

EQUINOX



COVID-19 Prevention Products



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EQUINOX

medical

EQUINOX

Product Overview

PPE



Critical Care Consumables



Orthopaedic Prostheses



Medical Equipment



Pathology Testing Equipment & Kits





EQUINOX

About WEGO and Equinox

WEGO and Equinox are partnering across the full Medical Device Range



- WEGO has a comprehensive medical implant range; Trauma, Spine, Hip and Knee & Dental
- Equinox have rights to their consumable products, as well as a full range of theatre products and imaging systems



The Weigao Group was established in 1988, and has since become one of the top medical device manufacturers in China.

Total workforce of 23,000, and 100,000 hectares of manufacturing facilities, based in Weihai, Shandong Province.

Dedicated staff of 10,000 involved in the production and sales of branded disposable medical devices.



Dominant local providers, emergent international players

- WEGO products have been registered in over 60 countries, with major launches in 2017 in the US, 2018 in Europe.
- WEGO is dedicated to innovation and reinvests almost 10% of all profits into R&D driving global growth.
- EQUINOX launched the WEGO brand in Australia and New Zealand in 2019, introducing high-quality orthopaedic devices for trauma and spinal surgery.
- EQUINOX is the exclusive distribution partner and is driving the expansion of the WEGO offering to encompass its full product offering.

WEGO has state-of-the-art manufacturing facilities, built to exceed the highest European and US standards:

- **Chinese Standard: GB19082-2009**
- **European standard: EN14126- Level 4** (liquid barrier performance level II or above).
- Internationally recognised leader in medical device manufacturing,
- Reputation for uncompromising quality of materials and design,
- Highest-grade medical grade materials, sourced with strict supplier controls,
- Every device and instrument undergoes rigorous quality checks using the latest testing equipment and procedures.

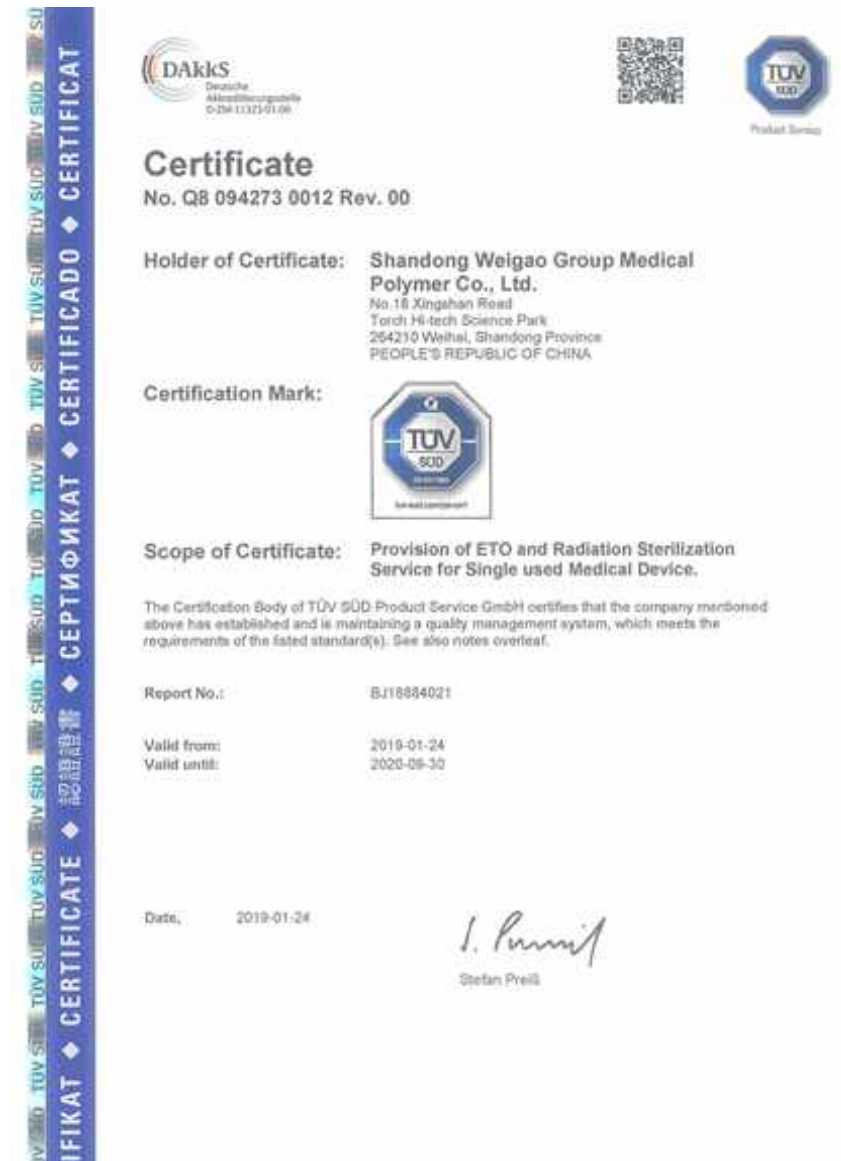


CE certification on ETO sterilization for medical devices

WEGO is one of few manufacturers in China that has capability of adopting ETO sterilization using ethylene oxide processes.

