



SERTİFİKA CERTIFICATE

BEREN MEDİKAL PAZARLAMA SAN. TİC. LTD. ŞTİ.

İOSB FATİH SAN SİT 3B BLOK NO:3-4 BAŞAKŞEHİR / İSTANBUL

MEDİKAL KAYIT KAĞITLARI VE ULTRASON PRİNER KAĞITLARI TASARIMI VE ÜRETİMİ, YOĞUN BAKIM CİHAZLARI KURULUM, MONTAJ VE TEKNİK SERVİSİ

PRODUCTION AND SALES OF MEDICAL RECORD & CHART PAPERS, ULTRASOUND IMAGING PAPERS, INSTALLATION AND AFTERSALES TECHNICAL SERVICES OF INTENSIVE CARE DEVICES

kapsamında
with a scope of

ISO 13485:2016

*Tıbbi Cihazlar Kalite Yönetim Sistemine uygun bir sistem kurmuştur.
has established that is in compliance with the Medical Devices Quality Management System Standard.*

Sertifika No : MDD1024

Certificate No.

İlk Yayın Tarihi : 19.07.2019

Initial Date

Sertifika Yayın Tarihi / Rev No : 19.07.2019/00

Date of This Certificate / Rev.No.

Sertifika Geçerlilik Tarihi : 18.07.2020

Certificate Expiry Date

Yeniden Belgelendirme Tarihi : 18.07.2022

Date of Re-Certification



Zühtü Özdemir
GENEL MÜDÜR
General Manager

Özdemir



Bu belge YBM'nin belgelendirme kurallarına uyulması ve periyodik ara denetimlerin başarıyla tamamlanması kaydıyla geçerlidir. Daha fazla bilgi için lütfen bizi arayınız.
This certificate is effective if it is complied with the certification rules of YBM and periodic surveillance audits are completed successfully. Please call us for more information.

Yönetim Belgelendirme Merkezi Test ve Gözetim Hizmetleri Ltd. Şti.

Tofaş Mah. Güllük Sok. No:7-3 Kat:1 D:4 Zeytinburnu / İstanbul Tel: 0212 547 91 00
info@ybm.com.tr www.ybm.com.tr



MINISTERUL SĂNĂTĂȚII, MUNCII
ȘI PROTECȚIEI SOCIALE
AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА
И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ

MD-2028, mun. Chișinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: ansp@ansp.md; anticamera@ansp.md

DOCUMENTAȚIE MEDICALĂ / Медицинская документация
FORMULAR / Форма Nr. 303-2/e
APROBAT DE MSMPS al RM / Утверждена МЗТРС 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
Accreditat în Sistemul Ministerului Sănătății, Muncii
și Protecției Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и
Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR
PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. P-1911/2019
Санитарное заключение для пищевых и непищевых продуктов

din/om "24." iunie a./z. 2019

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea și desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования
Articole parafarmaceutice în asortiment conform anexei

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)

Indicații Metodice nr.29 FT/1683 din 14.05.01, Directiva Europeană 93/42/EEC privind
dispozitivele medicale

Organizația-producătoare/importatoare, țara de origine / организация произв./импортёр, страна происхождения
DISPOTECH ZAO Yaroslavl Rezintehnika, Sterilance Medical, Huaian Tianda Medical
Instruments Co, Nutrex Textil Nakis San. Tic. Ltd. Italia F. Rusă, Malaysia, Turcia

Destinatarul avizului sanitar / получатель санитарного заключения

"M-INTER-FARMA" SA, Republica Moldova, mun. Chișinău, str. Grenoble, nr. 23

Ca temel pentru recunoașterea conformității produselor Regulamentului (lor) sanitar (e) menționat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr. 50/297 din 19.03.2019, facturi, certificate de origine, calitate, conformitate, aviz
sanitar nr. 3347 din 30.11.2017

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

Caracteristica sanitară a produselor / санитарная характеристика продукции:

Parametrii (factorii) / показатели (факторы)

