

# NITRILE GLOVES

ニトリルグローブ

ホワイト | パウダーフリー

商品資料

 **BEAUKEN**

発売：株式会社ビューケン

使い捨てタイプの手袋は様々な材質の種類があります。  
弊社の製品は、合成ゴムであるニトリルを使用し、ラテックスグローブによるアレルギーを防ぐための代替品として近年大きく需要を伸ばしている製品です。



## ニトリルゴム製手袋

材質は合成ゴムです。  
油・薬品に強く強度があります。  
手にぴったりフィットするタイプです。  
パウダー有り、無しがあります。

価格：やや高め



## ラテックス製手袋

材質は天然ゴムです。  
油・薬剤・溶剤に弱いです。  
天然ゴムアレルギーの方はご注意ください。  
パウダー有り、無しがあります。

価格：安価



## ポリエチレン製手袋

材質はポリエチレンです。  
油・薬品・溶剤に強いですが、強度はあまりありません。  
着脱しやすく頻繁に交換する作業向きです。

価格：最も安価



## PVC製手袋

材質は塩化ビニールです。  
油・薬品・洗剤・漂白剤に強いですが、フタル酸含有のため、食品に使うことはできません。

価格：安価



商品名	スカイエアー ニトリルグローブ ブルー パウダーフリー
材質	ニトリルゴム (合成ゴム)
色	ブルー
サイズ	3種類 (S/M/L) ※各サイズは次ページ参照
箱入り数	1箱100枚入り
カートン入り数	1カートン20箱 (2,000枚) 入り
生産国	ベトナム
輸入元	アプローチスタッフ株式会社
販売元	株式会社ビューケン
適合規格	ISO13485 (医療機器品質マネジメントシステム) 米国FDA認証 (10077644 D417824)、ヨーロッパCE認証
特徴	<ul style="list-style-type: none"> <li>●経済的な左右兼用タイプ</li> <li>●手にフィットして素手に近い感覚で使えます</li> <li>●食品衛生法に適合しています (厚生省告示第370号)</li> <li>●ノンパウダーなので粉落ちが気になりません</li> <li>●ニトリル製で環境に優しくラテックスアレルギーの心配がありません</li> <li>●衛生的な使い切り (使い捨て) タイプです</li> </ul>
使用上の注意	<ul style="list-style-type: none"> <li>●体質によっては、かゆみ、かぶれ、発疹などを起こすことがあります。異常を感じたら、直ちに使用を中止してください。</li> <li>●薬品や溶剤によっては浸透や膨張する場合がありますので、事前にご確認の上で使用ください。</li> <li>●水や油などの液体の中では使用しないでください。</li> <li>●爪先、金属タワシ、刃物など鋭利なものに触れると破れたり穴があくことがありますのでご注意ください。</li> <li>●品質保持のため、直射日光、高温、多湿での保管は避けてください。</li> </ul>
備考	<p>出荷開始予定 : 2021年3月末</p> <p>納期 : 在庫がある場合、注文後、2営業日以内に発送</p> <p>送料 : 込み (北海道、九州、沖縄、離島は別途送料を申し上げます)</p> <p>キャンセル・返品 : 注文後のお客様都合による返品、キャンセルは不可</p>

## NITRILE GLOVES

ニトリルグローブ  
ホワイト | パウダーフリー



3種類のサイズ展開 (S/M/L)

左右兼用

パウダーフリー (ノンパウダー)