This means that the WEGO sterilized products won't be corroded and can be wrapped and completely package to keep them sterile.

- ETO sterilization can kill all microorganisms, including spores, bacteria & viruses
- The sterilized articles can be wrapped and packaged together to keep them sterile before use.
- ETO sterilization does not corrode plastics, metals or rubber, and does not cause items to turn yellow and brittle
- Ethylene oxide can sterilize items with irregular shapes and complex structures





Workshop Production Site



Specialized Production Equipment

CE Mark certification for single used medical devices



- Ethylene oxide can kill all microorganisms, including spores, bacteria, viruses, etc.
- The sterilized articles can be wrapped and packaged as a whole to keep them sterile before use.
- Ethylene oxide does not corrode plastics, metals or rubber, and does not cause items to turn yellow and brittle
- Ethylene oxide can sterilize items with irregular shapes and complex structures

EC Certificate
 Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class III, IV or V)
 No. G1 087117 0013 Rev. 00

Manufacturer: Weigao Medical International Co., Ltd.
 No. 1 Weigao Road
 High-tech Industrial Development Zone
 264210 Weihai, Shandong Province
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative: MedNet GmbH
 Bahnhofstr. 10, 48143 Münster, GERMANY

Product Category(ies): Non-active devices for anaesthesia, emergency and intensive care, Non-active devices for injection, infusion, transfusion and dialysis, Non-active instruments, Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART), Bandages and wound dressings, Suture material and clamps, Active surgical devices. (for detailed products information see attachment)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality management system for design, manufacture and final inspection of the respective devices (device categories in accordance with MDD Annex II, TÜV quality assurance system conforming to the requirements of the Directive and is subject to periodic surveillance. For marking of these II devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: B11684021

Valid from: 2019-04-17
Valid until: 2024-04-18

Date: 2019-04-17
J. Pannit
 Stefan Preil

Page 1 of 2
 TÜV SÜD Product Service GmbH is notified body with identification no. 2112
 TÜV SÜD Product Service GmbH • Certification Body • Kellerstrasse 49 • 81531 Munich • Germany

EC Certificate
 Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class III, IV or V)
 No. G1 087117 0013 Rev. 00

Facilities: Weigao Medical International Co., Ltd.
 No. 1 Weigao Road, High-tech Industrial Development Zone,
 264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Attachment:
 Sterile Infusion Sets for single use, Sterile Transfusion Sets for single use, Sterile Hypodermic Syringes for single use, Sterile Plastic Blood Bag for single use, Sterile Intravenous Needles for single use, Sterile Blood Collection Needles for single use, Sterile High Pressure Angiographic Syringes for single use, Sterile Retractable Auto-Disable Syringes for single use, I.V. Catheter for single use, Sterile Hypodermic Needles for single use, Retractive safety I.V. catheter, Haemocentrifuge for single use, Arterial blood line filter, Refusum tubing set for single use, Single use cardiology delivery system, Suction devices for single use, Oocyte Pick-up Needle, IVF Embryo Transfer Catheter, NPWT Dressing Kit, NPWT Dressing, Heart Fixation Device, Membrane Oxygenator, Negative Pressure Drainage Device, Urthral catheter, Tracheostomy Tubes, Insulin syringe, Tubula needles, Tracheal Tubes, Silence Foley catheters, Hydrogel Dressing, Hydrocolloid Wound Dressing, Alginate Dressing, Suction Needles For Single Use, Insulin needles for single use, safety scalp vein set, Sponlock for Single Use, Disposable Circular Stapler, Disposable Nonreturn and Frotape Stapler Set, Disposable Linear Cutting Stapler and reload, Disposable Linear Stapler and reload, Disposable Tmcor, Disposable Cavity Cutting Stapler and reload, Sterile Micro-Filter Syringes for Single Use.