Normativul sanitar / санитарный норматив

Articolele parafarmaceutice sunt conforme Directivei Europene 93/42/EEC

Domeniu de utilizare / Область применения: Scopuri medicinale

Condițiile necesare de utilizare, depozitare, transportare, măsurile de securitate / Необходимые условия
использования, хранения, транспортировки, меры безопасности:

importul plasarea pe piață se va efectua în
condițiile respectării legislației în vigoare în R. Moldova, termenii de valabilitate, condițiile de păstrare

AVIZUL SANITAR este valabil până la / Санитарное Заключение действительно до: 30.06.2020

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ

Nicolae FURTUNĂ

(numele, prenumele și P.N.O.)



10-XVI-09



ANSP

0004



Producătorul (производитель) **DISPOTECH, ZAO Yaroslavl Rezinotehnica, Sterilance Medical, Huaian Tianda Medical Instruments Co, Nurtek Textil Nakis San. Tic. Ltd.**
Țara de origine (страна происхождения) **Italia, Federația Rusă, Malaysia, Italia, Turkey**

Nr.	Denumirea produselor (наименование продукта)	Firma producătoare, Țara
1.	Aspirator de saliva 15cm N100 /DISPOTECH	Dispotech, Italia
2.	Container pentru pastrarea servetelilor din plexiglas	Dispotech, Italia
3.	Husa p-u fotoliu stomatologic 33cm x 25cm N1	Dispotech, Italia
4.	Husa sterila pentru tub camera video 14x 250cm	Nurteks Tekstil Nakis San. Tic. Ltd. Sti; Turkey
5.	Husa pentru fotoliu stomatologic din 2 componente	Dispotech, Italia
6.	LAMA sterila chirurgicala p-u bisturiu	Nurteks Tekstil Nakis San. Tic. SteriLance Medical (Suzhou); China
7.	LAMA sterila chirurgicala p-u bisturiu	Sterilance Medical, China
8.	LAMA sterila chirurgicala p-u bisturiu	Huaian Tianda Medical Instruments Co., China
9.	Lant pentru fixarea bavetelor stomatologice	Dispotech, Italia
10.	MINI-RULOU din vata Nr.1 300 g	Dispotech, Italia
11.	MINI-RULOU din vata Nr.2 300 g	Dispotech, Italia
12.	MUSAMA MEDICALA	ZAO Yaroslavl-Rezinotehnica, Federația Rusă
13.	Rulou de pachete p-u steriliz. instrum. 100mm X 200m.	Dispotech, Italia
14.	Rulou de pachete p-u steriliz. instrum. 150mm X 200mm	Dispotech, Italia
15.	Rulou de pachete p-u steriliz. instrum. 200mm X 200m	Dispotech, Italia
16.	Rulou de pachete p-u steriliz. instrum. 250mm X 200m.	Dispotech, Italia
17.	Rulou de pachete p-u steriliz. instrum. 50mm X 200m.	Dispotech, Italia
18.	Rulou de pachete p-u steriliz. instrum. 75mm X 200m.	Dispotech, Italia
19.	SCARIFICATOR (lancet) steril N1	Huaian Angel Medical Instruments Co., China
20.	SERVETEL stomatologic 45cm X 33cm, 3 straturi N500	Dispotech, Italia
21.	SERVETEL stomatologic 50cm X 60cm rulou cu legare	Dispotech, Italia

Directorul interimar al Agenției pentru
Sănătate Publică



Nicolae FURTUNĂ



ОРГАН ПО СЕРТИФИКАЦИИ
АССОЦИАЦИЯ ПО СЕРТИФИКАЦИИ "РУССКИЙ РЕГИСТР"
АТТЕСТАТ АККРЕДИТАЦИИ ФЕДЕРАЛЬНОЙ СЛУЖБЫ
ПО АККРЕДИТАЦИИ № РОСС RU.0001.21ГА45



СЕРТИФИКАТ

Настоящим удостоверяется, что система менеджмента качества

Общества с ограниченной ответственностью "Лега"

606025, Российская Федерация, Нижегородская обл.,
Дзержинск, б-р Мира, 29а-22

была проверена и признана соответствующей требованиям стандарта

ГОСТ Р ИСО 9001-2015

в отношении производства, выпуска и поставки
перекиси водорода, полимерных микросфер, аммиака водного,
бисульфита натрия и термоэластопластов

№: 18.2044.026
от 9 ноября 2018 г.

