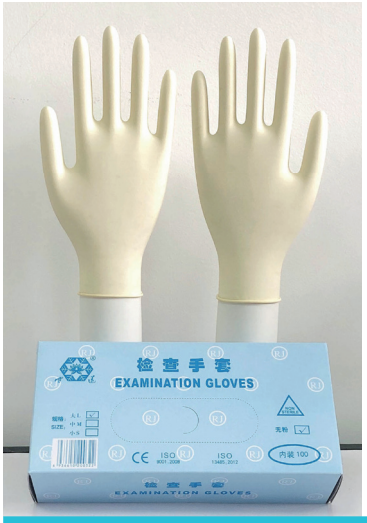
检查手套（雪莲） 产品编码：LEG-XL

检查手套，无粉麻面，采用进口优质天然胶乳加工而成，适用于低风险的医疗护理、医疗检查、卫生防护等，可以为医护人员及患者提供可靠的安全防护，同时也可用于生物制药、实验检测、食品加工、美容美发、家居清洁、轻工业及电子等行业。产品为加厚款，防护性能更优于常规产品。



产品性能及优点：

- 现有规格：S，M，L；
- 不消毒，一次性使用，左右手均可穿戴；
- 手套呈乳白或淡黄色，双手通用，灵活佩戴；
- 使用进口天然胶乳，柔软舒适、弹性好、不易变形；
- 全麻表面防滑处理，干湿环境均可呈现优越的抓握力；
- 采用真正无粉工艺，使用前可省略掸粉环节，穿戴更方便、更爽滑、更舒适；
- 使用低蛋白天然胶乳，过敏原含量更低，可降低因使用本产品造成的过敏风险。

手套袖口为卷边设计，佩戴安全，不易脱落，使您的操作更加灵活。
出色的拉伸强度降低手套破损风险，有效保护使用者的安全。

物理性能和尺寸规格参数表（参照GB10213最新标准）

尺寸代码	标称尺寸	最小长度 单位：mm	宽度 单位：mm	最小厚度 单位：mm	老化前		老化后	
					扯断力 N	伸长率%	扯断力 N	伸长率%
6 和 6 以下	特小号（XS）	220	≤80	光面 0.08 麻面 0.11	≥7.0	≥650	≥6.0	≥500
6.5	小号（S）	220	80±5					
7	中号（M）	230	85±5					
7.5	中号（M）	230	95±5					
8	大号（L）	230	100±5					
8.5	大号（L）	230	110±5					
9	特大号（XL）	230	≥110					

注意事项：

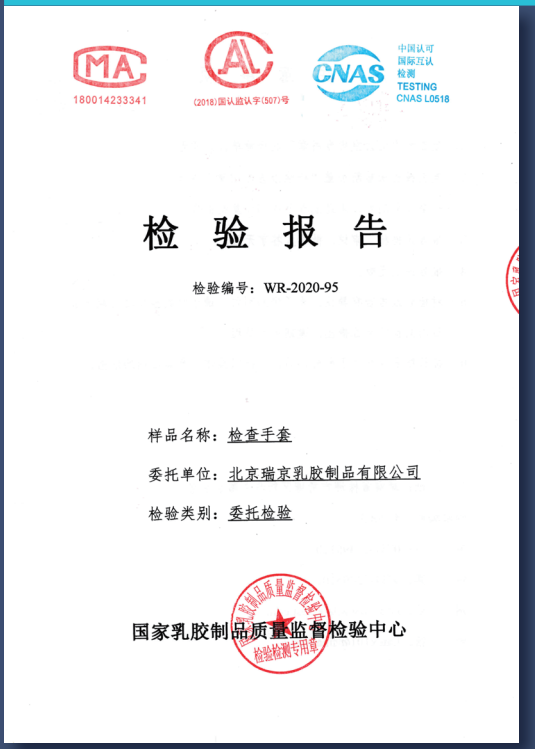
本产品应贮存在相对温度不超过80%、室内温度为30℃以下、通风良好、阴凉干燥的场所，贮存期内不得接触油、酸、碱、铜、锰等有害于橡胶的物质。

包装规格：

- 100只/盒，盒子尺寸：24.5x12.5x6.5cm
- 2000只/箱，外箱尺寸：51x35x27cm

*我们可以按照客户提出的包装要求做成消毒包装。

产品符合欧盟EN455、ISO11193、ASTM D3578、GB10213最新版标准，并获得欧盟CE证书和美国FDA 510(K)号。



检 验 报 告

检验编号：WR-2020-95

样品名称：检查手套

委托单位：北京瑞京乳胶制品有限公司

检验类别：委托检验

国家乳胶制品质量监督检验中心

检测报告

国家乳胶制品质量监督检验中心

检 验 报 告

检验编号：WR-2020-95　　共 2 页第 1 页

样品名称	检查手套	规格型号	M（7.5）号 麻面无粉
商标	雪莲	来样方式	客户邮寄
委托单位名称及地址	北京瑞京乳胶制品有限公司 北京市通州区台湖镇北神树村东光供电一体化产业基地兴光五街 6 号		
样品来源信息	北京瑞京乳胶制品有限公司		
送（抽）样者	杨新锐	送（抽）样日期	2020.5.8
样品状态	盒装，样品完好	样品批号	2020030521
批量(抽样基数)	100000 只	来样数量	300 只
到样日期	2020.5.12	检验依据	GB 10213-2006 GB 24788-2009
检验日期	2020.5.12-5.21	环境条件	（21-25）℃
检验类别	委托检验	报告编写者	黄超
检验结论： 经检验，样品所检表面残余粉末含量和水抽提蛋白质含量性能达到 GB 24788-2009 标准的要求，其余所检项目性能达到 GB 10213-2006 标准的要求。 签发日期：2020年5月21日			
备注：/			

