7.2 Market Access Certifications (e.g., Medical Device Registration)

China NMPA Class III Registration Certificate

China Class III Medical Device Registration Certificate

This product is regulated as the highest-level (Class III) medical device in China, with its safety endorsed by the state.

中华人民共和国医疗器械注册证

注册证编号：国械注准20163140807

注册人名称	南京神奇科技开发有限公司
注册人住所	南京市浦口区石桥桥北路8号
生产地址	南京市浦口区石桥桥北路8号-1201
代理人名称	/
代理人住所	/
产品名称	长效抗菌材料
型号、规格	喷雾型（P）：10ml、20ml、30ml、40ml、50ml、60ml、80ml、100ml、200ml、250ml、500ml。
结构及组成	该产品为装在喷雾罐中的乳白色或淡黄色液体，其杀菌有效成分为有机硅季铵盐（含量为1%-3%）。
适用范围	该产品适用于因病原微生物引起的炎症感染创面及物理、机械、热力因素引起的创面，以杀灭和隔离细菌、真菌及病毒。
附　　件	产品技术要求
其他内容	/
备　　注	原注册证编号：国械注准20163640807

审批部门：国家药品监督管理局

批准日期：二〇二一年九月一日

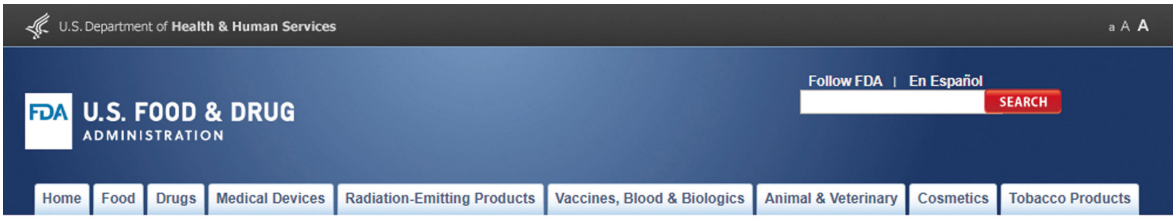
有效期至：二〇二六年八月三十一日

U.S. FDA Registration

FDA Registration Certificate

FDA Registration for the Medical Device and Establishment (Registration No.: 3005613390)

Status: Active (valid as of 2026)



Establishment Registration & Device Listing

Proprietary Name:	Spray Dressing; Gel Dressing; Liquid Dressing; Cream; Oral Dressing
Classification Name:	DRESSING,WOUND,HYDROGEL W/OUT DRUG AND/OR BIOLOGIC
Product Code:	NAE
Device Class:	1
Regulation Number:	878.4022
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	NMS TECHNOLOGIES
Registered Establishment Number:	3005613390
Owner/Operator:	NMS TECHNOLOGIES
Owner/Operator Number:	9083481
Establishment Operations:	Foreign Exporter; Manufacturer

Page Last Updated: 02/23/2026

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=94882&lpcd=NAE

Establishment Registration & Device Listing

Establishment:	NMS TECHNOLOGIES 8 Qiaobei Road Shiqiao, Pukou District Nanjing Jiangsu, CN 211804
Registration Number:	3005613390
FEI Number*:	3005613390
Status:	Active
Date Of Registration Status:	2026
Owner/Operator:	NMS TECHNOLOGIES 8 Qiaobei Road Shiqiao Town, Pukou Dist Nanjing, CN-32 CN 211804
Owner/Operator Number:	9083481
Official Correspondent:	Youliang Cai 8 Qiaobei Road Shiqiao Town, Pukou Dist NANJING, Jiangsu CN 211804
Phone:	86-25-83400310
US Agent:	Leeyeo Kee Regrek LLC 19 Holly Cove Ln. Dover , DE US 19901
Phone:	302 6089028 Ext
Email:	Regrek.Cs@Hotmail.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 02/23/2026

EU Market Access Registration and CE Certification Documents

RIOMAVIX

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Regulation (EU)2017/745 Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: NMS Technologies Co., Ltd.

ADDRESS: 8 Qiaobei Road, Shiqiao, Pukou District, Nanjing, China

The manufacturer has provided Riomavix S.L. with a Declaration of Conformity in accordance with European Council Regulation (EU) 2017/745 and has declared its responsibility for the truthfulness and accuracy of the materials provided.