Сертификат действителен до 9 ноября 2021 г.

Уточнение области сертификации приведено в Приложении. Сертификат теряет силу в случае невыполнения условий сертификации (<http://www.rusregister.ru/doc/004.00-105.pdf>). Сертификат является собственностью Ассоциации по сертификации "Русский Регистр".



RUSSIAN REGISTER РУССКИЙ РЕГИСТР

01-011277ЛР

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



Приложение к Сертификату
№ 18.2044.026
от 9 ноября 2018 г.
бланк № 01-011277/ГР

**Область сертификации системы менеджмента
Общества с ограниченной ответственностью "Лега"
включает:**

1. Общества с ограниченной ответственностью "Лега"

Юридический адрес: 606025, Российская Федерация, Нижегородская обл.,
Дзержинск, б-р Мира, 29а-22

Фактический адрес: 606000, Российская Федерация, Нижегородская обл.,
Дзержинск, Восточный промрайон Оргстекло, 5 км+500 м Игуменского шоссе, 1
Виды деятельности: разработка технологической документации, производство,
выпуск и поставка перекиси водорода, аммиака водного, бисульфита натрия и
термоэластопластов.

2. Общества с ограниченной ответственностью "Лега"

Юридический адрес: 606025, Российская Федерация, Нижегородская обл.,
Дзержинск, б-р Мира, 29а-22

Фактический адрес: 606000, Российская Федерация, Нижегородская обл.,
Дзержинск, Восточный промрайон АО "Дзержинское Оргстекло", корп. 66
Виды деятельности: разработка технологической документации, производство,
выпуск и поставка полимерных микросфер.

Генеральный директор Ассоциации
по сертификации "Русский Регистр"



А.В. Владимирцев





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2016-MDD/QS-008/A

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the medical device of Class III,

Sterile Absorbable Surgical Suture with or without Needle
Brand Name: Lactisorb, Lactisorb Rapid, PGA, PDO, Monoquick, R1-Loc

Sterile Non-Absorbable Surgical Suture with or without Needle
Brand Name: Polypropylene, PVDF, Polyester-CV
(for detailed list refer to Annex)

manufactured by company

R1 Suture LTD
94, Industrialna Street, 3rd floor, 8000 Burgas, Bulgaria

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310213 and the Final protocol No. 310213/2016 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until April 4th, 2021 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended by 2007/47/EC, Annex II (4) is required.



In Bratislava, on April 3rd, 2017

Version A) supersedes the EC Certificate No. 2016-MDD/QS-008 issued on April 5th, 2016

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Van Oostveen Medical B. V.

Herenweg 269
3648 CH Wilnis
The Netherlands

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Skalpellklingen, Skalpelln, Bluttransfusionssets, Blutlanzen, elektronische Blutdruckmessgeräte, Kondome, Trachealtuben, Foley Ballon Katheter, chirurgische Handschuhe, Infusionssets, Intravenöse Katheter, Nadeln, Paraffingaze, Intravenöse Infusionsbestecke, Kopfhautvenen, Spritzen komplett mit Kanüle, Tuberkulinspritzen, Insulinspritzen, digitale Thermometer, 3-Wegehähne, Aneroid Blutdruckmessgeräte, Thermometer, Untersuchungshandschuhe, Spritzen, Urinbeutel, Tropfer für Medikamente.

Blades, Scalpels, Blood Administration Sets, Blood Lancets, Electronic Sphygmomanometers, Condoms, Tracheal Tubes, Foley Balloon Catheters, Surgical Gloves, Infusion Sets, Intravenous Catheters, Needles, Paraffin Gauze, Scalp Vein Infusion Sets, Syringes complete with Needle, Tuberculin Syringes, Insulin Syringes, Digital Thermometers, Three Way Stopcocks, Aneroid Sphygmomanometers, Thermometers, Examination Gloves, Syringes, Urine Bags, Droppers for Medicine.

