

- **Company Profile**
- **Licence and Test Report**
- **Fevel Cooling Patch (Adult)**
- **Fevel Cooling Patch (Kids)**

Qingdao Haishi Hainuo Group is a biotechnology enterprise integrating R & D, production and sales. The Group was founded in 2004 and now has more than 20 subsidiary corporations. Our headquarter is located in Jiangshan Industrial Park in Laixi Qingdao, with superior geographical location and convenient transportation, covering an area of over 500 acres, which is adjacent to Jiangshan Lake, Qingrong Light Rail, major highways, Qingdao International Airport and Qingdao Port, and It's one step away from Huashan International Golf Course. We have several modern workshops and logistics storage facilities that meet international standards, equipped with advanced production facilities and high-precision testing instruments. There are nearly 2,000 employees including experts, professors and licensed pharmacists from the Chinese Pharmaceutical Association. Technical support and collaboration are provided by many scientific research institutions and companies from USA, Germany and Taiwan, China.





国家企业信用信息公示系统网址:

国家市场监督管理总局监制

Business License

第一类医疗器械备案信息表

备案号: 鲁青械备 20140017号

备案人名称	青岛海诺生物工程有限公司
备案人统一社会信用代码	913702857180717488
备案人注册地址	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
产品名称	医用退热贴
型号/规格	型号: 成人型、儿童型。 规格: 50mm × 120mm, 55mm × 110mm, 50mm × 100mm, 40mm × 110mm, 80mm × 120mm。 备注: 产品尺寸不得超过标称值±2mm。
产品描述	由无纺布背衬层、凝胶层、聚乙烯薄胶膜基层等部分组成, 不应含有发挥药理学、免疫学或者代谢作用成分。
预期用途	用于物理退热、冷敷理疗, 仅用于符合包装规格。
备注	
备案单位和日期	青州市食品药品监督管理局 备案日期: 2014年11月17日
变更情况	2016年12月15日规格型号变更为: 型号: 成人型、儿童型。 规格: 50mm × 120mm, 55mm × 110mm, 50mm × 100mm, 40mm × 110mm, 80mm × 120mm, 45mm × 130mm, 65mm × 130mm。 备注: 产品尺寸不得超过标称值±2mm。 2017年4月13日规格型号变更为: 型号: 成人型、儿童型。 规格: 50mm × 120mm, 55mm × 110mm, 50mm × 100mm, 40mm × 110mm, 50mm × 110mm, 60mm × 100mm, 80mm × 120mm, 45mm × 130mm, 65mm × 130mm, 尺寸公差为±10%。 2017年5月3日规格型号变更为: 型号: 成人型、儿童型、通用型。 规格: 50mm × 120mm, 55mm × 110mm, 50mm × 100mm, 40mm × 110mm, 50mm × 110mm, 60mm × 100mm, 80mm × 120mm, 45mm × 130mm, 65mm × 130mm, 尺寸公差为±10%。 2017年10月16日生产地址变更为: 青岛市莱西市姜山镇工业园海诺生物工程新区1号

第一类医疗器械备案凭证

青岛海诺生物工程有限公司:

根据相关法规要求, 对你单位第一类医疗器械: 医用退热贴予以备案, 备案号: 鲁青械备 20140017号。



Medical device record certificate



PAGE 1 of 2

CERTIFICATE OF FDA REGISTRATION

Certification No.: WZ148-2012313

Dear Official Correspondent:
This document provides notification of the registration number assigned to your establishment:

Establishment: Qingdao Hainuo Biological Engineering Co., Ltd.
Address: Jiangshan Industrial Area of Jiangshan Town, Laixi, Qingdao, Shandong, 266603, CHINA

Owner/Operator Number: 10040387
Registration Number: 3008808560

Fei Chen

General Manager
CIC REGISTRATION LLC
Email: cc-086@hainuo.com
Web: <http://www.cic-086.com/>



Validity: Nov. 7, 2019 – Dec. 31, 2020

Conclusion:
This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CIC assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CIC is not affiliated with the U.S. Food and Drug Administration.

FDA Official Website: <https://www.fda.gov/>

CERTIFICATE

CERTIFICATE



PAGE 2 of 2

ANNEX TO CERTIFICATION

Qingdao Hainuo Biological Engineering Co., Ltd.

Listing Number	Premarket Submission Number	Product Code(s)	Device Name(s) / Proprietary Name	Activities
D361412	Exempt	LRFJ	Disinfectant, medical devices / Isoline swab	Manufacturer
D145666	Exempt	KGX	Tape and bandage, adhesive / Medical Tape, Adhesive Bandage, Wound Plaster	Manufacturer
D361413	Exempt	JES	WOUND DRESSING / Flexi patch	Manufacturer
D333093	Enforcement Discretion	OBR	Manufactured, over-the-counter / Face Mask	Manufacturer
D145667	Exempt	FQM	BANDAGE, ELASTIC / Elastic Bandage, Gauze Bandage	Manufacturer
D145668	Exempt	EMD	PACK, HOT OR COLD, DISPENSABLE / Warm Patch, Cold Patch, Cool Patch, Fever Relief Patch, Cool gel, Freeze gel	Manufacturer
D333094	Enforcement Discretion	LXB	Pack alcohol device disinfectant / Alcohol Wipes, Alcohol prep pad	Manufacturer
D300241	Exempt	KXF	APPLICATOR, ABSORBENT / TYPED, NON-STERILE / Cotton Swab	Manufacturer
D300240	Exempt	NOI	Dressing, wound, hydrophilic / Wound Dressing, I.V. Adhesive Dressing	Manufacturer
D333093	Exempt	NXB	Gauze / sponge, nonresorbable for external use / Gauze Pad, Underpad, Cotton balls	Manufacturer
D361541	Enforcement Discretion	OHO	First aid kit without drug / First aid kit	Manufacturer

THIS ANNEX IS ONLY VALID IF ATTACHED TO THE CERTIFICATION MENTIONED ABOVE.

CERTIFICATE

CERTIFICATE

FDA Registration



Item NO.:C651

Name: Fever Cooling Patch (Kids)

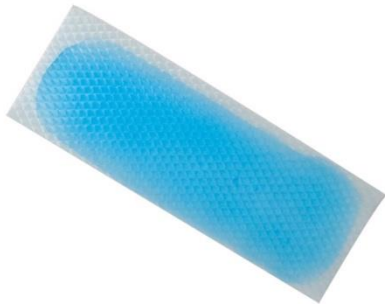
Material:PP non woven&PE&Gel

Size:40*110 mm

Package: 1 pcs/ aluminum foil bag 6 pcs / box
250 boxes / carton

Effective cooling time:8 Hours

Recommended position:Forehead, neck, armpit, thigh base



Fever Cooling Patch (Kids)



Item NO.:C652

Name: Fever Cooling Patch (Adults)

Material:PP non woven&PE&Gel

Size:50*120mm

Package:1 pcs/ aluminum foil bag 6 pcs / box
250 boxes / carton

Box size: 18.5 * 10 * 2.5 CM Carton size: 66 * 39
* 53CM

Effective cooling time:8 Hours

Recommended position:Forehead,
neck, armpit, thigh base



Fever Cooling Patch (Adults)