

GOWNING CONFIGURATION FOR GRADE B CLEAN AREA(1)



■ EU GMP

Grade B (including access / interventions into grade A): appropriate garments that are dedicated for use under a sterilised suit should be worn before gowning. Appropriately sterilised, non-powdered, rubber or plastic gloves should be worn while donning the sterilised garments. Sterile headgear should enclose all hair (including facial hair) and where separate from the rest of the gown, it should be tucked into the neck of the sterile suit. A sterile facemask and sterile eye coverings (e.g. goggles) should be worn to cover and enclose all facial skin and prevent the shedding of droplets and particles. Appropriate sterilised footwear (e.g. over-boots) should be worn.

Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained. Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas. Single or two-piece facility trouser suits covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C. Facility suits and socks should not present a risk of contamination to the gowning area or processes.

The Rules Governing Medicinal Products in the European Union
 Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Brussels, 22.8.2022 C(2022) 5938 final, 7.13, 7.14 Annex 1
 Manufacture of Sterile Medicinal Products Personnel

■ GOWNING CONFIGURATION FOR GRADE B CLEAN AREA(1)

	PRODUCT	MODEL
SCHEME 1	Upgraded 3-in-1 coverall	L-3111X
	Undergarment	N-1101WX
	Mask	K-002
	Cleanroom shoes	X-002B
	Medical isolation goggles	SHB-Z-003
	Two-layer cleanroom bag	D-002
	Cleanroom shoes bag	X-010



L-3111X



N-1101WX



K-002



X-002B



SHB-Z-003



D-002



X-010

Gaible

UPGRADED 3-IN-1 CLEANROOM COVERALL

MODEL: L-3111X

PRODUCTION STANDARD: GB12014-2019

COLORS:



SIZES: XS-6XL(unisex)

APPLICATION AREA: A/B, C grade clean area

SIZES: XS-6XL(unisex)

FABRIC: 98% Polyester filament+ 2% conductive fiber

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree

APPLICATION INDUSTRY: Pharmaceutical, food process, electronic and cosmetic industry.

PERFORMANCE: Cleanliness, isolation, anti-static performance, durability. Comfort and soft to wear. It achieves an impressive point-to-point resistance of $1.0 \times 10^5 \sim 1.0 \times 10^{11} \Omega$. Whole piece resistance $< 0.6 \mu c / \text{piece}$.



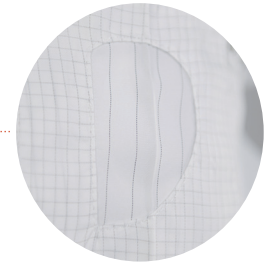
Hood can be adjusted with different sizes using a buckle designed in the back.



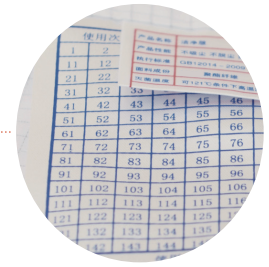
The thumb pull on the cuff prevents the sleeve from going up when raising hands.



Hidden buckles added in the waist and cuff to avoid contact with the ground when dressing.



Special fabric in the ear area to make the hearing is not affected when hooded.



Cleaning and sterilization cycle label to record The times of cleaning and sterilization



The leg-opening are designed with hidden buttons to prevent the clothes from touching the ground when dressing.

- DRESSING AND FOLDING TRAINING VIDEO ARE PROVIDED FOR CUSTOMERS.
- HIGH PERFORMANCE AND PROPERTIES, IN LINE WITH GMP CERTIFICATION REQUIREMENTS.
- NATIONAL PATENTS : ZL 2013 2 0213972.X, ZL 2013 2 0213959.4, ZL 2013 1 0145401.1.

Gaible

UPGRADED CLEANROOM UNDERGARMENT

MODEL: N-1101WX

PRODUCTION STANDARD: GB12014-2019

COLORS: 

SIZES: XS-6XL(unisex)

APPLICATION AREA: A/B, C grade clean area

SIZES: XS-6XL(unisex)

FABRIC: 98% Polyester filament+ 2% conductive fiber

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree.

APPLICATION INDUSTRY: Pharmaceutical, food process, electronic and cosmetic industry.

PERFORMANCE: Superfine polyester fiber, comfort and soft, sweat-absorbing, non-fibber shedding. Dressing and folding training video are provided for customers.



Face tightness adjustment for different head size.



Special fabric in the ear area to make the hearing is not affected when hooded.



Ankle tightener designs make it fit to the legs better, easy to wear.



Elasticated pinball buckle in the waist can adjust to different waist size.



- Dressing and folding training video are provided for customers.
- High performance and properties, in line with GMP certification requirements.

CLEANROOM ACCESSORIES(1)

STERILIZABLE BOOTS



MODEL: X-002B

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree.

APPLICATION AREA: A/B, C grade clean area

SIZES: 35-50

COLORS:

PRODUCTION STANDARD: GB12014-2019

FABRIC: Imported TPV+clean canvas+polyester filament with conductive fiber

MEDICAL ISOLATION GOGGLES



MODEL: SHB-Z-003

PROPERTIES: Resistant to repeated sterilization in 121 centi degree condition

APPLICATION AREA: A/B, C grade clean area

PRODUCTION STANDARD: GB 14866-2006

COLORS:

FABRIC: Imported polymer material (lens)+ medical grade silicone (frame and strap)



CLEANLINESS

Repeatedly cleaning and sterilization



ANTI-STATIC

The anti-static function of the clean shoes can effectively dissipate the static electricity generated by the human body. It reaches to $1.0 \times 10^5 \sim 1.0 \times 10^9 \Omega$ under dry and wet conditions



ANTI-SLIP

Sole made of environment-friendly TPV material which is durable and anti-slip.



STERILIZABLE

Repeatedly sterilization under 121 centi degree moist heat condition for 20 times (30min each time)



ANTI-FOGGING

The lens are treated with anti-fogging technique. The lens are replaceable. The air valve can be opened and closed freely.



WIDE SURFACE

Glasses can be worn inside. The lens are changeable.

CLEANROOM ACCESSORIES(2)

CLEANROOM MASK



MODEL: K-002

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree.

PRODUCTION STANDARD: GB12014-2019

APPLICATION AREA: A/B, C grade clean area

COLORS:

FABRIC: 98% SUPERFINE POLYESTER FIBER+ 2% CONDUCTIVE FIBER

TWO-LAYER SUITS BAG



MODEL: D-002

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree.

PRODUCTION STANDARD: GB12014-2019

APPLICATION SUGGEST: Use for storage of cleanroom suits and masks

SHOES BAG



MODEL: X-010

PROPERTIES: Resistant to repeated washing and sterilization in 121 centi degree.

PRODUCTION STANDARD: GB12014-2019

APPLICATION SUGGEST: Use for storage of cleanroom shoes.



STERILIZABLE

Repeatedly sterilization under 121 centi degree.



VENTILATION FUNCTION

Ventilation holes on the side to effectively expel hot air to prevent fog.



FUNCTIONAL DESIGN

The head-strap with pinball buckle design can better fit the different face sizes