ORDIN DE PLATA NR.: 72 TIP.DOC. 1
DATA EMITERII:11 martie 2019

PLATITI: 2565-00 LEI: Doua Mii Cinci Sute Sasezeci s
i Cinci lei 00 bani

PLATITOR: (R) ERICON SRL CODUL IBAN:MD60VI2224000081004O1MDL
CODUL FISCAL :1003600000316/

:

PRESTATORUL PLATITIOR CODUL BANCII
B.C."VICTORIABANK"S.A. fil.nr.8 Chisinau :VICBMD2X802

BENEFICIAR (R)SCM SFANTA TR CODUL IBAN:MD22ML000000000225166614
EIME CODUL FISCAL :1003600152592 /

:

PRESTATORUL BENEFICIAR CODUL BANCII
BC"Moldindconbank"S.A. :MOLDMD2X

DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI
oferta la licitatia publica ID 21005442: NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:11/03/2019 : _____
DATA EXECUTARII: : _____
: SEMNATURILE
: EMITENTULUI

CONDUCATOR:ERICON SRL
MIIFygYJKoZIhvcNAQcCoIIFuzCCBbcCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb
3
DQEHAaCCBFEwggRNMIIDNaADAgECAgocoG6YAAAAAVAtMA0GCSqGSIb3DQEB :
BQUA
MC4xGDAWBgoJkiaJk/IsZAEZFgh2YjtEQz1tZDESMBAGA1UEAxMJd2ViY :
(semnatura electronica)
CONTABIL-SEF:ERICON SRL
AMAsGCSqGSIb3
DQEHAaCCBFMwggRPMIIDN6ADAgECAgpIOsCnAAAAAUCPMA0G :
1UEAxMJd2ViY2xpZW50
MB4XDTE4MDgwMjEyNDA0M1oXDTE5MDgwMjEyNTA0M1 :
CSqGSIb3DQEBBQUA
MC4xGDAWBgoJkiaJk/IsZAEZFgh2YjtEQz1tZDESMBAGA :
(semnatura electronica)

L.S.

CONDUCATOR: _____
(semnatura manuala)
CONTABIL-SEF: _____
(semnatura manuala)

_____
SEMNATURA L.S.
BANCII

_____
SEMNATURA BANCII :

MOTIVUL REFUZULUI : L.S.

Digitally signed by Bunic Gheorghe
Date: 2019.03.11 20:32:06 EET
Reason: MoldSign Signature
Location: Moldova

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
CERTIFICADO
N° 26638 rev. 4

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by
GMED certifica que el sistema de gestión de la calidad adoptado por

LABORATOIRES ANIOS
Pavé du moulin
59260 LILLE-HELLEMMES FRANCE

pour les activités */ for the activities* / para las actividades
Conception, développement, fabrication, prestations associées et vente de produits antimicrobiens, détergents et matériels pour procédés de désinfection de dispositifs médicaux dédiés aux hôpitaux et cliniques.

Design, development, manufacturing, servicing and sales of antimicrobial products, detergents and materials for disinfecting processes of medical devices dedicated to hospitals and clinical sectors.

Diseño, desarrollo, fabricación, servicios y venta de productos antimicrobianos, detergentes y materiales para los procesos de desinfección de dispositivos médicos dedicados a hospitales y clínicas.

réalisées sur le(s) site(s) de */ performed on the location(s)* / que se realizan en

LABORATOIRES ANIOS
Pavé du Moulin 59260 LILLE-HELLEMMES FRA
LABORATOIRES ANIOS
3330 rue de Lille 59262 SAINGHIN-EN-MELANTOIS FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards
es conforme a las exigencias de las normas internacionales

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité */ Effective* / Fecha efectiva **August 3rd, 2018 (included)**
Valable jusqu'au */ Expiry date* / Fecha de expiración **June 10th, 2021 (included)**
Etabli le */ Issued on/* Fecha de preparación **August 3rd, 2018**

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ_ESP-F-V0-07-

GMED N° 26638–4
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 26638-3

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ERICON"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1003600000316

Data înregistrării **20.10.1992**

Data eliberării **19.04.2005**

Dragomir Ala, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 177

MD 0033559

VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA

Filiala nr. 8 Chişinău
Bd. Decebal, 99
MD-2060, mun. Chişinău
Republica Moldova
Tel.: (+373 22) 57-48-00
Fax: (+373 22) 53-05-12
SWIFT: VICBMD 2X802
IDNO 1002600001338
Capital social - 250 000 910 lei
www.victoriabank.md