Medical Device: Spray Dressing

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU)2017/745 are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is **RPS/849/2026**

RIOMAVIX R RIOMAVIX RIOMAVIX

Issue date: 13/Apr/2026
Cert. No.: R20260402-1

CE

EU CE Class I Device Certification

TÜVRheinland®

CE Technical Documentation Review Report

Manufacturer:	**Nanjing Magic Science and Technology Development Co., Ltd.** 8 Qiaobei Road, Shiqiao, Pukou District, Nanjing, Jiangsu 210003, China
Report Number:	15087045 001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	Spray Dressings
Type(s)/Model(s):	Aerosol
Classification:	Class I non-sterile, rule 4 (according to manufacturer's declaration)
Review result:	During the examination of the provided Technical Documentation (No.: CE Technical Construction File, Rev. A/0, Date: 2013 Jan.27), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (Shanghai) Co., Ltd.

Products · Quality Assurance TÜVRheinland® Approved

Shanghai, 2015-08-27

Daniel ZHU
Lead Auditor, Product Assessor
Medical Device Services

TÜV Rheinland (Shanghai) Co., Ltd.
Unternehmensgruppe
TÜV Rheinland Group

TUV Building, No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P.R.China

Tel: (86/21) 6108 1188
Fax : (86/21) 6108 1199

e-mail : service-gc@tuv.com
Internet : http://www.tuv.com

Multi-Country Market Access Documents

This document certifies that the technology has been reviewed and approved/classified by government health authorities across multiple jurisdictions.

Region / Country	Regulatory Authority	Certificate / Document Type	Page No.
South Korea	**MFDS** (Ministry of Food & Drug Safety)	**Medical Device Import License** Permit No. 14-1699. (Approved: 2014)	P.2
Taiwan	**MOHW** (Ministry of Health & Welfare)	**Medical Device Permit** License No. 000727. Class II/III Device	P.3
Singapore	**HSA** (Health Sciences Authority)	**Medical Device Registration** Registered as Low-Risk Medical Device	P.4
Malaysia	**MOH** (Ministry of Health)	**Product Classification** Confirmed definition as "Medical Device"	P.5
Hong Kong	**Department of Health**	**Regulatory Notification** Confirmed compliance (Non-drug/poison classification)	P.6
Honduras	**ARSA** (Sanitary Regulation Agency)	**Sanitary Registration Certificate** (Certificado de Registro Sanitario)No.27437.	P.8

South Korea ： Medical Device Import License

문서확인번호: 1397-7019-9653-7481 (신청인 : 염미정)

Medical Device Approval

수허 14-1699 호

의료기기 수입 허가증

업허가번호 : 제 2805호

구분	수입	품목/품목류	품목
제품명 (상품명, 품목명, 모델명)	(주)에이엠티코리아·JUC spray dressing,점착성투명창상피복재,JUC10 외 2건	분류번호 (등급)	B07070.01(2)
모양 및 구조	별첨		
원재료	별첨		
제조방법	별첨		
사용목적	사용목적 : 별첨, 성능 : 별첨		
사용방법	별첨		
사용 시 주의사항	별첨		
포장단위	별첨		
보관조건	저장방법 : 별첨, 사용(유효)기한 : 별첨		
시험규격	제 의기심 10-03-20140321-0334호(2014.04.04)		
제조(수입)업자 정보	제조(수입)업자 : (주)에이엠티코리아, 서울특별시 은평구 통일로87길 18-6 2층(갈현동)		
	제조원 : 별첨		
허가조건			
비고			

「의료기기법」 제15조 및 같은 법 시행규칙 제18조제3항에 따라 위와 같이 허가합니다.

