RUMEX™

眼科产品

AFFORDABLE
INNOVATIONS

关于我们

Rumex仪器有限公司是一家领先的制造商之一的手持式手术的眼科仪器。

我们介绍新的医疗技术为医院和医疗专业办公室提供外科手术器械。我们培养医生和医务人员以创新的手段来工作，我们要改善患者的生活质量作出贡献。

 自一九九四年以来

 一百个国家

 八十名员工

 超过两千产品组合

RUMEX™

关于我们

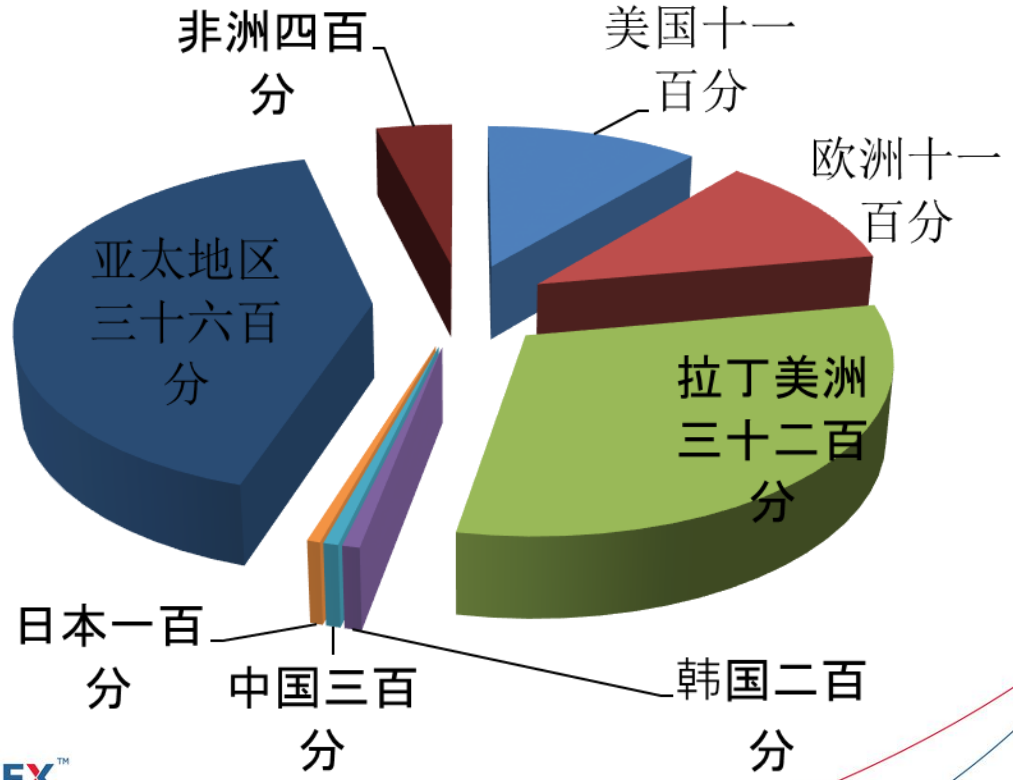
我们高度熟练的产品和销售经理考虑到专业化，每个医院的工作人员建议和预算。
作为一个创新和以客户为导向的公司，Rumex International 总是开放新的想法 - **如果你的外科技**术（或偏好）需要特**殊的工具** - **我**们会为您创建它