批准：　审核：　主检：

职称：教授级高工

检测报告

第一类医疗器械生产备案凭证

备案编号：京通食药监械生产备20140004号

企业名称	北京瑞京乳胶制品有限公司		
住所	北京市通州区台湖镇北神树村东光机电一体化产业基地兴光五街6号		
生产地址	北京市通州区台湖镇北神树村东光机电一体化产业基地兴光五街6号		
法定代表人	曹文操	企业负责人	曹文操
生产范围	Ⅰ类：Ⅰ-6864医用卫生材料及敷料***		

生产产品列表	产品名称	产品备案号	登载日期	备注
	检查手套	京通械备20140013号	2014-12-19	—
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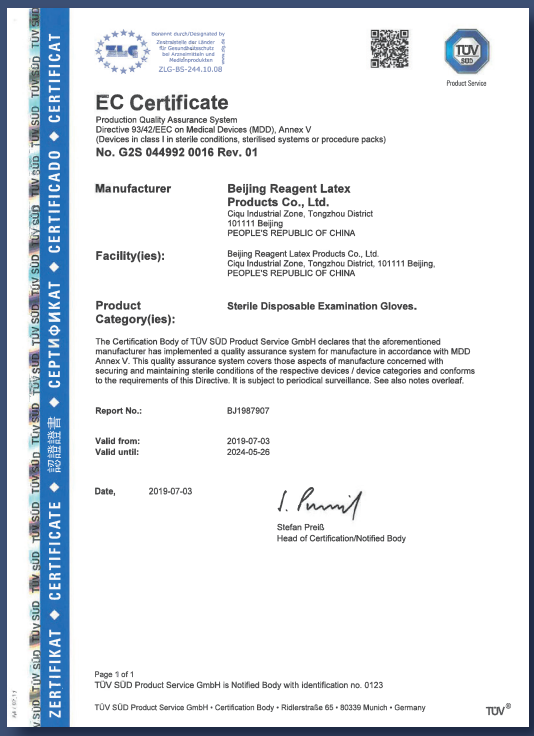
备案部门：

备案日期：2020年07月16日

备案专用章

09

第一类医疗器械生产备案证书



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 044992 0016 Rev. 01

Manufacturer Beijing Reagent Latex Products Co., Ltd.
Ciqu Industrial Zone, Tongzhou District
101111 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Beijing Reagent Latex Products Co., Ltd.
Ciqu Industrial Zone, Tongzhou District, 101111 Beijing,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Sterile Disposable Examination Gloves.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ1987907

Valid from: 2019-07-03
Valid until: 2024-05-26

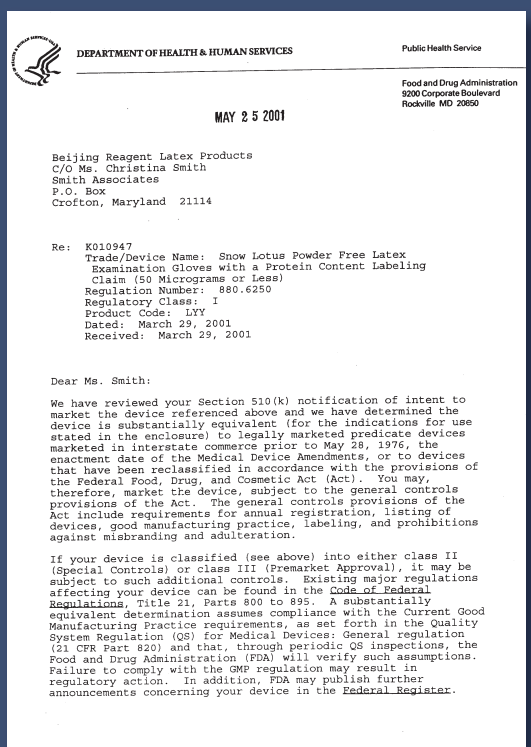
Date, 2019-07-03

Stefan Preiß
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

欧盟CE证书



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2001

Beijing Reagent Latex Products
C/O Ms. Christina Smith
Smith Associates
P.O. Box
Crofton, Maryland 21114

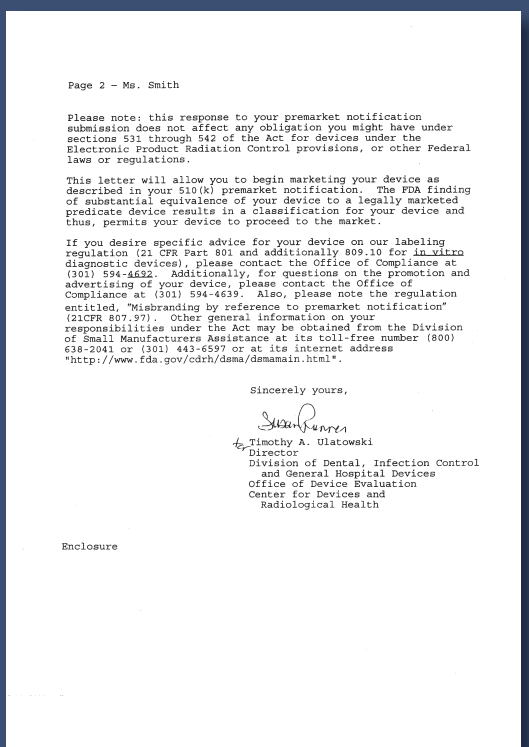
Re: K010947
Trade/Device Name: Snow Lotus Powder Free Latex Examination Gloves with a Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: March 29, 2001
Received: March 29, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

美国FDA 510K证书



Page 2 - Ms. Smith

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

美国FDA 510K证书