CERTIFIED ISO 9001:2015 COMPANY

Page 2 of 2
 TÜV SÜD Product Service GmbH is notified body with identification no. 2112

Certificate
 No. QB 094273 0012 Rev. 00

Holder of Certificate: Shandong Weigao Group Medical Polymer Co., Ltd.
 No. 18 Xingshan Road
 Torch Hi-tech Science Park
 264210 Weihai, Shandong Province
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Provision of ETO and Radiation Sterilization Service for Single used Medical Device.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: B11684021

Valid from: 2019-01-24
Valid until: 2020-05-30

Date: 2019-01-24
J. Pannit
 Stefan Preil

+ CERTIFICATION



+ CERTIFICATION

ISO 14001



OHSAS 18001



CE



ISO 13485



+ CERTIFICATION

中华人民共和国医疗器械注册证

注册证编号：鲁械注准 20202140135

注册人名称	威海威高医用材料有限公司
注册人住所	山东省威海火炬高技术产业开发区兴山路 18 号
生产地址	山东省威海市旅游度假区东鑫路 30 号
代理人名称	-
代理人住所	-
产品名称	医用一次性防护服
型号、规格	A-S、A-M、A-L、A-XL、A-XXXL、B-S、B-M、B-L、B-XL、B-XXL、B-XXXL
结构及组成	采用聚丙烯纺粘覆 PE 膜非织造布材料制成，结构为连体式，由连帽上衣、裤子、脚套（可选配）组成，袖口、脚踝口、脚套口为弹性收口，帽子面部收口及腰部收口采用弹性收口。
适用范围	供临床医务人员在工作时接触到的具有潜在感染性的患者血液、体液、分泌物等提供阻隔、防护用。
附件	产品技术要求：鲁械注准 20202140135
其他内容	
备注	疫情急需，应急审评审批，核发注册证后三个月内需补充完善产品的全性能检验报告、生物学试验报告、灭菌验证、效期验证、包装及包装完整性验证资料。

审批部门：山东省药品监督管理局

注册日期：2020 年 02 月 05 日
有效期至：2021 年 02 月 04 日

审批部门盖章

第一类医疗器械备案信息表

备案号：鲁械备 20200006 号

备案人名称	威海威高医用材料有限公司
备案人组织机构代码	913710007372079036
代码	
备案人注册地址	山东省威海火炬高技术产业开发区兴山路 18 号
生产地址	山东省威海市旅游度假区东鑫路 30 号
代理人	/（进口医疗器械适用）
代理人注册地址	/（进口医疗器械适用）
产品名称	隔离衣
型号/规格	型号：A 型、B 型、C-1 型、C-2 型、C-3 型、C-4 型；规格：S、M、L、XL、XXL、XXXL
产品描述	采用 PP 非织造布或 PP 非织造布+PE 膜为主要原料，经裁剪、缝制而成，非灭菌提供，一次性使用。
预期用途	用于医疗机构门诊、病房、检查室等件普通隔离。
备注	/
备案单位	威海市市场监督管理局
和日期	备案日期：2020 年 02 月 05 日
变更情况	/

