we hereby declare that:

KIMA sas – Via Leonardo Da Vinci 22 – 35028 piove di Sacco - (PD) - ITALY

appoints "GBG-MLD" SRL – STR. TIGHINA 65. - 2001 CHISINAU –MOLDOVA

as authorized distributor of KIMA plastic labware products in the territory of MOLDOVA

GBG MLD has the right to import and distribute KIMA plastic labware products.

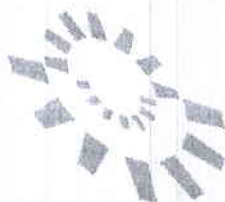
This Agreement is valid one (2) years from the present date.

The Distributor does not have any possibility to oblige the company KIMA sas with quantities or delivery time as well as prices without prior written authorization from KIMA sas.

KIMA sas keeps the right to modify the prices according to the market of the raw materials.

Renzo Chiarin
Managing Director

KIMA S.R.L.
Via Leonardo Da Vinci, 22
35028 PIOVE DI SACCO (PD)
Partita IVA 01466290283



ICIM

CERTIFICATO n.
CERTIFICATE No.

4265/4/C

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

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - 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

EA: 29

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.

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

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

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.*



SGQ N° 004 A

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



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.



CERTIFICATO n.
CERTIFICATE No.

4264/4/C

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

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 29

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.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

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

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

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address: info@icim.it.

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022


ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A

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



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.

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.



We

Name of manufacturer

MACHEREY-NAGEL GmbH & Co. KG

Address:

MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following test strips for professional use:

Name of product	Reference numbers
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG, Neumann-Neander-Str. 6-8, 52355 Dueren, Germany

DE / International:

Tel.: +49 24 21 989-0

Fax: +49 24 21 989-199

E-mail: info@mn-net.com

CH:

Tel.: +41 62 388 55 00

Fax: +41 62 388 55 05

E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 88 22 68

Fax: +33 388 51 76 88

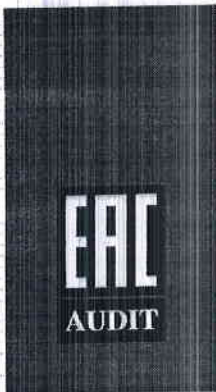
E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0984

Fax: +1 484 821 1272

E-mail: sales-us@mn-net.com



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:



(подпись)

В. И. Погодин

(подпись)

Е. Д. Курбатова

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

Федеральное агентство по техническому регулированию и метрологии



Система добровольной сертификации "НОПСС" РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

выдан

Общество с ограниченной ответственностью

«МиниМед»

ИНН 3234007127 / ОГРН 1023202138432

241520, Бокситовская область, Бокситовский район, с. Сопкинское, ул. Пирогова, д. 17А

Подтверждает, что система менеджмента качества
соответствует требованиям ГОСТ ISO 9001-2015 (ISO 9001:2015)

При осуществлении работ согласно приложению №1 к настоящему сертификату

Сертификат выдан на основании решения экспертной комиссии

от 24.09.2018

Срок действия до 24 сентября 2021

Номер в едином реестре системы СИ256

Руководитель органа
по сертификации:

Подпись

Платонов Б.А.

Настоящий сертификат обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации СИ256 "НОПСС" и подтверждаться при прохождении ежегодного инспекционного контроля.

Федеральное агентство по техническому регулированию и метрологии



Система добровольной сертификации "НОПСС" РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

ПРИЛОЖЕНИЕ №1

К сертификату соответствия № СИ256

Применительно к видам деятельности:

Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

НОПСС

Руководитель органа
по сертификации:

Подпись

Платонов Б.А.



THE POWER OF **CONNECTED**

EU Declaration of Conformity

Personal Protective Equipment:

Brand: Honeywell
Name: Polysafe
Item Code: 1002550
Type: Eye Protection - Safety Eyewear

Manufacturer:

HONEYWELL SAFETY PRODUCTS USA INC
10 Thurber Boulevard
02917 Smithfield
UNITED STATES

This declaration of conformity is issued under the sole responsibility of the manufacturer:

HONEYWELL SAFETY PRODUCTS USA INC

The object of the declaration described above is in conformity with:

- the relevant Union harmonization legislation: Personal Protective Equipment Regulation (EU) 2016/425

The fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.

- the relevant harmonised standard(s) and/or technical specification(s): EN 166:2001

The notified body: satra Technology Europe Ltd
Number: 2777

Performed the EU type-examination and issued the EU type-examination certificate number: 2777/12512-01/E00-00 .

Signed for and on behalf of:

HONEYWELL SAFETY PRODUCTS USA INC

Place of issue:

Smithfield

Date of issue:

4/16/2019

Name:

Manuel Reynoso

Function:

Quality Assurance Manager Sr

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация,
196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
**ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО
ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.**

Место и дата:
Москва, 21 июня 2018



FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва,
Российская Федерация

S. Groobme

Сергей Грубин
Представитель руководства



Issued to: 277712512-01

SATRA customer number: P19012

EU Type-Examination Certificate

Certificate number: 277712512-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category II product.

Product reference: Polysafe
Description: Protective Spectacle with clear lenses

Classification:

Model	Frame	Scale number	Lens	Lens coating	Performance
1002550	Polysafe	2C-1.2	Clear	Uncoated	1F
1002549	Polysafe Plus	2C-1.2	Clear	Ultra-Dura	1F
1015744	Visitor Spec	2C-1.2	Clear	Uncoated	1F

Standards/Technical specifications applied:
EN 166: 2001

Technical reports/Approval documents:
INSPEC Certificate: PPE19161309
INSPEC Reports: 1.17.08.48, 03.04.38, 04.11.54, 04.11.129, 94.10.60, 94.10.61, 08.05.14

Signed on behalf of SATRA:
Date first issued: 05/04/2019
Date of issue: 05/04/2019

DMcKeown
Dave McKeown
Expiry date: 05/04/2024

Geoff Graham

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.