1箱100枚入り

指先エンボス加工

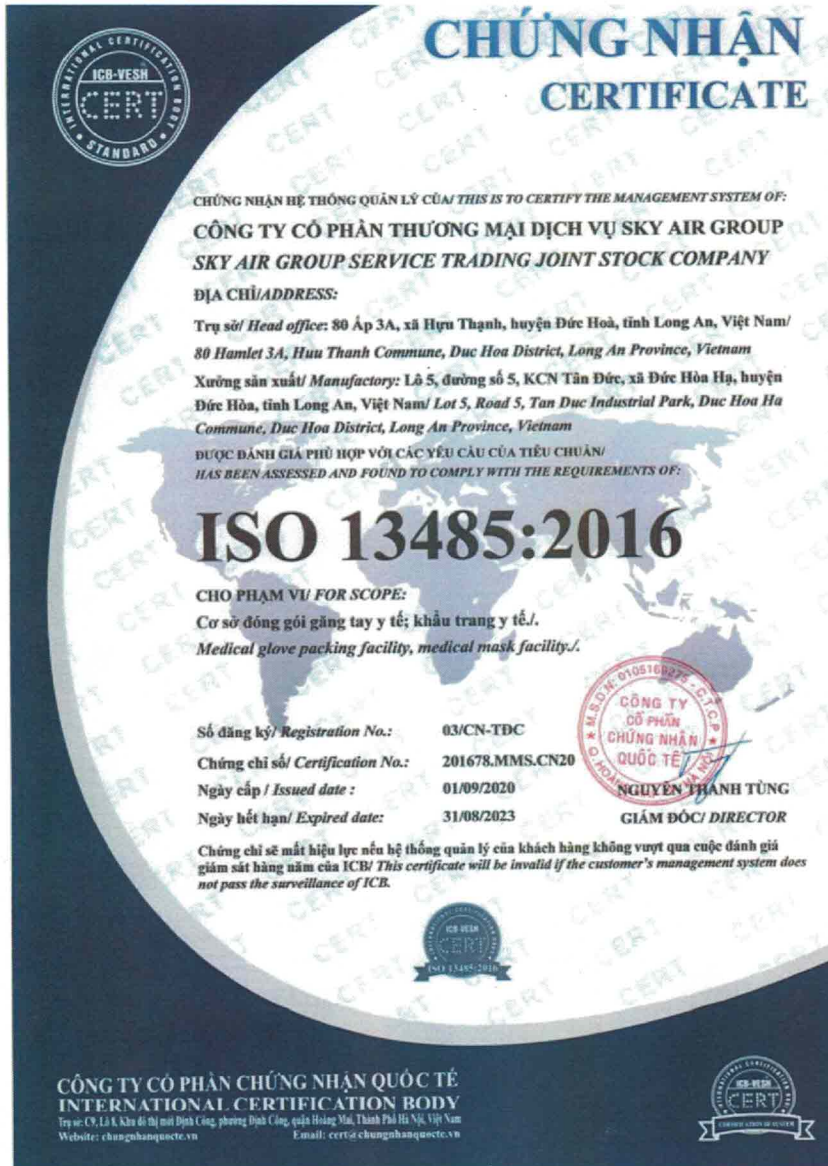
米国FDA認証

毎月安定的に入荷

		S	M	L
パッケージ				
サイズ	全長	230mm	230mm	230mm
	手の幅周り	166mm	178mm	190mm
	中指の長さ	75mm	80mm	85mm
	厚さ	0.08mm	0.08mm	0.08mm
				
商品番号		BA31010	BA31020	BA31030
JANコード		4571558720017	4571558720024	4571558720031
包装用商品コード		24571558720011	24571558720028	24571558720035

※サイズは製品によって表記のサイズから±3mmの誤差があります。





**CHỨNG NHẬN  
CERTIFICATE**

CHỨNG NHẬN HỆ THỐNG QUẢN LÝ CỦA/ THIS IS TO CERTIFY THE MANAGEMENT SYSTEM OF:  
**CÔNG TY CỔ PHẦN THƯƠNG MẠI DỊCH VỤ SKY AIR GROUP  
SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY**

ĐỊA CHỈ/ADDRESS:  
Trụ sở/ Head office: 80 Ấp 3A, xã Hậu Thạnh, huyện Đức Hoà, tỉnh Long An, Việt Nam/  
80 Hamlet 3A, Hau Thanh Commune, Duc Hoa District, Long An Province, Vietnam  
Xưởng sản xuất/ Manufacturer: Lô 5, đường số 5, KCN Tân Đức, xã Đức Hòa Hạ, huyện Đức Hòa, tỉnh Long An, Việt Nam/ Lot 5, Road 5, Tan Duc Industrial Park, Duc Hoa Ha Commune, Duc Hoa District, Long An Province, Vietnam  
ĐƯỢC ĐÁNH GIÁ PHÙ HỢP VỚI CÁC YÊU CẦU CỦA TIÊU CHUẨN/  
HAS BEEN ASSESSED AND FOUND TO COMPLY WITH THE REQUIREMENTS OF:

**ISO 13485:2016**

CHO PHẠM VI FOR SCOPE:  
Cơ sở đóng gói găng tay y tế; khẩu trang y tế./  
Medical glove packing facility, medical mask facility./

Số đăng ký/ Registration No.: 03/CN-TĐC  
Chứng chỉ số/ Certification No.: 201678.MMS.CN20  
Ngày cấp / Issued date : 01/09/2020  
Ngày hết hạn/ Expired date: 31/08/2023

NGUYỄN VĂN TÙNG  
GIÁM ĐỐC/ DIRECTOR

CHỨNG CHỈ SẼ MẤT HIỆU LỰC NẾU HỆ THỐNG QUẢN LÝ CỦA KHÁCH HÀNG KHÔNG VƯỢT QUA CUỘC ĐÁNH GIÁ GIÁM SÁT HÀNG NĂM CỦA ICB/ This certificate will be invalid if the customer's management system does not pass the surveillance of ICB.

**CÔNG TY CỔ PHẦN CHỨNG NHẬN QUỐC TẾ  
INTERNATIONAL CERTIFICATION BODY**  
Trụ sở: 09, Lê Á, Khu đô thị mới Bình Chánh, phường Bình Chánh, quận Hoàng Mai, Thành Phố Hà Nội, Việt Nam  
Website: chunghanquocte.vn Email: cert@chunghanquocte.vn



