

# QINGDAO HAINUO GROUP

## About us

Hainuo Group was founded in 2004 and now has more than 20 subsidiary corporations. Our headquarter is located in Jiangshan industrial park in Laixi, Qingdao, which is very close to the main highway, Huashan International Golf Course, Qingdao International Airport and Qingdao Harbor. Our factory covers an area of 220,000 square meters with super geographical position and convenient transportation.

We have a dozen up-to-date factories, multiple Class 100,000 cleanrooms and Class 300,000 cleanrooms, modern logistics and storage facilities, advanced production facilities and detecting instruments. More than 2,000 professional staffs devote themselves to their job and the development of Hainuo, a lot of them are experts, professors and licensed pharmacists from Chinese Pharmaceutical Association as well as the State Council. We also have technology support and cooperation of many research institutions and companies from USA, Germany and Taiwan, China.

Hainuo keeps moving forward and we're always open to your ideas and advices. Please don't hesitate to let us know if you're interested in working with us and a deeper level of cooperation!

## OUR BRANDS



*HYNAUT for Overseas Market*



*HAINUO for Domestic Market*



# Isopropyl Alcohol Prep Pad



Your Professional Partner  
of Medical Care



## Isopropyl Alcohol Prep Pad

Hynaut Isopropyl Alcohol Prep Pad is made of spunlace non-woven fabric, saturated with 75% ( $\pm 5\%$ ) isopropyl alcohol.

### FEATURES:

- △ Topical antiseptic helps to reduce bacteria on the skin and makes these pads ideal for use prior to injections.
- △ Ideal for removal of oils and residue from skin.
- △ Each pad is individually wrapped and sealed to keep it protected and moist.



Specification	Carton Size	Packaging	GW
6*3cm	46.5*35*33.5cm	100pcs/box*100boxes=10000pcs	9.78kgs
6*6cm	58*38.5*33cm	100pcs/box*100boxes=10000pcs	14.61kgs
12*12cm	58*32*31cm	50pcs/box*60boxes=3000pcs	12.8kgs

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## Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for Establishment Registration  
or FEI Number : 3008808560

New Search

Establishment Name	Registration Number	Current Registration Yr
QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD. CHINA	3008808560	2020
<ul style="list-style-type: none"> <li>Floss, Dental - Floss Pick</li> <li>First Aid Kit Without Drug - First Aid Kit</li> <li><b>Pad, Alcohol, Device Disinfectant - Alcohol Wipes, Alcohol Prep Pad</b></li> <li>Dressing, Wound, Hydrophilic - Wound Dressing, I.V. Adhesive Dressing</li> <li>Tape And Bandage, Adhesive - Medical Tape, Adhesive Bandage, Wound Plaster</li> <li>Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie Guidance</li> <li>Mask, Scavenging - Disposable Mask</li> <li>Disinfectant, Medical Devices - Iodine Swab</li> <li>Pack, Hot Or Cold, Disposable - Warm Patch, Cold Pack, Cool Patch, Fever Relief Patch, Cool Gel, Freeze Gel</li> <li>Bandage, Elastic - Elastic Bandage, Gauze Bandage</li> <li>Non-Surgical Isolation Gown</li> <li>Gauze / Sponge, Nonresorbable For External Use - Gauze Pad, Underpad, Cotton Balls</li> <li>Cover, Shoe, Operating-Room</li> <li>Mouthguard, Over-The-Counter - Face Mask</li> <li>Applicator, Absorbent Tipped, Non-Sterile - Cotton Swab</li> <li>Cap, Surgical</li> </ul>		Manufacturer

FDA

NDC

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Hynaut Alcohol Prep Pad	78149-002-01	70 mL/100g	CLOTH	TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-002	Alcohol	ALCOHOL	HUMAN OTC DRUG	06/23/2020	N/A	OTC MONOGRAPH NOT FINAL	1 PATCH in 1 PACKAGE (78149-002-01) > 2.7 g in 1 PATCH
Alcohol Prep Pads	78149-201-02	75 g/100g	SWAB	EXTRACORPOREAL; TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-201	Alcohol Prep Pads	ISOPROPYL ALCOHOL	HUMAN OTC DRUG	05/20/2020	N/A	OTC MONOGRAPH NOT FINAL	100 PATCH in 1 BOX (78149-201-02) > .7 g in 1 PATCH (78149-201-01)
Alcohol Prep Pads	78149-201-04	75 g/100g	SWAB	EXTRACORPOREAL; TOPICAL	part333A	Qingdao Hainuo Biological Engineering Co., Ltd.	78149-201	Alcohol Prep Pads	ISOPROPYL ALCOHOL	HUMAN OTC DRUG	05/20/2020	N/A	OTC MONOGRAPH NOT FINAL	100 PATCH in 1 BOX (78149-201-04) > 1.05 g in 1 PATCH (78149-201-03)

# Isopropyl Alcohol Prep Pad

## ISO 13485



2020-09-03

### To Whom It May Concern

This is to confirm that Extension Audit, Re-certification Audit for ISO 13485, Surveillance Audit for MDD was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body (CE0197) as follows:

**Applicant:** Qingdao Hainuo Biological Engineering Co., Ltd.  
**Address:** Jiangshan Industrial Area of Jiangshan Town, Laixi, 266603  
Qingdao City, Shandong, China

**MDDScope:** Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Wound Plasters, Sterile Wound Dressings, Medical Face Masks

**qsScope:** Manufacture and Distribution of Sterile Wound Plasters, Sterile Wound Dressings, Medical Adhesive Tapes, Surgical Sponges, Medical Cotton Tipped Applicators, Medical Cotton Balls, Medical Alcohol Prep Pads, Medical Alcohol Cotton Balls, Medical Iodine Cotton Balls, Medical Face Masks, Medical I.V. Adhesive Dressings, Human Chorionic Gonadotropin(HCG)Test Strips (colloidal gold), Luteinizing Hormone (LH)Test Strips (colloidal gold), Medical Fever Relief Patches, Gauze Bandages, Elastic Bandages, Medical Underpads, Medical Instant Cold Packs, Medical Exam Gloves, Liquid Dressings

**Standards:** EN ISO 13485:2016, MDD 93/42/EEC Annex V

**Date:** 2020-06-22~24  
**Report No.:** 15081837 011

The result of on-site audit is positive. The auditors will recommend that TÜV Rheinland LGA Products GmbH Notified Body (CE0197) Certificate for a Quality Assurance System should be issued after the corrective actions proposed by the company are accepted.