2014년 04월 17일

서울지방식품의약품안전청장 (인)

Taiwan：Medical Device Permit

Medical Device Approval

衛生福利部醫療器材許可證

衛部醫器陸輸字第 000727 號

發審文件號碼：DHA09200072705

中文名稱： 潔悠神抗菌材料

英文名稱： JUC Spray Dressing

類　　別： 第J類:一般醫院及個人使用裝置

規　　格： 詳如中文仿單核定本

藥商名稱： 傑宏貿易有限公司

製造廠名稱： NMS TECHNOLOGIES CO., LTD

製造廠地址： 8 Qiaobei Road, Shiqiao, Pukou District, Nanjing, China

效　　能： 詳如中文仿單核定本

處　　方： 空白

前項醫療器材經本部審核與藥事法之規定相符應發給許可證以資證明

衛生福利部

部長蔣丙煌

輸入大陸物品另須依經濟部國際貿易局之大陸物品法令規定辦理。

發證日期 105 年 01 月 30 日

有效日期 110 年 01 月 30 日

核准展延至	115年1月30日	年 月 日	年 月 日	年 月 日
文號	096027626			

MF 002605

Singapore：Medical Device Registration

Health Sciences Authority

Singapore Government
Integrity • Service • Excellence

Contact Info | Feedback | Sitemap

Logon ID : S0080294H (Submitter) | Company Name : Mediquest Pte Ltd | Transaction No. : TMD11568037P

Mediquest Pte Ltd (Unique Entity No.(UEN) : 200003944M)
[Licence Type : **Registrant**, Importer, Wholesaler]
16, JALAN KILANG, HOI HUP BUILDING, #04-05, SINGAPORE 159416
Main Tel. No. : 68373387, Fax No. : 68370824
Contact Person : CHRISTABEL MONTEIRO, Contact Tel. No. : 68373387
Contact Email : chris@mediquest.com.sg

MD0840 - REGISTRATION FOR LOW RISK MEDICAL DEVICE > Pending

APPLICATION FORM

1. Applicant Info	2. Device Info	3. Product Owner Info	Please refer to the Guidelines on the...
4. Manufacturing Site(s) Info	5. Model(s) Info	6. GMDN Info	
7. Importer & Wholesaler Info	8. Supporting Document(s)	9. Remarks	

Job Reference No. : MD11540122Y
Status Date : 10/10/2011
Submission Date : 10/10/2011
Status : Pending
View Payment Advice

1. APPLICANT INFO

Christabel Monteiro (NRIC/Passport No. : S0080294H), Tel. No. : 68373387, Fax No. : 68370824, Email : chris@mediquest.com.sg

2. DEVICE INFO

1. **JUC SPRAY DRESSING** (CLASS A) [Professional Use - Yes], [General Hospital], [FAMILY], SPRAY - ON NANO FILM ON SURFACE OF SKIN; FORMS PHYSICAL BARRIER AGAINST INFECTION, SPRAY - ON NANO FILM ON SURFACE OF SKIN; FORMS PHYSICAL BARRIER AGAINST INFECTION, HS Code:30051090, Professional use only:Y

3. PRODUCT OWNER INFO

NMS TECHNOLOGIES CO., LTD : 8 QIAOBEI ROAD, SHIQIAO, PUKOU DISTRICT, NANJING, CHINA

4. MANUFACTURING SITE(S) INFO

1. **NMS TECHNOLOGIES CO., LTD :** 8 QIAOBEI ROAD, SHIQIAO, PUKOU DISTRICT, NANJING, CHINA

5. MODEL(S) INFO

Product Code for Accessories:Not Applicable

1. **JUC SPRAY DRESSING 10ML** (Model # : -), 10 ML
2. **JUC SPRAY DRESSING 30ML** (Model # : #01030), 30 ML

6. GMDN INFO

1. Dressing, aerosol [Code : 45010]

7. IMPORTER & WHOLESALER INFO

1. Mediquest Pte Ltd [ES0001293] - Importer
2. Mediquest Pte Ltd [ES0001294] - Wholesaler

8. SUPPORTING DOCUMENT(S)

S/No.	Document Name	Description	Size (KB)	Submission Date
1.	CE Certificate JUC spray.pdf	Other document	48	28/09/2011

Malaysia：Product Classification

MEDICAL DEVICE CONTROL DIVISION
MINISTRY OF HEALTH MALAYSIA
Level 5, Building Plot 3C4,
No.26, Jalan Persiaran Perdana,
Precinct 3,
62675 Putrajaya

Tel : (03) 8885 0600
Fax : (03-8885 0759
http://www.mdb.gov.my/

Our Ref: (4) dlm.KKM-153(BPP)TEK 4/30 jld [25'K-[
Date: || November 2011

Syarikat Wellchem Sdn Bhd
928-929, Jalan 17/38
46400, Petaling Jaya
Selangor Darul Ehsan
Malaysia.
(u/p: Mr. Yim Weng Kai)

Sir/Madam,

PRODUCT CLASSIFICATION

With reference to the above, I am pleased to inform you that the product as listed in the Attachment falls under the definition of **Medical Device**.