Nr. 1110 din "2" februarie 2016

La Nr. _____ din "_____" _____ 201 mun. Chişinau

C E R T I F I C A T

Eliberat agentului economic ERICON SRL, cod fiscal 1003600000316 cu sediul în Republica Moldova, mun. Chişinau, str. Zelinski 15, precum că deţine cont curent în MDL nr. MD60VI222400008100401MDL, EUR MD39VI0002224017081004O1EUR, USD MD14VI0002224001081004O1USD şi RUB MD36VI0002224050081004O1RUB la Filiala nr.8 Chişinau BC "Victoriabank" SA, codul băncii VICBMD2X802.

Directorul Filialei nr. 8
BC "Victoriabank" SA

M. Bartcovschi

Contabil-şef al filialei nr.8
BC "Victoriabank" SA

S. Talpa

Executor: Siniucova Elena
Tel: 022 57-48-12

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **10406** din **19.06.2017**

Denumirea completă: **Societatea cu Răspundere Limitată «ERICON».**

Denumirea prescurtată: **«ERICON» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1003600000316.**

Data înregistrării de stat: **20.10.1992.**

Sediul: **MD-2003, str. Vasile Lupu, 6, or. Durlești, mun. Chișinău, Republica Moldova**

Obiectul principal de activitate:

1 Editarea cărților, broșurilor și altor publicații;

2 Tipărirea ziarelor;

3 Publicitate;

4 Comerțul cu amănuntul al cărților, ziarelor și rechizitelor de birou;

5 Comerțul cu amănuntul al articolelor medicale și ortopedice.

Capitalul social: **449852** lei.

Administrator: **BUNIC GHEORGHE.**

Asociați:

1. BUNIC GHEORGHE 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 19.06.2017.

Specialist coordonator **Minciună Corina**
tel. 022-266-256

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA CAMERA ÎNREGISTRĂRII DE STAT Î.S. 1004600077777 101

A A 7 * E A * 0 4 1 7 1 3 3 E A

Date cu caracter personal. **Deținător:** Î.S. „Camera Înregistrării de Stat", **NUID (număr de identificare unic)** 0000151-001

TRANSGLOBAL QUALITY ASSESSORS LLP

Management System Certificate

Certificate No. MD.QMS.91.006.06.16

This is certify that

Marflow AG

at

Soodstrasse 57, CH-8134 Adliswil, Zürich, Switzerland.

has been found to conform to Management System Standard

ISO 13485: 2003

This certificate valid for the following product / service ranges:

DESIGN AND MANUFACTURE OF NON-ACTIVE AND ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES FOR UROLOGY AND GASTROENTEROLOGY

Internal Certification : 23.06.2016
Valid until : 22.06.2019

(Authorized Signatory)
Transglobal Quality Assessors LLP

This is an accredited certificate authorised for issue by Accreditation Services for certifying bodies (Europe) Limited, who have assessed Transglobal Quality Assessors LLP Located at PUNE, INDIA, against defined criteria and in cognisance of ISO 17021, "Conformity Assessment Requirements for bodies providing audit and certification of management systems". This certificate is only valid when confirmed by register listed in the International register of Quality Assessed Organisation : www.irqao.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 03 33038 018

Holder of Certificate: **Cook Ireland Limited**
O'Halloran Road
National Technology Park
Limerick
IRELAND

Facility(ies):
Cook Ireland Limited
O'Halloran Road, National Technology Park,
Limerick, IRELAND

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Obstetric / Gynaecological, Gastroenterological, Pulmonary, Urological, Vascular Devices and Accessories and Drug Eluting Peripheral Stents with Delivery Systems.**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 75933316

Valid from: 2016-06-01
Valid until: 2019-05-31

Date, 2016-05-24

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

DAkkS CRT2 / 10.13

Lloyd's Register
LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 4000228

Certificate No:	4000228/C
Original Approval:	April 12, 2006
Current Certificate:	May 1, 2014
Certificate Expiry:	April 30, 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Lloyd's Register
LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM

CERTIFICATE 4000228/C SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404, USA

