DISTRAUMA MEDICAL

Avda. de l'Ebre, nau 4
08184 Palau Solità i Plegamans
(Barcelona)
Tel.: 93 864 46 23 • Fax: 93 864 42 94
e-mail: info@distrauma.com
www.distraumamedical.com

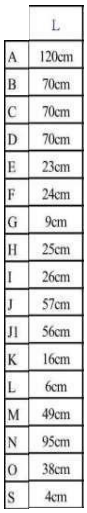
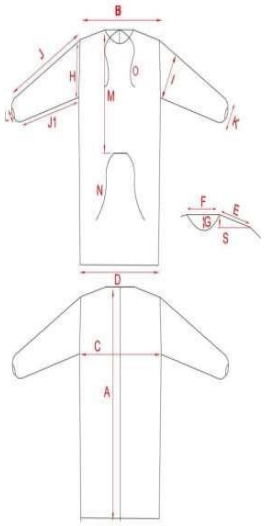
BATA DE PROTECCIÓN TEJIDO SIN TEJER, NO ESTÉRIL

Identificación de la empresa

Razón social	DISTRAUMA MEDICAL, S.L.
NIF	B-61435079
Fabricante/ Distribuidor	Distribuidor

Datos del producto específicos

Referencia	13125GWN120140
Marca comercial	Distrauma Medical

DESCRIPCIÓN	Bata de polipropileno hidrófoba de 25 gramos de manga larga en medida de 120x140cm con cierre en la parte trasera (cintura) y en el cuello, puño elástico ajustable. Cuello redondo anatómico.
FOTOGRAFÍAS	 
FABRICACIÓN	Fabricante: Zhejiang Mediunion Healthcare Group Co.Ltd.
MATERIALES UTILIZADOS	Tejido no tejido 100% Polipropileno hidrófobo de spunbond de 25 g/m2. No tóxico y biodegradable. Libre de látex. Hipoalergénica.
CARACTERÍSTICAS	Bata diseñada y fabricada en polipropileno spunbond que cubre tronco, brazos y extremidades. Confortable, cómoda, resistente y transpirable. Sin bolsillos. Cierre en la parte trasera. De color verde. Talla única. Bata fabricada con polipropileno hidrófobo que repele los líquidos. No desprende partículas.
PRESENTACIÓN	Caja de transporte de 100 unidades. Bolsas interiores de 10 unidades. Dimensiones de la caja de transporte: 52x34x34
CERTIFICADOS	CE (Clase I no estéril) acorde a 93/42/EEC. DIN EN ISO 13485:2016
CONSERVACIÓN	Almacenar en lugar fresco y bien ventilado, mantener alejado de fuentes de ignición y llamas, así como agentes oxidantes fuertes, corrosivos y materiales combustibles.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 092925 0004 Rev. 01

Manufacturer

ZHEJIANG MEDIUNION HEALTHCARE GROUP CO., LTD.
No.167 Yening Street
315010 Ningbo
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Technomed
Logport Office-Center,, Bliersheimer Str.80A,, 47229 Duisburg, GERMANY

Product Category(ies):

Disposable Umbilical Cord Clamps, Disposable I.D. Bracelets, Disposable Colostomy Bags, Disposable Dressing Kits, Surgical Gowns,Isolation Gowns, Masks, Caps, Coveralls, Shoe Covers, Gauze Swabs(Sponges), Wound Dressings, Wound Plasters, Bandages, Alcohol Swabs/Pads, Surgical Drape, Absorbent Cotton Balls, Absorbent Cotton Rolls,First-aid kit, Light Handle Covers, Medical Cotton Tipped Applicators, Dressing Eye pads, Sterile Surgical Kit, Sterile Tongue Depressors, Vaginal Speculums, Surgical Brushes, Transport Swabs, Aprons, Ear/Ulcer Syringe,Urine Bag

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1799703-01

Valid from: 2018-09-25
Valid until: 2021-05-17

Date, 2018-09-25

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

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No. G2S 092925 0004 Rev. 01

Facility(ies):

ZHEJIANG MEDIUNION HEALTHCARE GROUP CO., LTD.
No.167 Yening Street, 315010 Ningbo, PEOPLE'S REPUBLIC OF CHINA

