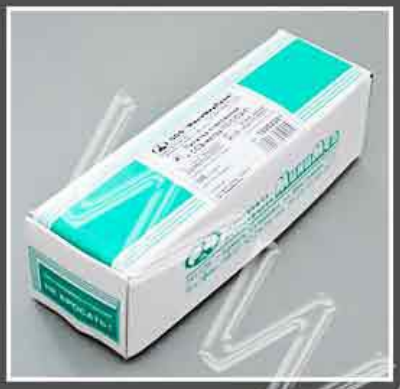
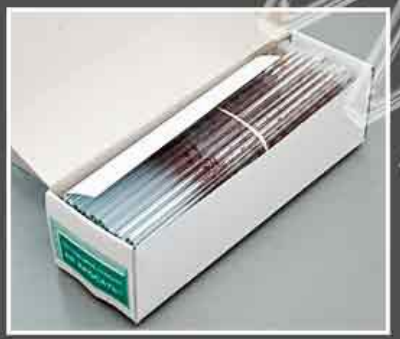




ООО "МиниМедПром"

242600, Брянская обл.,
г. Дятьково, ул. Ленина, д. 182, корп. 5

Тел./факс (48333) 3-44-05
тел. 3-27-02

Пипетка стеклянная к СОЭ-метру ПС/СОЭ-01

KZ Шыны тамшуырлар СОЭ-метрлік (ПС/СОЭ-01)

BY Піпетка шкляная да СОЭ - метру (ПС/СОЭ-01)

РУ № ФСР 2011/11702 от 17.08.2011 г.