中华人民共和国医疗器械注册证

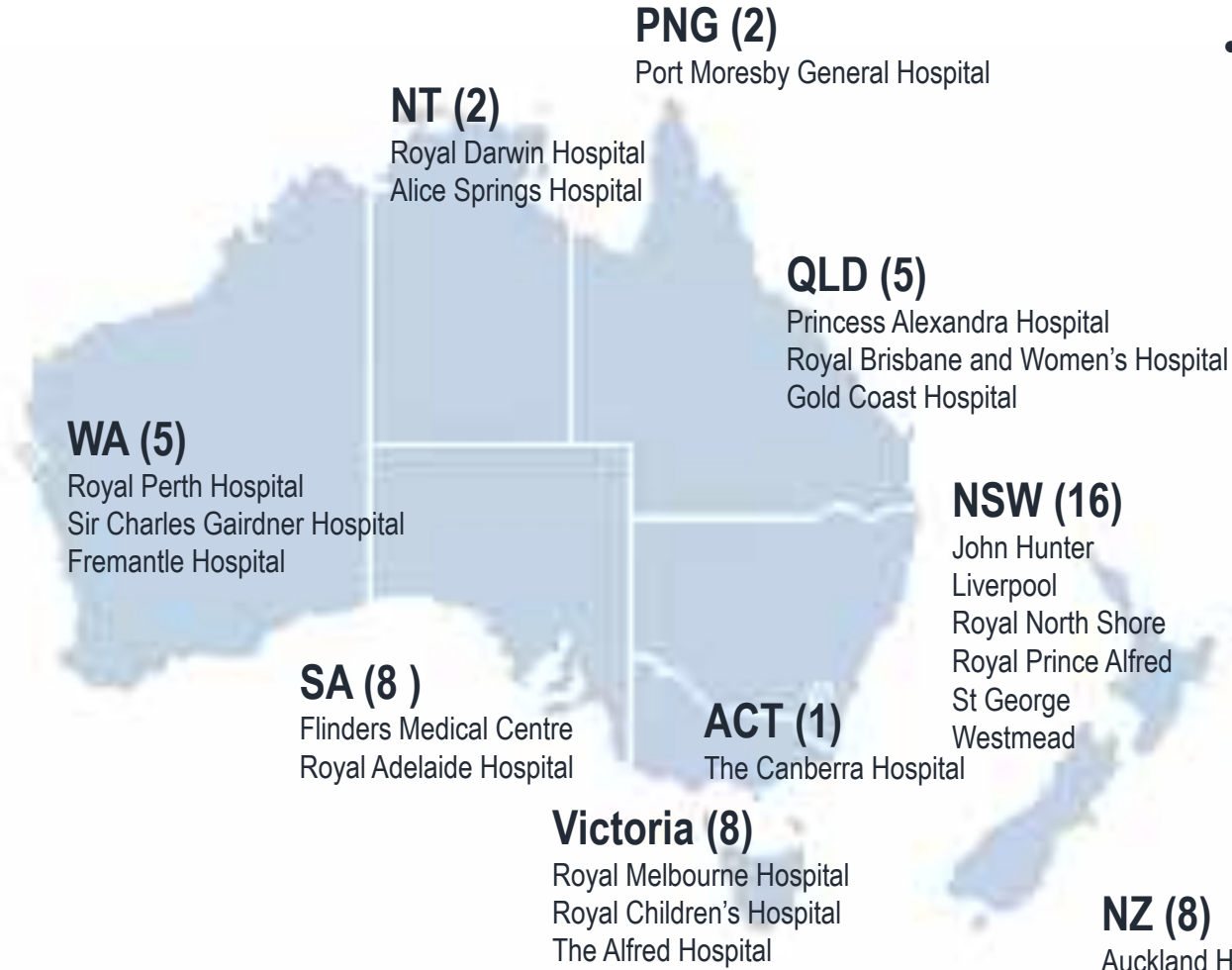
注册证编号：鲁械注准 20182640288

注册人名称	威海威高医用材料有限公司
注册人住所	山东省威海火炬高技术产业开发区兴山路 18 号
生产地址	山东省威海市旅游度假区东鑫路 30 号
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	一次性使用手术衣
型号、规格	型号为：标准性能型和高性能型。 规格为：S、M、L、XL、XXL 型。
结构及组成	一次性使用手术衣产品采用非织造布、覆膜非织造布等材料制成，为连体式结构，由衣身、袖子、腰部系带和颈部系带（或子母扣）、加强层组成。加强层适用于高性能型的手术衣。袖口采用弹性收口。
适用范围	供手术人员穿着，降低感染源向病人手术创面传播以防止术后创面感染。
附件	注册产品技术要求：鲁械注准 20182640288
其他内容	
备注	

审批部门：山东省药品监督管理局

注册日期：2018 年 02 月 27 日
有效期至：2023 年 02 月 26 日

审批部门盖章



- Equinox and EWE logistics bring unprecedented value and excellence to logistics supply, Australia-wide





EQUINOX

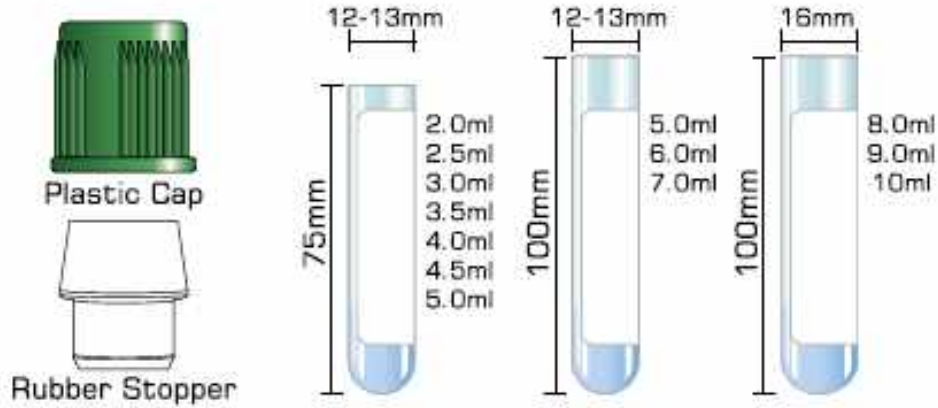
Critical Care Consumables

WEGO Vacuum Blood Tube Series brings low cost, without quality compromise



Vacuum blood collection tubes feature:

- Compatibility with gold standard pathology centrifuges machines
- Shipped with additives dependant on application
- Colour co-ordinated
- High quality single use materials
- vacuum blood collection tube has include sharp blood collection needles and deginated holder.



SERUM	PLASMA	COAGULATION	SERUM SEPARATOR	ESR	WHOLE BLOOD	BLOOD GLUCOSE
PLAIN	HEPARIN	SODIUM CITRATE 1:9	GEL	SODIUM CITRATE 1:4	EDTA	FLUORIDE

*Heparin Plasma tube pictured



WEGO Syringe Series bring low cost, without the quality compromise



- The disposable syringe one of WEGO's most accomplished product lines, manufactured since its foundation in 1992.
- WEGO has over 120 sets of injection moulding machines, 15 sets of full-automation assembling machine, 20 Sets of cube ethylene oxide sterilization containers for syringe production lines
- Syringe series includes; common syringe, safety syringe, auto-disable syringe (AD), pump syringe, polycarbonate colourful syringe (PC) and insulin syringe.
- All kinds of needles are provided across the range
- WEGO is committed to delivering a quality service and supply of disposable syringe products.
- Current markets include; USA, EU, Russia, South Africa, Brazil, Turkey, India and over 65 other countries.