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 04 232 041335
Bericht Nr. / Report No. 3523 7665



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
bis / until 2024-03-11
Edition 4

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



ANLAGE / ANNEX

Anlage 1, Blatt 1 von 5
Annex 1, page 1 of 5

Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse Im
Products of class Im

UMDNS

Thermometer, Quecksilber frei
Thermometer, Mercury free

14-028

Blutdruckmeßgerät, aneroid
Sphygmomanometers, Aneroid

16-156

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

Note: For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Bericht Nr. / Report No. 3523 7664



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Essen, 2019-03-12

TÜV NORD CERT GmbH

Langemarckstraße 20

45141 Essen

www.tuev-nord-cert.de

medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zertifizierungsstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16



ANLAGE / ANNEX

Anlage 1, Blatt 2 von 5
Annex 1, page 2 of 5

Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse Is
Products of class Is

UMDNS

Spritzen 2- und 3-teilig
Syringes 2- and 3-part

13-929

Harnauffangbeutel
Urinary Collection Bags

14-298

Harnauffangbeutel, Säugling
Urinary Collection Bags, Infant

16-782

Untersuchungshandschuhe, steril
Examination gloves sterile

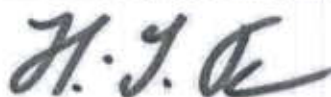
11-882

Tropfer, Medikamente
Dropper, Medicine

12-506

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungs-
schritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: For products of class I sterile the certification process is restricted to the aspects of manufacture concerned
with securing and maintaining sterile conditions.

Bericht Nr. / Report No. 3523 7664



Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kann-Nr. 0044 / Notified Body ID. No. 0044



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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-236.10.16



ANLAGE / ANNEX

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Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse IIa
Products of class IIa

Klinge, Messer
Blades, Knife

Messer, Skalpell
Knives, Scalpel

Bluttransfusionsbesteck
Blood Administration Set

Lanzette, Blut
Lancets, Blood

Blutdruckmeßgerät, elektronisch
Sphygmomanometers, Electronic

Endotracheal Tubus
Endotracheal tubes

Katheter, Harnwege, Foley
Catheters, Urinary, Foley

Handschuhe, chirurgisch
Gloves, Surgical

UMDNS

12-234

12-252

10-421

10-440

16-157

14-085

10-720

11-883

Bericht Nr. / Report No. 3523 7664

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16



ANLAGE / ANNEX

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Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse IIa
Products of class IIa

Intravenöses Infusionsbesteck, allgemeine Verwendung
Intravenous Administration Sets, General Purpose

Katheter, intravenös, peripher
Catheters, Intravenous, Peripheral

Intravenöses Infusionsbesteck Kopfhautvene
Intravenous Administration Sets, Scalp Vein

Nadeln, hypodermisch
Needles hypodermic

Verband, nichthaftend
Dressing, Nonadherent

Spritze, subkutan
Syringe, hypodermic

Spritze, Tuberkulin
Syringes, Tuberculin

Spritze, Insulin
Syringes, Insulin

UMDNS

12-157

10-727

17-825

12-745

11-325

13-940

13-945

13-941

Bericht Nr. / Report No. 3523 7664

H. J. K.

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Essen, 2019-03-12

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
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Medizinprodukten
ZLG-BS-236.10.16



ANLAGE / ANNEX

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Reg.-Nr. / Reg. No. 04 232 041335

Produkte der Klasse IIa
Products of class IIa

Thermometer, elektronisch
Thermometers, Electronic

Dreiwegehahn
Three-way stopcock

UMDNS

14-032

13-803

Produkte der Klasse IIb
Products of class IIb

Kondome, männlich
Condoms, Male

UMDNS

18-080

Bericht Nr. / Report No. 3523 7664

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Gültigkeit / Validity
von / from 2019-03-12
Edition 5

Essen, 2019-03-12

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