ТУ 9443-005-52876351-2002

100 шт/дана

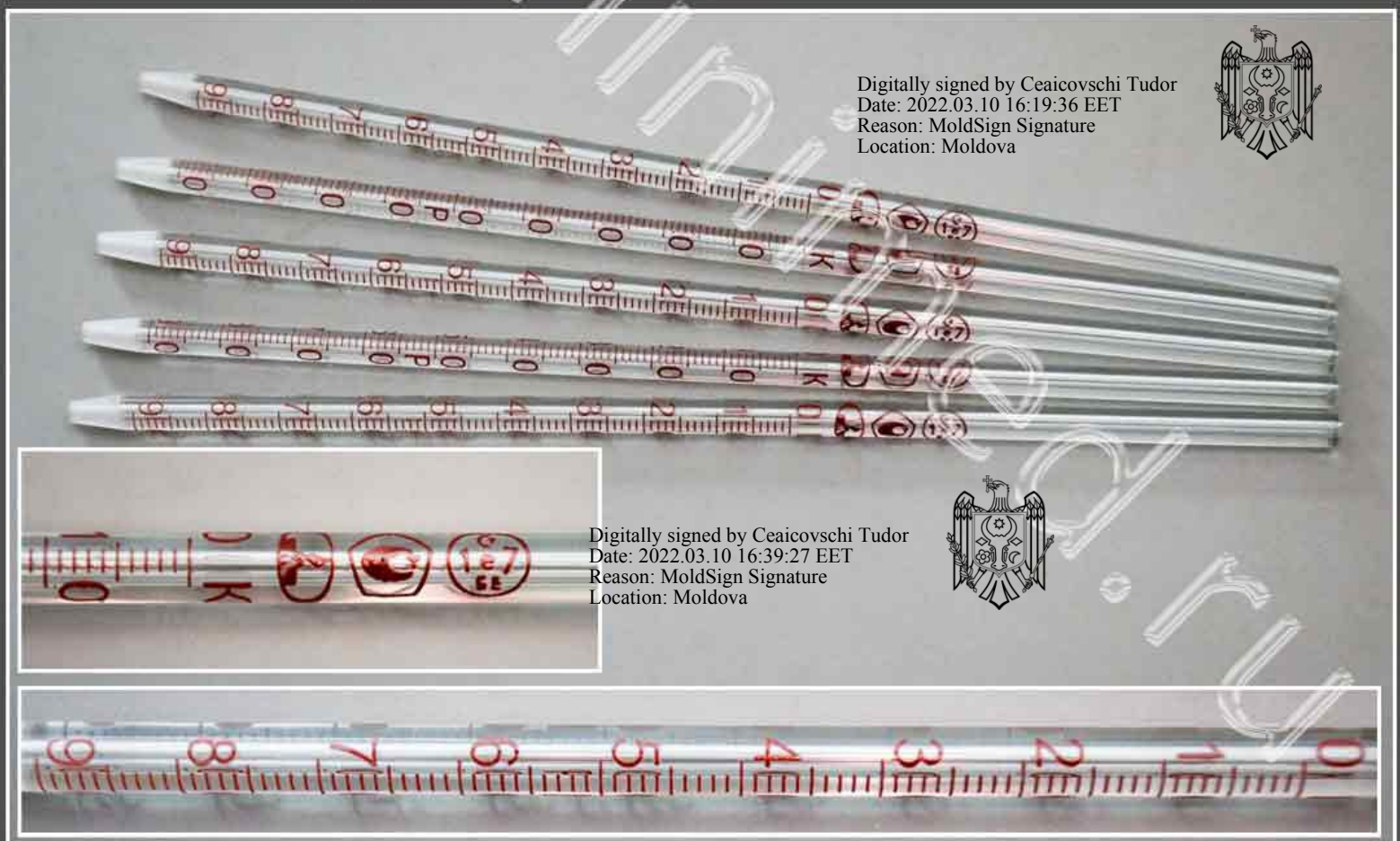
арт. **10002001**

дата изготовления _____

упаковщик _____

Изготовитель / Өндіруші / Вытворца:
ООО «МиниМедПром»

2 000008 910019



Digitally signed by Ceaicovschi Tudor
Date: 2022.03.10 16:19:36 EET
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.10 16:39:27 EET
Reason: MoldSign Signature
Location: Moldova

ГОСУДАРСТВЕННЫЙ КОМИТЕТ
ПО СТАНДАРТИЗАЦИИ
РЕСПУБЛИКИ БЕЛАРУСЬ

STATE COMMITTEE FOR
STANDARDIZATION OF THE
REPUBLIC OF BELARUS

СЕРТИФИКАТ

ОБ УТВЕРЖДЕНИИ ТИПА СРЕДСТВ ИЗМЕРЕНИЙ

PATTERN APPROVAL CERTIFICATE OF MEASURING INSTRUMENTS

НОМЕР СЕРТИФИКАТА:
CERTIFICATE NUMBER: 11353

ДЕЙСТВИТЕЛЕН ДО:
VALID TILL: 26 апреля 2022 г.

Настоящий сертификат удостоверяет, что на основании решения Научно-технической комиссии по метрологии (№ 09-17 от 03.10.2017) утвержден тип средств измерений

"Пипетки стеклянные к СОЭ-метру ПС/СОЭ-01 "МиниМедПром",

изготовитель - **ООО "МиниМедПром", г. Дятьково Брянской обл., Российская Федерация (RU),**

который зарегистрирован в Государственном реестре средств измерений под номером **РБ 03 07 3340 17** и допущен к применению в Республике Беларусь с 3 октября 2017 г.

Описание типа средств измерений приведено в приложении и является неотъемлемой частью настоящего сертификата.

Председатель комитета В.В.Назаренко

3 октября 2017 г.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 19 августа 2015 года № ФСР 2008/03361

На медицинское изделие
СОЭ-метр ПР-3 по ТУ 9443-009-52876351-2008

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
242600, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 1

Номер регистрационного досье **№ РД-8057/35356 от 30.07.2015**

Вид медицинского изделия **176420**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции для медицинского изделия **94 4310**

приказом Росздравнадзора от 19 августа 2015 года № 5830
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.В. Пархоменко**

0013778

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.10 16:22:52 EET
Reason: MoldSign Signature
Location: Moldova

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing as well as associated in vitro diagnostic devices for sampling and analysis systems for rapid tests.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs and lancets.