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Declaration of Conformity

Manufacturer: Zhejiang Mediunion Healthcare Group CO.，LTD

Address: No.167,Yening Street, 315010,Ningbo,Zhejiang,People’s Republic of China

European: Technomed Logport Office-Center Bliersheimer Str. 80A 47229

Representative Duisburg,Deutschland/Germany

Product Face Mask, Coverall, Isolation gown，Surgical gown, Lab coat, Shoe cover, Apron, Arm sleeve, Caps, Bed sheet, Pillow case

Model code 175*95mm, S,M,XL,2XL,3XL,4XL

Classification (MDD, Annex Ⅸ): I sterile MDD 93/42/EEC Annex V, Rule 1

Conformity assessment route: Annex V

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical device directive: Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standards Applied:

Harmonized standards published in the official journal of the European communities are applicable to this product.

Notified Body: TUV SUD Product Service GmbH,
Ridlerstr.65, 80339 Munich, Germany

NB Identification number: 0123

Certificate: NO.G2S 0929250004 Rev.01

Expiry date of the certificate:2021-05-17

Start of CE Marking: 2018-09-25

Place, date of issue: Ningbo city. P.R. China 2020-5-12

浙江美联医疗用品股份有限公司
ZHEJIANG MEDIUNION HEALTHCARE GROUP CO.,LTD

Signature _____

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092925 0005 Rev. 01

Holder of Certificate: **ZHEJIANG MEDIUNION HEALTHCARE GROUP CO., LTD.**
No.167 Yening Street
315010 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Medical Devices (For detailed information see below)**

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.: SH1899704

Valid from: 2019-08-27
Valid until: 2022-05-17

Date, 2019-08-27

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092925 0005 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): ZHEJIANG MEDIUNION HEALTHCARE GROUP CO., LTD.
No.167 Yening Street, 315010 Ningbo, PEOPLE'S REPUBLIC OF CHINA

Design, Development, Production and Distribution of Non-absorbable Surgical Suture with and without Needles, Electrosurgical Pencils.

Production and Distribution of Venturi Mask, Nelaton Catheters, Suction Catheter, Anesthesia Mask, Anesthesia Breathing Circuit, Laryngeal Mask Airway, Suction Connecting Tube, Heparin Caps, Sterile Three-way Stopcocks for Single Use, Endotracheal Tubes, Latex Foley Catheter, Disposable Stomach Tubes, Sterile Feeding Tubes, Guedel/Oropharyngeal Airway, Resuscitator, Sterile Blood Lancets, Disposable Surgical Blades(with and without handle), Disposable Skin Staplers, Disposable Syringe Sets, Hypodermic Needles, Scalp Vein Sets, Infusion Sets, Blood Transfusion Sets, Disposable Blood Collection Needles, Vacuum Blood Collection Tubes with Needles, Disposable IV Catheters, Sterile Dental Needles for Single Use, Digital Thermometers, Humidifier Jar(Bubble Humidifier Jar), Disposable Umbilical Cord Clamps, Disposable I.D. Bracelets, Disposable Colostomy Bags, Disposable Dressing Kits, Surgical Gowns, Isolation Gowns, Masks, Caps, Coveralls, Shoe Covers, Sterile Lap Sponge, Sterile Gauze Ball with X-ray, Gauze Swabs(Sponges), Wound Dressings, Wound Plasters, Bandages, Alcohol Swabs/Pads, Surgical Tapes, Surgical Drape, Absorbent Cotton Balls, Absorbent Cotton Rolls, First-aid kit, Light Handle Covers, Medical Cotton Tipped Applicators, Dressing Eye pads, Wash Gloves, Non-woven surgical Bed Sheet, Surgical Clothing, Plastic Examination Glove, Disposable Nitrile Examination Gloves, Disposable Examination Vinyl Gloves, Nursing Napkin, Knife for Medical Skin Cleaning, Bedsore Prevention Mattress, Stethoscope, Walking Sticks, Wheelchairs, Oxygen Masks, Nasal Oxygen Cannula, Sterile Surgical Kit, Sterile Tongue Depressors, Aprons, Vaginal Speculums, Surgical Brushes, Transport Swabs, Urine Bag, Ear/Ulcer Syringe, Medical Forceps, Urine Collection Cups,Medical Prep Razors, Bibs, Sponge Oral Swabs, Emesis Basin, Bedpan

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