Class I Sterile

Torque Cables
Gastroenterology Catheters
Gastroenterology Balloon Catheters
Respiratory Management Catheters
Gastroenterology Sets
Esophageal Dilation Sets
Devices for Diagnostic Procedures through Body Orifices
Sterile Stopcocks, Fittings and Accessories
Connecting Tubes
Catheter Accessory Devices
Wire Guide Accessory Devices
Needle Accessory Devices
Sterile Syringes
Non-Vascular Dilation Balloon Catheters
External Gland Ductographic Devices
Urinary Tract Catheters
Urinary Tract Measurement Devices
Extractors
Occlusion Balloon Catheters
Body Orifice Introducer/Access
Dilator and Dilator Sets
Non-Invasive Devices & Accessories – Sterile
Intrauterine Insemination Devices
Biopsy Tissue Sampling Devices
Uterine Sounds
Cervical Cerclage Devices
IVF Pipettes
Flexipet Manipulation Denuding Tool
Vital Port Accessory Devices
Lead Extraction Accessory Devices
Doppler Extension Cable

Schedule Issue: Eight

Date of Schedule Issue: May 1, 2014

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

71 Fenchurch Street, London EC3M 4BS, United Kingdom

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
[illegible]

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170030

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **TURKUAZSAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLERİSAN.VE TİC, LTD. ŞTİ.**
Yakuplu Mah. Birlik Cad No:34/3 Beylikdüzü, İstanbul, Turkey

for design, manufacturing and final inspection of medical device(s)

Catheter gel with lidocain - class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **203303-01 of 30.5.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 05.06.2017 with validity until 04.06.2022.
The validity of this Certificate is limited until: 04.06.2022

05.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

203303-01

Certificate

SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI, ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS, STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND SMEAR SPRAY

belirlenen standardın uygulanması konusunda tıbbi cihazlar için yönetim sistemi yürürlüğe koyduğunu ve uygulamakta olduğunu taahhüt eder./ Effective medical devices management system and guarenteesthat you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMSwith the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021** tarihine kadar geçerlidir./ Its proven that requirements are provided. This certificate is valid until **08.08.2021** with the condition of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021

TÜRCERT

Türcert A.Ş.
Belgelendirme Bölümü Adına

ÖSAS
ÖSTERREICH
Spezielle Akkreditierung Service
austria
ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ
Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII Nr. 054664

Denumirea autorității de licențiere	**Camera de Licenţiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea cu Răspundere Limitată "ERICON"** mun. Chişinău, or. Durleşti, str. Vasile Lupu, 6
Data și numărul certificatului de înregistrare de stat a titularului de licență	19.04.2005 MD 0033559
Numărul de înregistrare a întreprinderii sau IDNO	1003600000316
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul şi comercializarea dispozitivelor medicale ***
Data eliberării licenței	20 ianuarie 2017
Valabilă pînă la	20 ianuarie 2022

Semnătura conducătorului autorității de licenţiere

Director al Camerei de Licenţiere

Octavian BODIŞTEANU

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

ANEXĂ LA LICENŢA

Seria A MMII **Nr.** 054664

Titular de licenţă Societatea cu Răspundere Limitată "ERICON"

Titularul de licenţă este obligat să respecte următoarele condiţii de licenţiere pentru desfăşurarea activităţii: * Importul şi comercializarea dispozitivelor medicale *

Reperfectată: 23.03.2017

1. Desfăşurarea activităţii licenţiate în conformitate cu cadrul legislativ şi normativ.
2. Asigurarea efectuării controlului metrologic legal a mijloacelor de măsurare, utilizate în domeniul sănătăţii şi siguranţei populaţiei.
3. Indicarea la loc vizibil al preţurilor la mărfuri şi a tarifelor pentru servicii într-o formă clară.
4. Deţinerea autorizaţiei sanitare, antiincendiare, ecologice şi de securitate a muncii.
5. Dispunerea de spaţii cu titlu de proprietate sau de locaţiune pentru desfăşurarea activităţii licenţiate.
6. Dispunerea de specialişti în domeniu (ingineri, bioingineri).

Activitatea licenţiată se desfaşoară pe adresa:
mun. Chişinău, str. M. Sadoveanu, 42/7
specialist - Bunic Gheorghe

* *

MINISTERUL ECONOMIEI AL REPUBLICII MOLDOVA * CAMERA DE LICENŢIERE *

L.Ş.

Notă: Anexa şi copiile ei sînt valabile numai cu ştampila originală a autorităţii de licenţiere.