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.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. Sven 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 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Manufacture and distribution
/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development and distribution
/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development and manufacture
/04	c/o nal von minden GmbH Raseweg 4 37124 Rosdorf Germany	Administration and distribution

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

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 60131398 0001

Report No.: 21200072 015

Manufacturer:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products:
- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

Expiry Date: 2023-11-27

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: 2018-11-28

Date: 2018-11-27

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 60131398 0001
Report No.: 21200072 015

Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products included:

In vitro diagnostica for self-testing:
- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:
- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

Site included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Activities: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1810016**

Certificate Holder:

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

including the locations according to annex

Scope:

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.
Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

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

Validity:

The certificate is valid from 2021-09-10 until 2024-09-09.
First certification 2018

2021-09-10

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 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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

исх. №303 от 23.11.2017г.

Информационное письмо.

В соответствии с действующим Постановлением Правительства РФ от 01.12.2009г. №982 «Об утверждении единого перечня продукции, подлежащей обязательной сертификации, и единого перечня продукции, подтверждение соответствия которой осуществляется в форме принятия декларации о соответствии», Карандаш (Vitrograf-маркер) по стеклу имеет общелабораторное назначение и по общероссийскому классификатору продукции относятся к группе товаров с кодом ОКП 025546 – «Составы восковые различного назначения», ОКПД2 19.20.41.190 «Воски нефтяные прочие», обязательной сертификации и декларированию не подлежит.

Начальник ОТК **Грузинцев С.А.**

ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ «МИНИМЕД» ДЛЯ ДОКУМЕНТОВ ИНН 3234007127 г. Брянск

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.10 16:24:30 EET
Reason: MoldSign Signature
Location: Moldova

Certification System

Works and Services, Management Systems

InterSertTest

CERTIFICATION BODY
LIMITED LIABILITY COMPANY
"ISO CONSULTING"

Premises 126, 127, 128, and 129, Block 2, Floor 2, 3, Davydkovskaya Str., Moscow, 121352

CERTIFICATE OF CONFORMITY

Issue 1. QMS is certified since January 2021

№ РОСС RU.C.04ША.СК.1558

Is given to: Research and Production Company "VINAR"
Limited Liability Company
("RPC "VINAR", LLC)

TIN 5023001024

Office VIII, Building 7A, 5, Gospitalniy Val, Moscow, 105094

THIS CERTIFICATE CERTIFIES THAT

Quality management system as applied to development, production and sales of the following products: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; packaging materials for sterilization and washing; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas; antiseptics and disinfectants

COMPLIES WITH THE REQUIREMENTS OF GOST ISO 13485-2017 (ISO 13485:2016)

By virtue of: *Decision of the Certification Body № 1558 dated 22 January 2021*

This Certificate shall bind the organization to maintain the state of the quality management system in the workable condition in compliance with the requirements of the above standard, to confirm this compliance by results of the annual inspection check-up in "ISO CONSULTING" LLC Certification Body within the entire period of the Certificate duration.

Issued: 25 January 2021 ***Expiry date: 25 January 2024***
(If the inspection control is passed)

Terms for the first inspection: Not later than 25 January 2022
Terms for the second inspection: Not later than 25 January 2023

T.V. GRICHANAYA — Head of the Certification Body

S.T. BUTKINA — Expert

Digitally signed by Ceaicovschi Tudor
Date: 2022.01.27 11:59:26 EET
Reason: MoldSign Signature
Location: Moldova

№ 005153

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/05017

от 06 марта 2013 года

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Научно-производственная фирма "ВИНАР" (ООО "НПФ "ВИНАР"), Россия, 105094, Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
и подтверждает, что медицинское изделие
Индикатор бумажный воздушной стерилизации химический многопараметрический одноразовый "МедИС-В-Винар" (модификация МедИС-В-180/60-1) по ТУ 9398-032-11764404-2004
производства
Общество с ограниченной ответственностью "Научно-производственная фирма "ВИНАР" (ООО "НПФ "ВИНАР"), Россия, 105094, Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
место производства:
141009, Московская обл., г. Мытищи, ул. Колонцова, д. 17/2

класс потенциального риска **2а** ОКП **93 9854**

вид медицинского изделия –

соответствующее регистрационному досье № РД-192/7166 от 26.02.2013

В соответствии с приказом Росздравнадзора от 06 марта 2013 года № 589-Пр/13 допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **Е.А. Тельнова**

0000186

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17797

Срок действия с 21.06.2016г. **по** 21.06.2019г.