Hypodermic Needle

WEGO



Polycarbonate Colourful Syringe (PC)



Insulin syringe

Butterfly Needle



WEGO

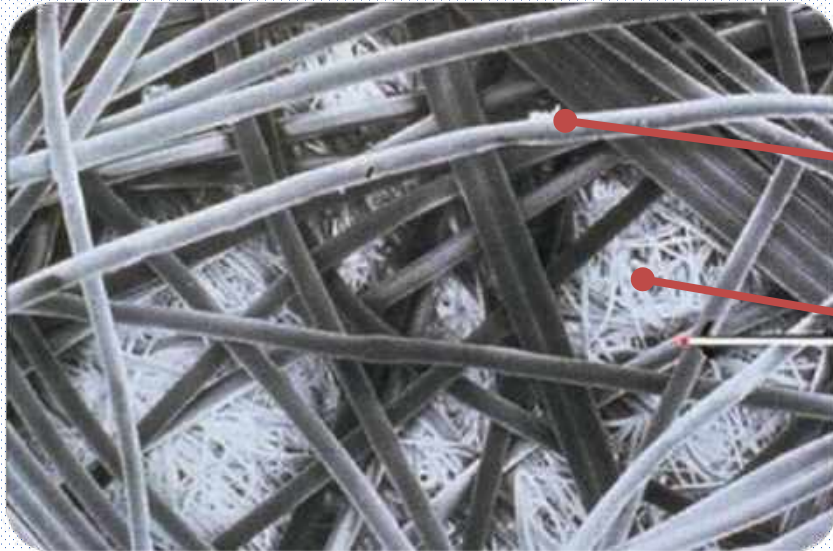
A grayscale photograph of a surgical team in an operating room, wearing masks and scrubs, focused on a procedure. The image is semi-transparent, serving as a background for the text.

EQUINOX

PPE Product Characteristics

1. Surgical Masks
2. Surgical Gowns (disposable)
3. Protective Clothing (disposable)
4. Isolation Gowns
5. Insulation Clothing (disposable)





Spun-bonded layer: providing enhanced strength

Melt blown layer: providing liquid control and a bacterial barrier



Fabric Design developed for SARS-CoV-2 control

Weigao Group (WEGO) is a national emergency response supplier assisting the government with protective suit development for SARS-CoV-2

WEGO procurement of fabric, trims, seal tape and zipper are in accordance with national and international standards. **Chinese Standard: GB19082-2009, European standard: EN14126- up to Level 4** (liquid barrier performance level II or above)

The protective suit is made of PP spunbond non-woven fabric laminated with PE film.

The raw material is high in strength, soft in touch, skin-friendly, comfortable to wear, and strong in antistatic performance.

It has a good anti-infiltration performance, high filtering efficiency, surface moisture resistance, strength and air permeability, which allows it to effectively to wet, reducing the chance of bacterial adhesion.



Antibacterial



Anti-static



Soft



Waterproof



Breathable



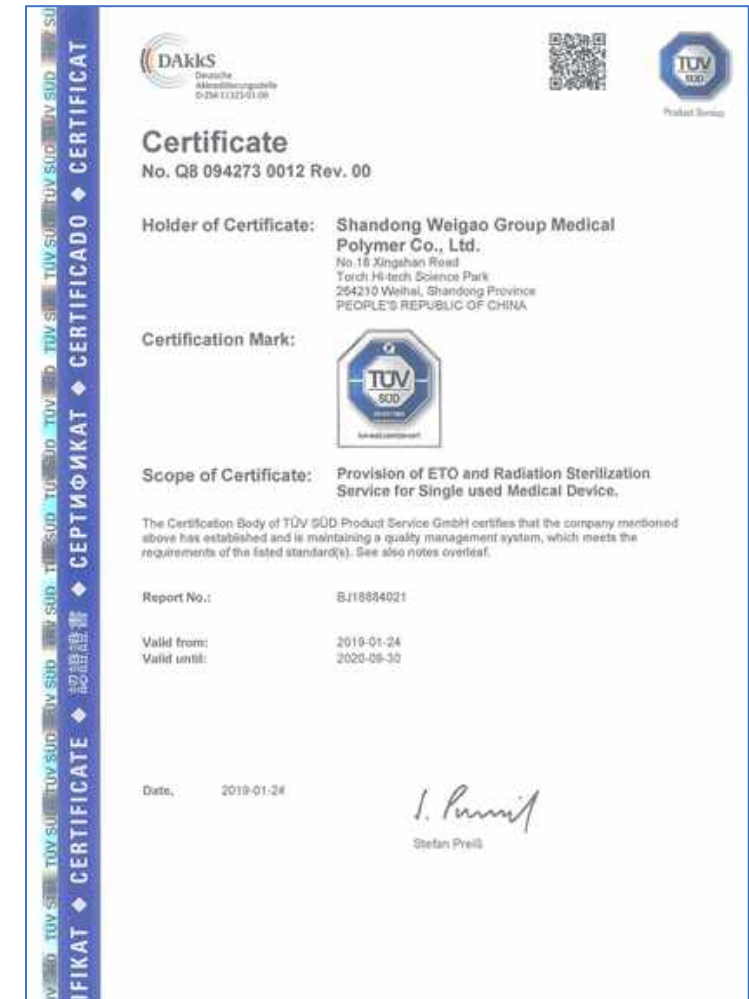
Materials:

