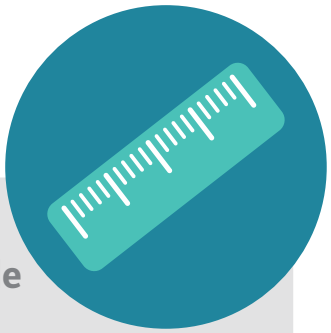
ZAZA
MEDICAL

DISPOSABLE
MEDICAL PRODUCTS

PRODUCT DESCRIPTION

- Convenience and easy to wear and off
- Light weight and soft feeling
- High strength and durability
- Permeate air and water vapor, but obstructs water-based liquids

- 35 gsm Non-woven SMMS fabric
- 40 gsm Non-woven SMMS fabric
- Knit Cuff Latex Free
- Splash Resistant
- Blue Color
- Sterile - Non-sterile



- SMMS or SMS composite Non-Woven
  Water phobic, latex free skin-friendly, breathable, comfortable

- Collar Design
  Simple round neck design
  Comfortable and not deformed
  Close to collar skin, safety protection

- Knit Cuff Design
  Easy to meet multiple work needs
  Extra Soft

- Lace-Up Design
  2 or 4 Strap-type knots
  Facilitate the wearing of the gowns
  Adjust the tightness of the clothes

- Back Collar Design
  Strong Adhesive
  Velcro on the back neckline
  Firm and safe to use

ZAZA MEDICAL

AAMI PB70 GUIDELINES

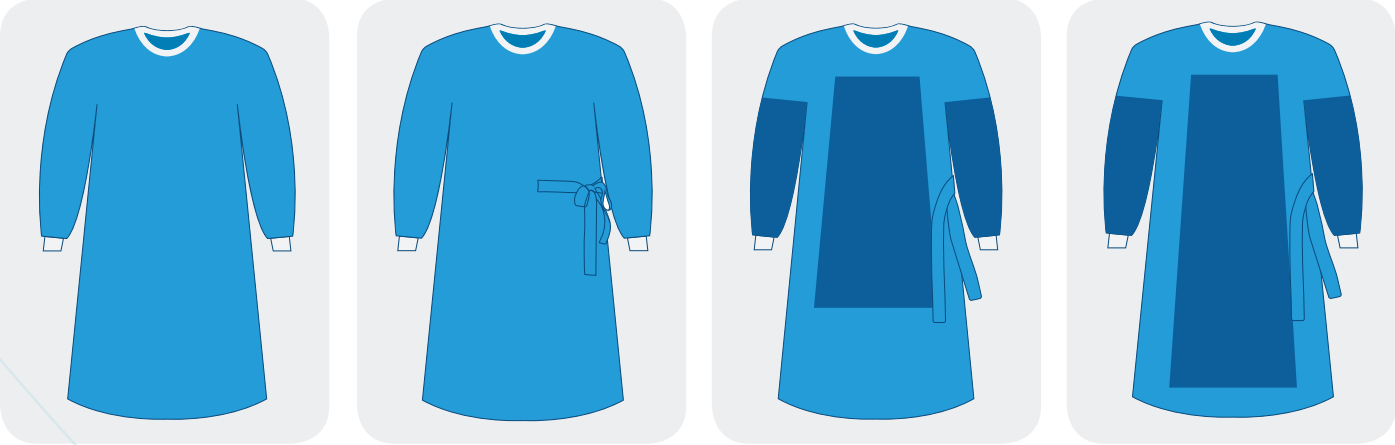
LEVEL	TEST METHOD	TEST DEFINITION	REQUIREMENT	EXPECTED BARRIER EFFECTIVENESS	ANTICIPATED FLUID EXPOSURE
AAMI LEVEL 1	AATCC 42 Impact penetration	Measures the ability of a material to resist water penetration under spray impact	Water impact ≤ 4.5 g	Minimal water resistance (some resistance to water spray)	**MINIMAL** FLUID LEVELS
AAMI LEVEL 2	AATCC 42 Impact penetration	Measures the ability of a material to resist water penetration under spray impact	Spray impact ≤ 1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	**LOW** FLUID LEVELS
	AATCC 127 Hydrostatic Pressure	Measures the ability of a material to resist water penetration under constant contact with increasing pressure	Hydrostatic pressure ≥ 20 cm		
AAMI LEVEL 3	AATCC 42 Impact penetration	Measures the ability of a material to resist water penetration under spray impact	Spray impact ≤ 1.0 g	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure	**MODERATE** FLUID LEVELS
	AATCC 127 Hydrostatic Pressure	Measures the ability of a material to resist water penetration under constant contact with increasing pressure	Hydrostatic pressure ≥ 20 cm		
AAMI LEVEL 4	ASTM F1671 Viral Penetration Test	Measures the resistance to penetration by blood borne pathogens using a surrogate microbe under conditions of continuous liquid contact.	Pass	Blood and viral penetration resistance (2 psi)	**HIGH** FLUID LEVELS