№ 1758743

ОРГАН ПО СЕРТИФИКАЦИИ № RA.RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д. 3 тел. (495) 683-97-92, факс (499)187-89-54
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикатор бумажный воздушной стерилизации химический многопараметрический одноразовый «МедИС-В-Винар» (модификации МедИС-В-160/150-1, МедИС-В-180/60-1) по ТУ 9398-032-11764404-2004
Серийный выпуск.

код ОК 005 (ОКП): 93 9854

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

ГОСТ ISO 11140-1-2011 (класс 4),

ГОСТ Р 50444-92 (р.р. 3, 5, 8)

код ТН ВЭД России: 3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII ИНН 5023001024
Место производства - 141009, Московская обл., г. Мытищи, ул. Колонцова, д. 17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-854 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационные удостоверения: № ФСР 2009/04944 от 06.03.2013г., № ФСР 2009/05017 от 06.03.2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

М.П.

Руководитель органа _____ (подпись) Е.И. Полянская (инициалы, фамилия)

Эксперт _____ (подпись) В.В. Русова (инициалы, фамилия)

Сертификат не применяется при обязательной сертификации

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2010/06938

от 03 марта 2010 года Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ООО НПФ "ВИНАР",
Россия, 111020, г. Москва, Госпитальный вал, д.4

и подтверждает, что изделие медицинского назначения

Индикаторы бумажные паровой стерилизации многопараметрические химические одноразовые "МедИС-"ВИНАР"
по ТУ 9398-027-11764404-2003

производства

ООО НПФ "ВИНАР", Россия, 111020, г. Москва, Госпитальный вал, д.4

класс потенциального риска **2а** ОКП **93 9854**

соответствующее комплекту регистрационной документации

КРД № 7046 от 09.02.2010

приказом Росздравнадзора **от 03 марта 2010 года № 1645-Пр/10**

разрешено к производству, продаже и применению на территории Российской Федерации

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **Е.А. Тельнова**
и социального развития

008137

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Date: 2022.02.11 14:20:05 EET
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DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

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

fabbricante
manufacturer
VACUTEST KIMA S.r.l. –
articoli per laboratori analisi - disposable labware

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

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

Identificazione dei prodotti **PROVETTE SOTTOVUOTO 13X75 MM PET K3EDTA ASP. 2 ML TAPPO VIOLA**

product identification **VACUUM TUBE 13X75 MM W. K3 EDTA FOR 2 ML LAVENDER CAP**

numero di catalogo *part number* **13005**
numero di lotto *batch number* **XZ2351**
scadenza *expiry date* **28/02/2023**

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

Si dichiara
sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *Dispositivi Medico–Diagnostici In Vitro*.

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva, e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, sono conservati a cura del Fabbricante

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

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date
Arzergrande, 05/10/2021

firma
signature
VACUTEST KIMA S.R.L.
Assicurazione Qualità

data 05/10/2021

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *Dispositivi Medico-Diagnostici In Vitro e s.m.i.*
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fabbricante
manufacturer

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

Identificazione dei prodotti **PROVETTA SOTTOVUOTO 13X75 MM PET EPARINA LITIO ASP. 2 ML TAPPO VERDE**

product identification **VACUUM TUBE 13X75MM W.LITHIUM HEPARIN FOR 2 ML GREEN CAP**

numero di catalogo *part number* **12005**
numero di lotto *batch number* **Z2031**
scadenza *expiry date* **31/01/2023**

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

Si dichiara
sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *Dispositivi Medico–Diagnostici In Vitro*.