- Polypropylene spunbonded
- PE film coated nonwovens
- Content: 100% Polyester

WEGO has fully adopted company-wide ETO (ethylene oxide) sterilization processes, unique for manufacturers in China

ETO sterilization:

- Kills all microorganisms, including spores, bacteria & viruses
- Does not corrode plastics, metals or rubber, and does not cause items to turn yellow and brittle
- Improves manufacturing efficiency, allowing for wrapping and packaging to occur together.
- Allows for maintenance of long term sterilization and product use.
- Allows the sterilization of items with irregular shapes and complex structures



A grayscale photograph of a surgical team in an operating room, wearing masks and scrubs, focused on a procedure. The image is semi-transparent, serving as a background for the text.

EQUINOX

Level 2 and Level 3 Surgical Mask

Surgical Mask (Indication)

Indication:

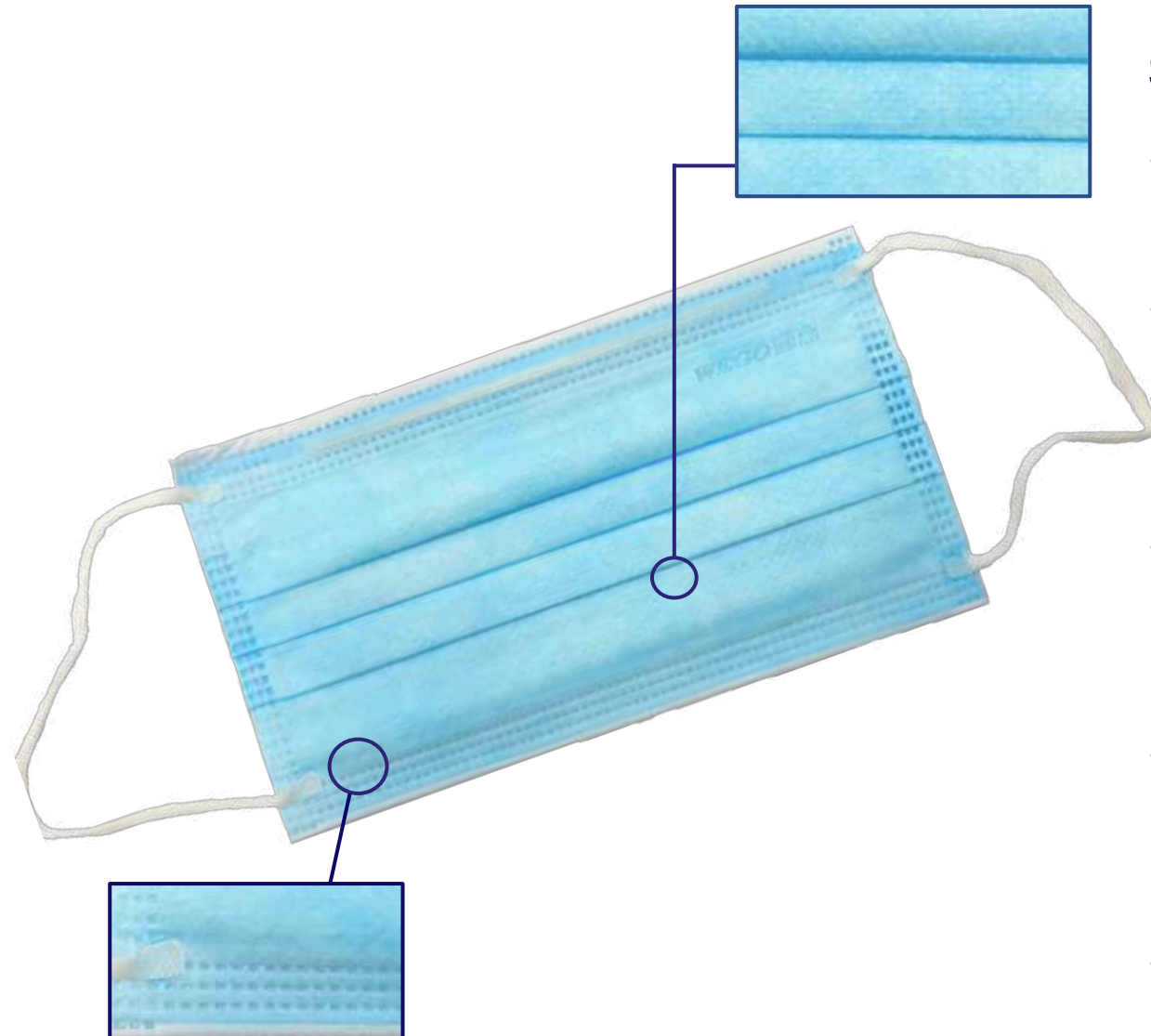
Designed to be worn by clinical medical staff during the invasive operation.