Yours sincerely,  
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Mr. SHENG Fuxiu  
Leader Auditor, Greater China  
Medical Services

TÜV Rheinland  
(Shanghai) Co., Ltd.

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## 中华人民共和国医疗器械注册证

注册证编号：鲁械注准 20172640675

注册人名称	青岛海诺生物工程有限公司
注册人住所	青岛市莱西市姜山镇工业园
生产地址	青岛市莱西市姜山镇工业园
代理人名称	(“进口医疗器械适用”)
代理人住所	(“进口医疗器械适用”)
产品名称	医用酒精消毒棉片
型号、规格	3cm×3cm、4.5cm×9cm、5cm×5cm、6cm×3cm、6cm×6cm、8cm×8cm、6cm×12cm、10cm×10cm、10cm×15cm、10cm×20cm、12cm×12cm、12cm×18cm、12.5cm×16cm、13cm×16cm。
结构及组成	由水刺无纺布片浸浓度为70%—80%（体积分数）的医用酒精制成。
适用范围	用于注射、输液前消毒完整皮肤。
附件	注册产品技术要求：鲁械注准 20172640675
其他内容	
备注	

审批部门：山东省食品药品监督管理局



## Business License


## Medical Device Registration

# Isopropyl Alcohol Prep Pad



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中国认可  
检验  
INSPECTION  
CNAS IB0071

NO.2820060104

## SAFETY DATA SHEET


**Product Name:** Isopropyl alcohol pads

**Effective Date:** 2020-06-28

**Compiler:** Zhoujiefei

**Checker:** Dongxueshang

**Approver:** Zhangxiuqin



Shanghai Research Institute of Chemical Industry Testing Co., Ltd.

## 货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2020063461

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样品名称 Sample Name	中文 Chinese	异丙醇棉片(单片装)
	英文 English	ALCOHOL PREP PAD
委托单位 Consignor	青岛海诺生物工程有限公司	
生产单位 Manufacturer	青岛海诺生物工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)	
样品外观与气味 Appearance & Odor	白色无纺布, 稍有气味 White Wet nonwoven, Weak odor	
IDENTIFICATION 鉴定结论 CONCLUSION	1. 危险性识别 (Hazards identification)	
	无。 None.	
	2. 海运按照IMO IMDG Code办理的类项 (Suggestion according to IMO IMDG Code) 根据特殊规定216, 可按非限制性货物条件办理。 The substance is not subject to IMO IMDG Code according to special provision 216.	
备注 Comment	3. 包装要求 (Packaging requirements)	
	无。 None.	
	检验日期: 2020-06-11	签发日期: 2020-06-11
	Inspection Date: 2020-06-11	Issue Date: 2020-06-11
		生效日期: 2020-06-11
		Effective Date: 2020-06-11

批准: Zhangxiuqin

审核: Dongxueshang

主检: Zhoujiefei


## Material Safety Data Sheet (MSDS)


# Isopropyl Alcohol Prep Pad




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of Medical Care



 海运  
By Sea

  
 NO.2020063461


 中国认可  
 检验  
 INSPECTION  
 CNAS 8027


## 货物运输条件鉴定书


Certification  
for Safe Transport of Chemical Goods

**非限制性货物**

样品名称： 异丙醇棉片(单片装)  
 Sample Name: ALCOHOL PREP PAD  
 委托单位： 青岛海诺生物工程有限公司  
 生产单位： 青岛海诺生物工程有限公司




 上海化工院检测有限公司  
 Shanghai Research Institute of Chemical Industry Testing Co., Ltd

 海运  
By Sea

货物运输条件鉴定书  
 Certification for Safe Transport of Chemical Goods  
 NO. 2020063461  
 Page 1 / 2

样品名称 Sample Name	中文 Chinese	异丙醇棉片(单片装)
	英文 English	ALCOHOL PREP PAD
委托单位 Consignor	青岛海诺生物工程有限公司	
生产单位 Manufacturer	青岛海诺生物工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)	
样品外观与气味 Appearance & Odor	白色湿无纺布, 稍有气味 White Wet nonwoven, Weak odor	
I D E N T I F I C A T I O N 结 论	1. 危险性识别 (Hazards identification)	无。 None.
	2. 海运按照IMO IMDG Code办理的类项 (Suggestion according to IMO IMDG Code)	根据特殊规定216, 可按非限制性货物条件办理。 The substance is not subject to IMO IMDG Code according to special provision 216.
3. 包装要求 (Packaging requirements)	无。 None.	
备注 Comment	无。 None.	

检验日期: 2020-06-11    签发日期: 2020-06-11    生效日期: 2020-06-11  
 Inspection Date: 2020-06-11    Issue Date: 2020-06-11    Effective Date: 2020-06-11

批准:     审核:     主检:   
 Approver:    Checker:    Appraiser:



## Certification for Safe Transport of Chemical Goods



**Contact us!**



**QINGDAO HAINUO GROUP**

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