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luogo e data
place and date
Arzergrande, 05/10/2021

firma
signature
VACUTEST KIMA S.R.L.
Assicurazione Qualità

data 05/10/2021

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *Dispositivi Medico-Diagnostici In Vitro e s.m.i.*
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fabbricante
manufacturer

VACUTEST KIMA S.r.l. –
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indirizzo
address

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

Identificazione dei prodotti **PROVETTA SOTTOVUOTO 13X75 MM PET EPARINA LITIO ASP. 2 ML TAPPO VERDE**

product identification **VACUUM TUBE 13X75MM W.LITHIUM HEPARIN FOR 2 ML GREEN CAP**

numero di catalogo *part number* **12020**
numero di lotto *batch number* **KZ2071**
scadenza *expiry date* **31/01/2023**

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

Si dichiara
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luogo e data
place and date
Arzergrande, 05/10/2021

firma
signature
VACUTEST KIMA S.R.L.
Assicurazione Qualità

data 05/10/2021

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *Dispositivi Medico-Diagnostici In Vitro e s.m.i.*
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fabbricante
manufacturer

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indirizzo
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fax *fax* ***+39-049-9720182***
posta elettronica *e-mail* **info@vacutestkima.it**

Identificazione dei prodotti **SIEROSEP IN SEKURPLAST 12X86 MM 5 ML ETICHETTATE CON ACCELERATORE**

product identification **STERILE VACUUM TUBE W. CLOT ACTIVATOR VOL. 4 ML 13X75 MM RED CAP**

numero di catalogo *part number* **11010**
numero di lotto *batch number* **G2351**
scadenza *expiry date* **28/02/2023**

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

Si dichiara
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luogo e data
place and date
Arzergrande, 05/10/2021

firma
signature
VACUTEST KIMA S.R.L.
Assicurazione Qualità

data 05/10/2021

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

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

fabbricante
manufacturer

VACUTEST KIMA S.r.l. –
articoli per laboratori analisi - disposable labware

indirizzo
address

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35020 Arzergrande (PD) - Italia

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

Identificazione dei prodotti
product identification

MICROPROVETTE TIPO EPPENDORF IN POLIPROPILENE 1,5 ML CONICHE CON TAPPO

VACUUM TUBES 4 ML NO ADDITIVE WHITE CAP

numero di catalogo *part number* **149415**
numero di lotto *batch number* **KG2501**
scadenza *expiry date* **31/03/2023**

classificazione dei prodotti
product identification

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

Si dichiara

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luogo e data
place and date

Arzergrande, 05/10/2021

firma
signature

VACUTEST KIMA S.R.L.
Assicurazione Qualità

data 05/10/2021

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fabbricante
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fax *fax* ***+39-049-9720182***
posta elettronica *e-mail* **info@vacutestkima.it**

Identificazione dei prodotti
product identification

MICROPROVETTE TIPO EPPENDORF IN POLIPROPILENE 1,5 ML CONICHE CON TAPPO

VACUUM TUBES 4 ML NO ADDITIVE WHITE CAP

numero di catalogo *part number* **149415**
numero di lotto *batch number* **KZ2561**
scadenza *expiry date* **31/03/2023**

classificazione dei prodotti
product identification

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

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Arzergrande, 05/10/2021

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Assicurazione Qualità

data 05/10/2021

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35020 Arzergrande (PD) - Italia

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

Identificazione dei prodotti **MICROPROVETTE TIPO EPPENDORF IN POLIPROPILENE 1,5 ML CONICHE CON TAPPO**

product identification **VACUUM TUBE 13X75MM 3,5ML WITH GEL + CLOT ACTIVATOR**

numero di catalogo *part number* **10010**
numero di lotto *batch number* **G2641**
scadenza *expiry date* **31/03/2023**

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

Si dichiara
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luogo e data
place and date
Arzergrande, 05/10/2021

firma
signature
VACUTEST KIMA S.R.L.
Assicurazione Qualità

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

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Date: 2022.02.04 15:01:57 EET
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Location: Moldova

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

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