Covering the mouth, nose and jaw of user, the mask provides a physical barrier, preventing the transmission of pathogens, microorganisms, body fluids and particles.

Characteristics:

- The non-woven fabric utilizes medical grade materials, which effectively prevent the inhalation of bacteria and dust.
- The nose clip can be freely adjusted to ensure a close fit, ensuring a tight seal.
- The chin design contours the face, ensures a secure fit, and improves wearing comfort. The mask is hypoallergenic, effectively blocks dust and microorganisms and can be worn comfortably for long periods.





Structural composition:

- The utility model is composed of a mask body, a nose clip and a mask belt.
- The mask body consists of a three-layer structure.
- The bottom layer and surface layer are made of spun-blown non-woven fabric.
- Spun-blown fabrics tend to have wide (but controllable) fiber size distribution thanks to the multi-row design of the spinnerette.
- Sub micron fibers are naturally co-mingled with big microfibers which would result in strong and high efficiency filter media with higher particle-holding capacity at low pressure drop.
- The middle layer is made of melt-blown non-woven fabric

Available sizes

Divided into WGP-a and WGP-b according to the strap design

WGP indicates that the mask is a flat design.

A Type - Is a mask with ear-based affixation.

B Type – represents the strap-type mask.



Adult and child masks are available.



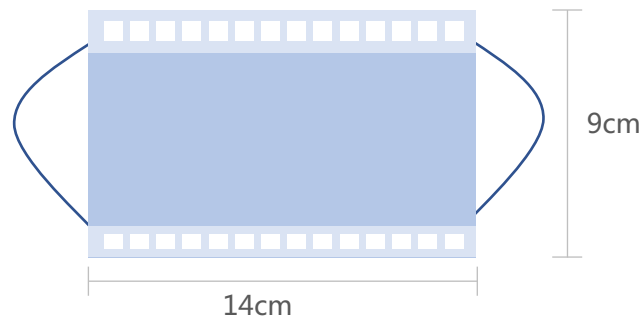
Paediatric Patterned Masks



Patterned Child Mask



Standard Child Mask : T/GDMDMA 0005-2020



Greater range available: swatches available upon request

A grayscale photograph of a surgical team in an operating room, wearing masks and scrubs, focused on a procedure. The image is semi-transparent, serving as a background for the text.

EQUINOX

**Sterile AAMI Level 3 Surgical Gowns:
manufactured by Weigao (WEGO),
distributed by Equinox**

Surgical Gown (Indication)

Indication:

- Disposable sterile gowns for use by all medical personnel in the operating theatre
- Conforms to EU performance standard (EN13795), AAMI AATCC 42 & 127 and ROW standard (YY/T0506)

Use:

1. Clothing to be worn by surgeons and other medical personnel during the procedure in the operating room
2. The clothing will protect both the patient and the medical staff from cross contamination whilst in the operating room



Structural composition:

- The surgical gown is sewn by ultrasonic technology, without pinholes, to help assure its bacterial and water resistance.
- Threaded cuffs provide enhanced comfort for the wearer in addition to preventing slip of the sleeve over the surgeon's gloves.
- **Hanging card:** Nurses do not need to hold objects in the operating rooms, reducing the risk of infection transmission.





1. Stretch hands and forearms into the sleeves, ensuring arms are level with the shoulders, and keeping them away from the body



2. The circulating nurse should pull the surgical gown over the shoulders, touching only the inside of the gown



3. Tie the neckline and the inner waist strap



4. Hand the belt card to the circulating nurse, then make a three-quarter turn to the left while nurse extends the outer belt to its full length and then ties to the side

Additional Features :

WEGO is in production of new gowns which will have the following features :-

- Huck towels either as 2 paper towels (see image) or 1 cotton towel
- Improved labelling
- Enclosed sterile wrap



EQUINOX

**Sterile Level 2 Isolation Gowns,
distributed by Equinox**



Contact Information

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Level 35, 100 Barangaroo Ave,
International Tower 1, Barangaroo,
Sydney, NSW 2000
www.equinox-orthopaedics.com

EQUINOX

medical

Indication:

- Disposable isolation gowns for use by all medical personnel during procedures anticipating contact with bodily fluids, secretions, excretions and other infectious materials.
- Conforms to EU performance standard (EN13795) and ROW standard (YY/T0506).