**Certificate of Compliance**

Application for  
Medical Device Directive (MDD) 93/42/EEC,  
Personal Protective Equipment (PPE) 2016/425/EU &  
Cosmetics Directive 76/768/EEC.  
This is to certify that the product(s):  
**Hand Sanitizer, Face Mask Medical Masks (3-Layer Medical Face Masks,  
4-Layer Medical Face Masks, Surgical Disposable), Medical Gowns (Non-  
Surgical Isolation Gowns, Surgical Isolation Gowns), Protective Clothes  
(Protective Coveralls), Medical Gloves (Nitrile Gloves/Non- Powdered Gloves),  
N95 Respirator (Respirator, Surgical), Sanitary,  
Cotton Sanitation, Cotton Swabs & Medical Cotton.**  
Manufactured by  
**SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY**  
80 Hamlet 3A, Hau Thanh Commune, Duc Hoa District, Long An Province, Vietnam  
Factory 1: Lot 5, Road 5, Tan Duc Industrial Park,  
Duc Hoa Commune, Duc Hoa District, Long An Province, Vietnam  
Complies with the requirement of the  
"MDD"  
has been assessed & found in accordance with the requirements of  
**MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile),  
Personal Protective Equipment (PPE) 2016/425/EU &  
Cosmetics Directive 76/768/EEC.**  
QCC is non-notified certification body, issue this  
'compliance certificate' after audit of manufacturer product(s) & technical file(s).  
This certificate applies to the tested sample only not for whole production.  
It's manufacturer sole responsibility to meet all the necessary conformity  
assessment activities according to **MDD 93/42/EEC, PPE 2016/425/EU &  
CD 76/768/EEC** and related standards before placing them on  
the market & CE mark on the product(s).

Certificate No. : CE/018376/0920  
Original Certificate Date : 12 - September - 2020  
Issue Date : 12 - September - 2020  
Expiry Date : 11 - September - 2021

To check this certificate status visit:  
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature  
**For Quality Control Certification**  
UK Office: 1929, Chynoweth House,  
Trevissome Park, Truro-TR48UN, Cornwall, UK

Quality Control Certification accredited by UASL, UK  
This certificate doesn't provide the certified organization with immunity from its legal obligations.  
This certificate remains the property of QC Certificate to whom it must be returned on request.

9/9/2020 FDA Registration for SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY

9/9/2020

## FDA | U.S. Food and Drug Administration

Registration Confirmation

Facility: SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY, Duc Hoa District, Long An, VIET NAM

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 80 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2026. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2026 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to [regist@cdrh.fda.gov](mailto:regist@cdrh.fda.gov) ([maltoregist@cdrh.fda.gov](mailto:maltoregist@cdrh.fda.gov)).

The Owner/Operator Number for this Registration is: 10077644

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**Facility Information**

Initial Importer:	N
Facility Name:	SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY
Address:	No.80, 3A Hamlet, Huu Thanh Commune Duc Hoa District, Long An, - VIET NAM
Foreign Trade Zone:	N

[https://www.access.fda.gov/ir/ir/ir.htm?\\_flowExecutionKey=\\_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D\\_244E996C-071D-F273-980B-A2001857953...](https://www.access.fda.gov/ir/ir/ir.htm?_flowExecutionKey=_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D_244E996C-071D-F273-980B-A2001857953...) 1/3

9/9/2020 FDA Registration for SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY

9/9/2020

### Owner/Operator Information

Owner/Operator Number:	10077644
Contact Name:	Quach Phuoc Xuan Nhung
Company:	SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY
Address:	No.80, 3A Hamlet, Huu Thanh Commune Duc Hoa District, LONG AN, - VIET NAM
Telephone:	84 - 902 - 417779
Fax:	-
E-mail:	quachnhung260483@gmail.com

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### Official Correspondent Information

Contact Name:	David Lennarz
Company:	Registrar Corp
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Telephone:	1 - 757 - 2240177
Fax:	1 - 757 - 2240179
E-mail:	david.lennarz@registrarcorp.com
DUNS Number:	139242874

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### United States Agent Information

Contact Name:	David Lennarz
Contact Title:	Mr
Business Name:	Registrar Corp
Address:	144 Research Drive Hampton, Virginia, 23666, UNITED STATES
Phone:	757 - 2240177
Fax:	757 - 2240179
DUNS Number:	139242874
E-mail:	david.lennarz@registrarcorp.com

[https://www.access.fda.gov/ir/ir/ir.htm?\\_flowExecutionKey=\\_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D\\_244E996C-071D-F273-980B-A2001857953...](https://www.access.fda.gov/ir/ir/ir.htm?_flowExecutionKey=_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D_244E996C-071D-F273-980B-A2001857953...) 2/3

9/9/2020 FDA Registration for SKY AIR GROUP SERVICE TRADING JOINT STOCK COMPANY

9/9/2020

### Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D417824	Enforcement Discretion	LZA	Polymer patient examination glove	Manufacturer Contract Manufacturer Remanufacturer	
D417825	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Manufacturer Contract Manufacturer Remanufacturer	

Date of Initial Registration: Wed Sep 09 16:28:39 EDT 2020

[https://www.access.fda.gov/ir/ir/ir.htm?\\_flowExecutionKey=\\_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D\\_244E996C-071D-F273-980B-A2001857953...](https://www.access.fda.gov/ir/ir/ir.htm?_flowExecutionKey=_cE9FBF1F1-FDA6-DD15-65A7-83C876FD21D_244E996C-071D-F273-980B-A2001857953...) 3/3