For your information, currently we are implementing the Voluntary Registration of Medical Device Establishment (MeDVER). All establishments or companies dealing with medical device are encouraged to register under MeDVER.

This letter does not constitute an approval for the products and shall not be used for the purpose of promoting or advertising the products.

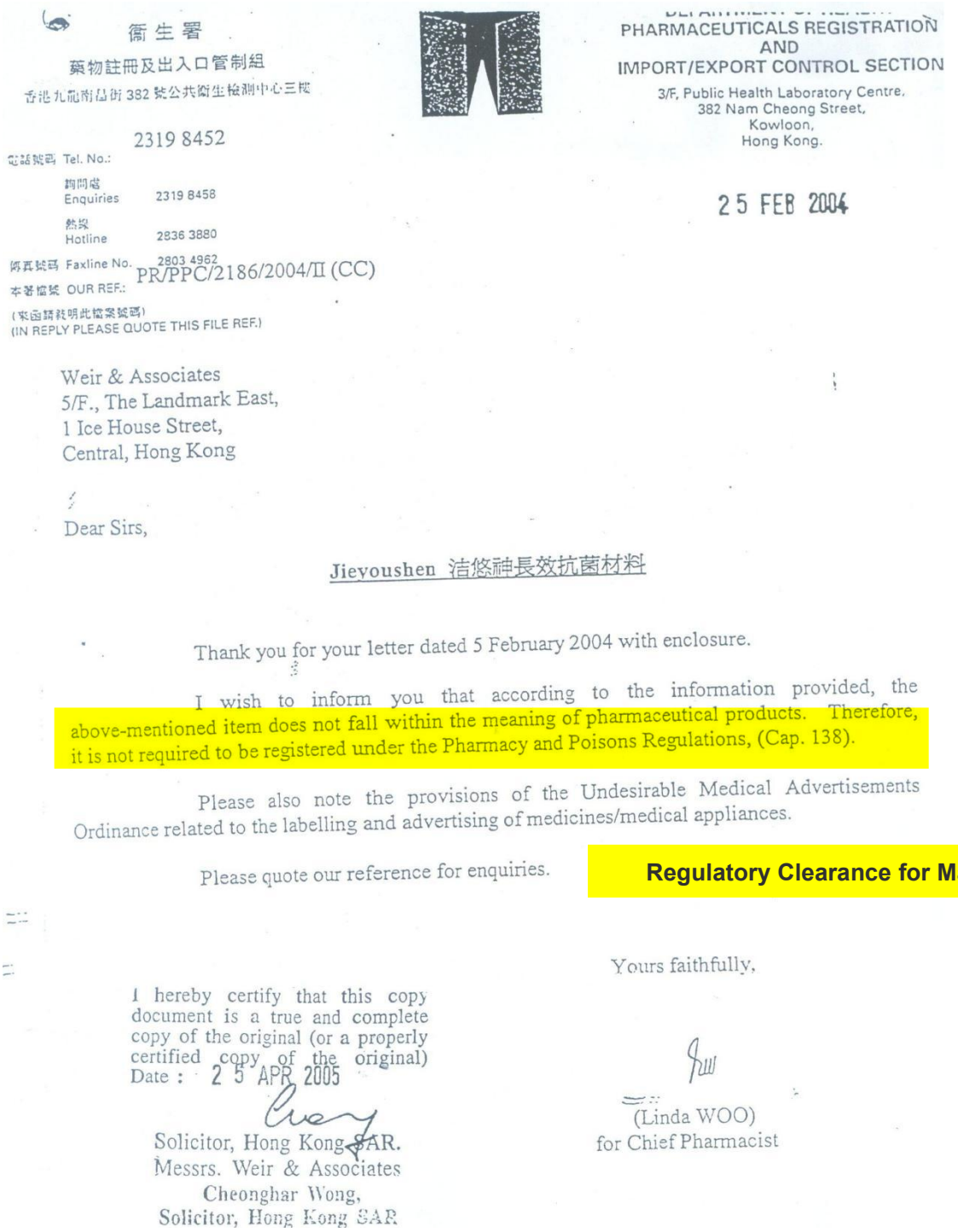
Thank you.