分销商：

- 亚洲二十四经销商
- 欧洲十九经销商
- 澳大利亚一经销商
- 非洲和中东十九经销商
- 拉丁美洲十八经销商

RUMEX™

客户端和营销。每个世界地区的销售额



RUMEX™

分销商

上海威视医疗设备有限公司

地址：中国200061上海市普陀区中山北路1777号902室

链接人：詹妮弗汉

电话：021-52902731

传真：021-52902730

售后：400-820-257

邮箱：vistaar@vip.163.com

网址：www.vistaar.com.cn

MSN: jennifer14314@hotmail.com

RUMEX™

分销商

M&L International Corporation

中国北京朝阳区建外水安东里甲3号通用时代国际中心A座1805室

电话：+86-10-58793908-801

传真：+86-10-58793920

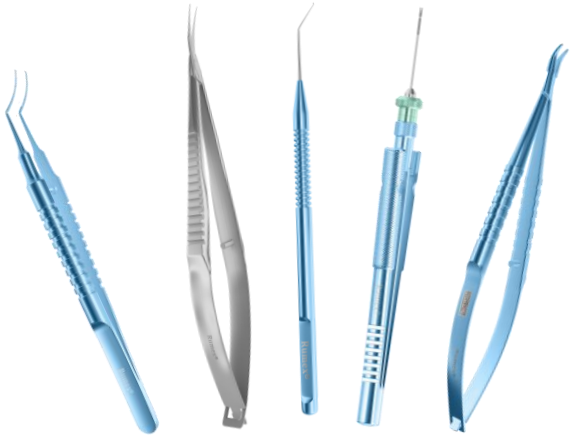
电子邮件：helen@mlcorp.cn

RUMEX™

眼科产品

可重复使用的仪器眼科手术

- 白内障
- 折射
- 角膜
- 玻璃体视网膜



RUMEX™

钛仪器

- 最佳钛合金生产在俄罗斯为航空航天和国防工业

- 高品质钛
- 钢铁工具的价格水平
- 钛比钢轻四十五百分
- 高强度和耐腐蚀性
- 材料被批准用于医疗设备
- 非磁性
- 低过敏
- 有吸引力的设计

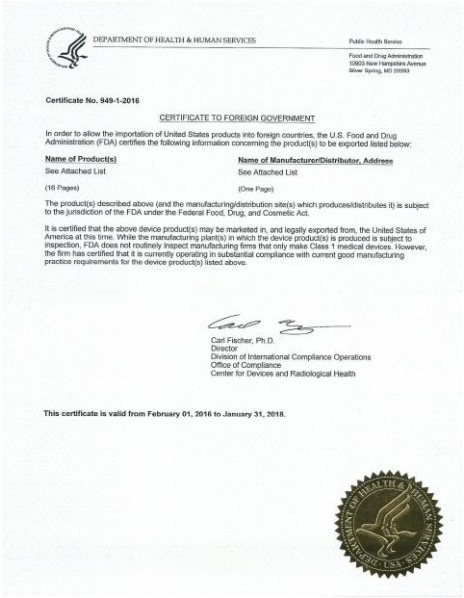
RUMEX™

创新

- 高创新率
- 高品质和实惠的价格的完美结合
- 与来自世界各地的顶级外科医生一起进行产品开发
- 经验丰富的工程队伍和雄厚的生产设施
- 定制产品
- OEM可能性

RUMEX™

证书



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 949-1-2016

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
See Attached List	See Attached List
(16 Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from February 01, 2016 to January 31, 2018.

Certificate

Quality Assurance

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2012.

ecm

Through an audit performed on behalf of

RUMEX INTERNATIONAL LTD
311 Shoreham Street, Sheffield, Yorkshire S24FA, United Kingdom

it could be demonstrated that a quality assurance system

according to **DIN EN ISO 13485:2012**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for **manufacturing, distribution, storage, quality control, sales and delivery of ophthalmic devices**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
571-13-1015	Z/13/03173	November 14th, 2018

Aachen, November 14th, 2013

Certification Body

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and
Certification Association "Russian Register"
hereby certify that the organization

"RUMEX Instruments" Ltd.
34, Sibirsky tract Str., building 4, 420029, Kazan, Republic of Tatarstan, Russia

for the following field of activities

design, manufacture,
sale of medical surgical and microsurgical instruments

has implemented and maintains a

Management System

which fulfils the requirements of the following standard

ISO 13485:2003

Issued on : 14th January, 2016
Validity date : 14th January, 2019

Registration Number : **RU-16.0003.026**

IQNet — *Michael Drechsel*, *President of IQNet*

Arkady Vladimirtsev, *Director General of Russian Register*

IQNet Partners*:
AENOR Spain AFNOR Certification France AIB-Vincotte International Belgium APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico Inspecta Certification Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SIQE Mexico SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St.Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Rumex生产符合最严格的全球质量标准

RUMEX™

证书

第一类医疗器械备案凭证

RUMEX INTL. CO.：

根据相关法规要求，对你单位第一类医疗器械：显微眼用钩具予以备案，备案号：国械备20160858号。

国家食品药品监督管理总局

（盖章）

日期：2016年06月13日

第一类医疗器械备案凭证

RUMEX INTL. CO.：

根据相关法规要求，对你单位第一类医疗器械：显微眼用剪予以备案，备案号：国械备20160856号。

国家食品药品监督管理总局

（盖章）

日期：2016年06月13日

第一类医疗器械备案凭证

RUMEX INTL. CO.：

根据相关法规要求，对你单位第一类医疗器械：吸用持针钳予以备案，备案号：国械备20160875号。

国家食品药品监督管理总局

（盖章）

日期：2016年06月15日

RUMEX™

证书

第一类医疗器械备案凭证

RUMEX INTL. CO.：

根据相关法规要求，对你单位第一类医疗器械：显微眼用镊予以备案，备案号：国械备20160887号。

国家食品药品监督管理总局

（盖章）

日期：2016年06月15日

第一类医疗器械备案凭证

RUMEX INTL. CO.：

根据相关法规要求，对你单位第一类医疗器械：显微眼用镊予以备案，备案号：国械备20160887号。

国家食品药品监督管理总局

（盖章）

日期：2016年06月15日

RUMEX™

数据矩阵条形码

- 条码机读
- 可控杀菌
- 会计
- 库存管理
- 透明的成本
- 增强患者安全
- 品质管制
- 订购方便
- 信息交流

我们为成为世界上第一家开始在眼科仪器上应用条形码的制造商而感到自豪！

RUMEX™

证书

总公司地址：

13770 58th Street North, Suite 303
Clearwater, FL 33760, USA

电子邮件：rumex@rumex.net

Skype: rumex.net

对于客户

电话：+1 727 535 96 00

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