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Notified Body N° 0459

ATTESTATION / *CERTIFICATE* / CERTIFICADO **n° 31390 rev. 5**

Délivrée à Paris le 12 juin 2018

Issued in Paris on June 12th, 2018

Establecido en Paris, el 12 junio 2018

ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

Aprobación del sistema completo de Seguro de la calidad

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

ANEXO II excluyendo el punto 4 Directiva 93/42/CEE relativa a los productos sanitarios

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / *Manufacturer* / Fabricante

LABORATOIRES ANIOS

Pavé du Moulin

59260 LILLE-HELLEMMES FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category* / Categoría del producto

Détergents désinfectants ou désinfectants pour DM Invasifs et/ou non invasifs.

Detergent disinfectant or disinfectant for invasive and/or non invasive devices.

Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177315, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P177315, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

El LNE/G-MED certifica que después del examen de los resultados indicados en el expediente P177315, el sistema de calidad para el diseño, la fabricación y el control final - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo II excluyendo el punto 4 de la Directiva 93/42/CEE.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* / Fecha efectiva : **June 11th, 2018 (included)**

Valable jusqu'au / *Expiry date* / Fecha de expiración :**June 10th, 2021 (included)**

Laboratoire national de métrologie et d'essais
LNE

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director
Por delegación para el Director de Certificación G-MED

GMED_b2p3_ESP-V3-01-2013

LNE - 31390 rev. 5
Renouvelle le certificat 31390-4

Addendum au certificat n° 31390 rev. 5 **page 1/2**
Addendum of the certificate n° 31390 rev. 5
Addendum al certificado n° 31390 rev. 5
Dossier / *File* / *Expediente* N° P177315

Catégorie du (des) dispositifs / *Device(s) category* / Categoría del producto :

Version française :
Détergents désinfectants ou désinfectants pour DM Invasifs et/ou non invasifs :
- **Désinfectants Circuits dialyse**
- **Désinfectants manuels et/ou machines pour DM invasifs**
- **Détergents Désinfectants manuels et/ou machines pour DM invasifs**
- **Détergents Désinfectants manuels et/ou machines pour DM non invasifs**
- **Sprays détergents désinfectants ou désinfectants pour DM invasifs**
- **Sprays détergents désinfectants ou désinfectants pour DM non invasifs**
- **Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs**
- **Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs**

Version anglaise :
Detergents disinfectants or disinfectants for invasive and/or non-invasive devices :
- *Disinfectants for dialysis circuits*
- *Disinfectants for manual use and/or automatic machines for invasive devices*
- *Detergent disinfectant for manual use and/or automatic machines for invasive devices*
- *Detergent disinfectant for manual use and/or automatic machines for non-invasive devices*
- *Detergent disinfectant or disinfectant sprays for invasive devices*
- *Detergent disinfectant or disinfectant sprays for non-invasive devices*
- *Detergent disinfectant or disinfectant wipes for invasive devices*
- *Detergent disinfectant or disinfectant wipes for non-invasive devices*

Version espagnole:
Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos :
- Desinfectantes para circuitos diálisis,
- Desinfectantes manuales y/o máquinas para DM invasivos,
- Detergentes desinfectantes manuales y/o máquinas para DM invasivos
- Detergentes desinfectantes manuales y/o máquinas para DM no invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos

Laboratoire national de métrologie et d'essais • LNE

LNE/G-MED	0459

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Manager
Por delegación para el Director de Certificación

Laboratoire national de métrologie et d'essais • [illegible]

Identification des dispositifs / *Identification of devices* / Identificación de los dispositivos

Les produits couverts par ce certificat sont référencés sur le document daté du 10 avril 2018 (11 pages), authentifié par le LNE/G-MED le 03 mai 2018

Medical devices covered by this certificate are referenced on the manufacturer's list of products dated April 10th, 2018 (11 pages) authenticated by LNE/G-MED on May 3rd, 2018

Los productos cubiertos por este certificado están referenciados sobre el documento del 10 de abril de 2018 (11 páginas) autentificado por LNE/G-MED el 3 de mayo de 2018

Ce certificat couvre le site et les activités suivants :
This certificate covers the following site and activities:
Este certificado cubre el sitio y las actividades siguientes:

- **LABORTAOIRES ANIOS – Pavé du Moulin 59260 LILLE-HELLEMMES FRANCE**
  Siège social – Activités de conception, de fabrication et de contrôle final
  Headquarters – Design, manufacturing and final inspection activities
  Domicilio social – Actividades de diseño, de fabricación y de control final