(ZAMANE BIN ABDUL RAHMAN)
Director
Medical Device Control Division
Ministry of Health, Malaysia

'Sila catatkan rujukan surat ini apabila menjawab'

Hong Kong：Regulatory Notification

This is the letter of exemption.



衞生署
藥物註冊及出入口管制組
香港九龍南昌街 382 號公共衞生檢測中心三樓

2319 8452

電話號碼 Tel. No.:
查詢電 Enquiries 2319 8458
熱線 Hotline 2836 3880
傳真號碼 Faxline No. 2803 4962
本署檔號 OUR REF.: PR/PPC/2186/2004/II (CC)
(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

PHARMACEUTICALS REGISTRATION AND IMPORT/EXPORT CONTROL SECTION
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street,
Kowloon,
Hong Kong.

25 FEB 2004

Weir & Associates
5/F., The Landmark East,
1 Ice House Street,
Central, Hong Kong

Dear Sirs,

Jieyoushen 洁悠神長效抗菌材料

Thank you for your letter dated 5 February 2004 with enclosure.

I wish to inform you that according to the information provided, the above-mentioned item does not fall within the meaning of pharmaceutical products. Therefore, it is not required to be registered under the Pharmacy and Poisons Regulations, (Cap. 138).

Please also note the provisions of the Undesirable Medical Advertisements Ordinance related to the labelling and advertising of medicines/medical appliances.

Please quote our reference for enquiries.

Yours faithfully,

(Linda WOO)
for Chief Pharmacist

I hereby certify that this copy document is a true and complete copy of the original (or a properly certified copy of the original)
Date : 25 APR 2005

Solicitor, Hong Kong SAR.
Messrs. Weir & Associates
Cheonghar Wong,
Solicitor, Hong Kong SAR

Regulatory Clearance for Market Access

Honduras：Sanitary Registration Certificate

Dirección General de Regulación Sanitaria

CERTIFICADO DE REGISTRO SANITARIO

El suscrito Director (a) de la Dirección General de Regulación Sanitaria

CERTIFICA

Que mediante Resolución No.27437 Fecha 10 de Septiembre del 2008 Expediente No. 24761
Registro Sanitario No. DM- 00002 Vigente Hasta: 10 de Septiembre del 2013
Ha quedado Registrado el Dispositivo Medico
Nombre Comercial: JUC VENDAJE ANTISÉPTICO EN SPRAY
Titular: GRUPO EVEREST S. DE R. L.
Domicilio: Honduras
Modalidad de Registro: Importar y vender
Laboratorio Fabricante: LABORATORIOS EVEREST S. DE R. L.
Domicilio: **Honduras**
Forma Farmacéutica: Spray
Presentación Comercial: Envase de Polietileno Conteniendo 30ml de Solución en Spray
Composición Solución Acuosa al 2% de Agente Activo Macromolecular Cationico (sal de Amonio)

Grupo Terapéutico: Vendaje Antiséptico

Vía de Administración: Tópica

Venta Sin Receta Médica

Observaciones: Las Etiquetas y Empaques deben llevar impreso el lote, vencimiento y número de Registro Sanitario.

El Registro del Producto aquí autorizado podrá en cualquier momento ser cancelado si el resultado de los análisis practicados en el Laboratorio Oficial no corresponde a la Fórmula Cuali-cuantitativa con que fue Registrado o que no llene las condiciones de calidad indispensables para este tipo de productos y cuando el Comité Técnico Asesor en Farmacología lo considere inconveniente para la Salud. Así mismo las etiquetas y empaques, la promoción y publicidad del Producto deben cumplir con lo establecido en el REGLAMENTO DE REGISTRO SANITARIO.

Y para fines que al interesado convenga se le extiende el presente **CERTIFICADO** en la ciudad de **Tegucigalpa, M. D. C. A los Veintidós días del mes de Septiembre del dos mil ocho.**

DRA. SONIA MARILINDA BENITEZ CACERES
DIRECTORA GENERAL DE REGULACIÓN SANITARIA