

## Disposable Isolation Protective clothing (Gown)

Specification:

- One-Piece, Tying version.
- Material: PP25G+PP18G) non-woven).
- Certification: FDA





## Fiscal Year 2020

# CERTIFICATION OF REGISTRATION

This certifies that:

**GUANGZHOU BAOLI HARDWARE & ELECTRONIC CO.,LTD.**

**Zhongyi Industrial Park,Zhongcun Town,Panyu District, Guangzhou,  
Guangdong, 511495, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

**Shenzhen CTB Testing Technology Co., Ltd.**

**Owner/Operator Number: 10060897**

**Registration Number: 3013823570**

**Device Listing#: See annex**

*CTB will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CTB makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CTB assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." 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, CTB is not affiliated with the U.S. Food and Drug Administration.*

**CTB**

**FDA**



Issued: March 12, 2020

Expiration Date: December 31, 2020



## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

**Annex to Device Listing# for Registration Number: 3013823570**

Listing No.	Code	Device Name	Proprietary Names	Activities
D354151	KYZ	SYRINGE, IRRIGATING (NON DENTAL)	Safety 1st(nasal aspirator)	Manufacturer Repackager/Relabeler Foreign Exporter
			Safety 1st(Medicine Syringe with PVC Bottle Adaptor)	
D352708	EFW	TOOTHBRUSH, MANUAL	Safety 1st ( toothbrush, finger tooth brush)	Manufacturer Foreign Exporter
D367331	KCM	DROPPER, ENT	Safety 1st(Medicine Dropper with Spill Guard)	Manufacturer Foreign Exporter
D367332	KYX	DISPENSER, LIQUID MEDICATION	Safety 1st (Medicine Spoon)	Manufacturer Foreign Exporter
D374560	OEA	Non-surgical isolation gown	Disposable Isolation Garment	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter
			Isolation gown protective clothing	
D374562	LRJ	Disinfectant, medical devices	Hand sanitizer	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter

**NOT END OF THE ANNEX**





# Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Registration Number: 3013823570

Listing No.	Code	Device Name	Proprietary Names	Activities
D374561	MSH	Respirator, surgical	Disposable Face Mask	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter
			Comfortable Protective Mask	
			N95 Mask	
D374563	FYF	CAP, SURGICAL	Disposable hat	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter
D374565	FXP	COVER, SHOE, OPERATING-ROOM	Disposable protective foot cover	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter
D374566	LYU	ACCESSORY, SURGICAL APPAREL	disposable glove	Manufacturer Contract Manufacturer Remanufacturer, Repackager/Relabeler Foreign Exporter

END OF THE ANNEX



Chief Engineer

Issued: March 12, 2020

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