Use:

1. Clothing to be worn by surgeons and other healthcare personnel during patient isolation situations.
2. The clothing will protect both the patient and the medical staff from transfer of bodily fluids, microorganisms and particulate material whilst exposed.



Structural composition:

- The isolation gown is produced using non-woven material, offering increased protection from liquid penetration.
- The isolation gown is latex free, with belt and neck ties ensuring a secure fit.
- Isolation gowns will be fitted with **thumb hooks** as shown in the adjacent image. This ensures no skin exposure when wearing gloves.



A grayscale photograph of a surgical team in an operating room, wearing masks and scrubs, focused on a procedure. The image is semi-transparent, serving as a background for the text.

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Protective Clothing
Standard: EN14126- Type 3

Indication:

- Provision of a protective barrier, for clinical staff at risk of exposure to potentially infectious patients due to exposure to blood, body fluids and secretions.
- **Standard: EN14126 and GB 19082-2009**

Structural composition:

- Made of a breathable film, nonwoven membrane material.
- The suit consists of a joined and sealed hooded top, pants and an optional foot cover.
- Cuffs, ankles, and foot vents exhibit elastic closings, as do the hat, facial and waist closings.

Use:

1. For protection when interacting with patients with infectious diseases such as those with multidrug-resistant bacteria and viruses.
2. For protection when caring for and interacting with patients in protective isolation.
3. For protection against splashes from the patient's blood, body fluids, secretions and excrement.
4. Whether or not to wear isolation clothing when entering the key wards shall be determined from a combination of internal regulations and on the purpose of the entering medical personnel in close proximity to the patients.

Characteristics:

- Conforms with the national standard GB19082-2009 "medical disposable protective clothing technical requirements".
- Bacterial resistance, anti-static, effective barrier from liquids and particulate matter.
- Soft, light, breathable and comfortable to wear.
- Stitching and zipper areas are sealed with rubber and glue, helping to prevent the invasion of bacteria and viruses.
- The outer layer has a smooth surface which is not easy to wet, reducing the chance of bacterial adhesion.



Protective Clothing - Characteristics (2)

Needle stitching:

- Bonding and heat-sealing processes are applied to the connection part of the protective suit.
- The holes of the stitches are sealed. The stitch pitch should be 8 to 14 stitches per 3 cm. The stitches are aligned and properly spaced.
- Bonded or hot-sealed parts shall be flat and sealed without air bubbles.

Zippers of the protective clothing should not be exposed, and the zipper puller should be self-locking.

The structure of the protective suit ensures conformity, with ease of removal.

The protective suit is in a unified structure, with tight seals, integrating the hooded top and pants.



Two-piece Hooded Design:

A two-piece hooded, three-dimensional cut and elastic band around the face opening, allows for optimized fitting to the face, improving overall protection.



Two-piece Hooded Design

Seam sealed tape workmanship:

All seams are sealed with tape and with an internal elastic band, applied to the waist.

This enhances the seam protection and the overall fit of the suit.



Seam sealed tape workmanship



Types of suit include:

A-Type (with foot cover) and
B-Type (without foot cover)

The sizes available are:

S, M, L, XL, XXL, XXXL

A type: gown type

B type: separate clothing without cap

C-1 type: one-piece type with cap and foot cover

C-2 type: one-piece type with cap and without foot cover

C-3 type: one-piece type without cap and with foot cover

C-4 type: one-piece type without cap and foot cover



SPECIFICATIONS

UNIT: CM

SIZE	HEIGHT	BUST	SLEEVE LENGTH	CUFF	HEM
160	165	120	84	18	24
165	169	125	86	18	24
170	173	130	90	18	24
175	178	135	93	18	24
180	181	140	96	18	24
185	188	145	99	18	24
200	200			18	24
DEVIATION	±2	±2	±2	±2	±2

A grayscale photograph of a surgical team in an operating room, wearing masks and scrubs, focused on a procedure. The image is semi-transparent, serving as a background for the text.

EQUINOX

Insulation Clothing
National Standard, Class 1

Indication:

- For medical institutions such as outpatient clinics, wards, laboratories, etc. for general isolation.

Structural composition:

- The use of non-woven or filament-woven fabric as the main raw material
- It is made by cutting and sewing under sterile conditions
- Provided Non-sterile and for single-use.



Sizing Available:

A type: gown type

B type: separate clothing without cap

C-1 type: one-piece type with cap and foot cover

C-2 type: one-piece type with cap and without foot cover

C-3 type: one-piece type without cap and with foot cover

C-4 type: one-piece type without cap and foot cover