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE •

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Manager
Por delegación para el Director de Certificación

laboratoires ANIOS

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

A. Prével

0 3 MAI 2018

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

1111

ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité / *Approval of full Quality Assurance System* / Aprobación del sistema completo de Seguro de la calidad

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux / *Annex II excluding section 4 directive 93/42/EEC concerning medical devices* / ANEXO II excluyendo el punto 4 directiva 93/42/CEE relativa a los productos sanitarios

Pour les dispositifs de classe III, un certificat CE de conception est requis / *For class III devices, a EC design certificate is required.*

Fabricant / *Manufacturer* / Fabricante

LABORATOIRES ANIOS

Pavé du Moulin

59260 LILLE-HELLEMMES France

Catégorie du (des) dispositifs / *Device(s) category* / Categoría del producto :

-**Désinfectants circuits dialyse**, *Disinfectants for dialysis circuits,* Desinfectantes para circuitos diálisis

-**Désinfectants manuels et/ou machines pour DM invasifs,** *Disinfectants for manual use and/or automatic machines for Invasive devices,* Desinfectantes manuales y/o máquinas para DM invasivos

-**Détergents désinfectants manuels et/ou machines pour DM invasifs,** *Detergent disinfectant for manual use and/or automatic machines for Invasive devices,* Detergentes desinfectantes manuales y/o máquina para DM invasivos

-**Détergents désinfectants manuels et/ou machines pour DM non invasifs,** *Detergent disinfectant for manual use and/or automatic machines for non invasive devices,* Detergentes desinfectantes manuales y/o máquina para DM no invasivos

-**Sprays détergents désinfectants ou désinfectants pour DM invasifs,** *Detergent disinfectant or disinfectant sprays for Invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM invasivos

-**Sprays détergents désinfectants ou désinfectants pour DM non invasifs,** *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos

-**Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs,** *Detergent disinfectant or disinfectant wipes for Invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM invasivos

-**Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs,** *Detergent disinfectant or disinfectant wipes for non invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos

10/04/2018

Pavé du Moulin - 59260 Lille-Hellemmes
Tél. +33 3 20 67 67 67 - Fax : +33 3 20 67 67 68
SIREN N° 823 326 061 - S.A.S. au capital de 773 630 132 €

Laboratoires ANIOS

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

A. Prével

03 MAI 2018

6/11

Catégorie du (des) dispositifs	Réf commerciale du dispositif ou code article *Device commercial reference or article code* *Ref. comercial del dispositivo o código artículo*	Classe du DM *DM Class* *Clase del DM*
Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos	SURFA SAFE (1568)	**IIa**
Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos	ANIOSPRAY SURF 29 (2421)	**IIa**
Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos	SURFA'SAFE PREMIUM (2419)	**IIa**
Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos	ANIOSPRAY SURF 41 (2420)	**IIa**
Sprays détergents désinfectants ou désinfectants pour DM non invasifs, *Detergent disinfectant or disinfectant sprays for non invasive devices,* Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos	ANIOSPRAY QUICK NPC (2454)	**IIa**
Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs, *Detergent disinfectant or disinfectant wipes for Invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM invasivos	LINGETTE WIP'ANIOS (1316)	**IIb**
Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs, *Detergent disinfectant or disinfectant wipes for Invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM invasivos	LINGETTE WIP'ANIOS PREMIUM (2088)	**IIb**
Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs, *Detergent disinfectant or disinfectant wipes for Invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM invasivos	WIP'ANIOS EXCEL (2446)	**IIb**
Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs, *Detergent disinfectant or disinfectant wipes for non invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos	LINGET'ANIOS (299)	**IIa**
Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs, *Detergent disinfectant or disinfectant wipes for non invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos	WIP'ANIOS EXCEL TRAVEL (2617)	**IIa**
Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs, *Detergent disinfectant or disinfectant wipes for non invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos	ANIOS QUICK WIPES (2333)	**IIa**
Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs, *Detergent disinfectant or disinfectant wipes for Invasive devices,* Toallitas detergentes desinfectantes o desinfectantes para DM invasivos	WIP'ANIOS ENZYMATIC (2828)	**IIb**

Pavé du Moulin - 59260 Lille-Hellemmes
Tél. +33 3 20 67 67 67 - Fax : +33 3 20 67 67 68
SIREN N° 823 326 061 - S.A.S. au capital de 773 630 132 €