The Association for the Advancement of Medical Instrumentation (AAMI) *standards are designed to help medical-device companies meet global standards for the safe use of medical devices.* ***ANSI/AAMI PB70:2012***

ZAZA MEDICAL

DISPOSABLE
ISOLATION GOWNS

ZAZA MEDICAL



LATEX
Latex Free

2
Single Use

Our Level 1, 2 and 3 gowns are intented to be used in situations where minimal, low, and moderate fluid barrier protection is needed. Level 4 gowns are prepared for the highest fluid and microbial barrier protection to protect the user against long, fluid-intensive procedures. Also for operations on patients with potential blood-borne pathogen risk.

LEVEL 1
LEVEL 2
LEVEL 3
LEVEL 4

LONDON, UNITED KINGDOM

Zaza London Limited
Company registered in England No: 06958087
Vat : GB204955806
Phone : +44 203 488 0031 / +44 770 248 0316
Address : 2 Meyrick Road, NW10 2EJ, London, UK

ISTANBUL, TURKEY

Pratik Istanbul Import & Export Ltd.
VKN : 7330674060
Phone : +90 532 546 2121
Address : Demirtas Mah. Hayriye Hanim Sk. No:7/3-4 Fatih, Istanbul, TR

www.zazamedical.com | info@zazamedical.com

CE ISO 9001:2015 ISO 13485 2016 FDA REGISTERED TSE EN - 13795 + A1

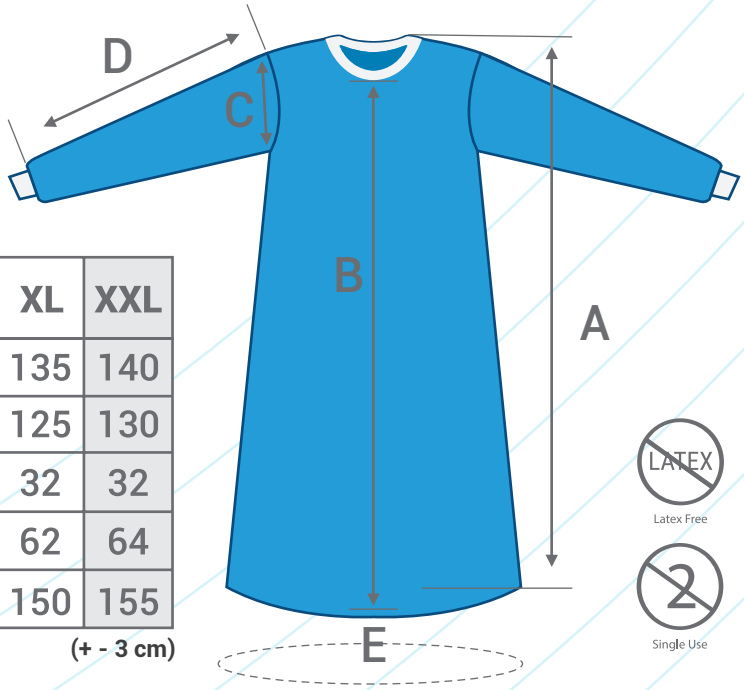
Minimal
Fluid Barrier Protection

LEVEL 1

COMPOSITION

SMMS Hydrophobic (Spunbond, Meltblown, Meltblown, Spunbond) - Polypropylene (PP)

FABRIC WEIGHT	**25 - 40 GSM**
COLOUR	**BLUE**
SIZE EU	**S, M, L, XL, XXL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE ISOLATION GOWN**



SIZE CHART (cm)		S	M	L	XL	XXL
A	Length *(Shoulder to Hem)*	105	115	125	135	140
B	Length *(Collar to Hem)*	103	105	115	125	130
C	Upper Arm	29	29	29	32	32
D	Sleeve Length	56	58	60	62	64
E	Hem Width	140	145	150	150	155

(+ - 3 cm)

PACKING

Each Carton Box Contains: 90 pcs
Each Carton Weight: 9 KG
Carton Box Dimensions: 40 x 60 x 40 cm
ISOLATION GOWNS ARE PACKED IN PE BAGS.

ZAZA MEDICAL

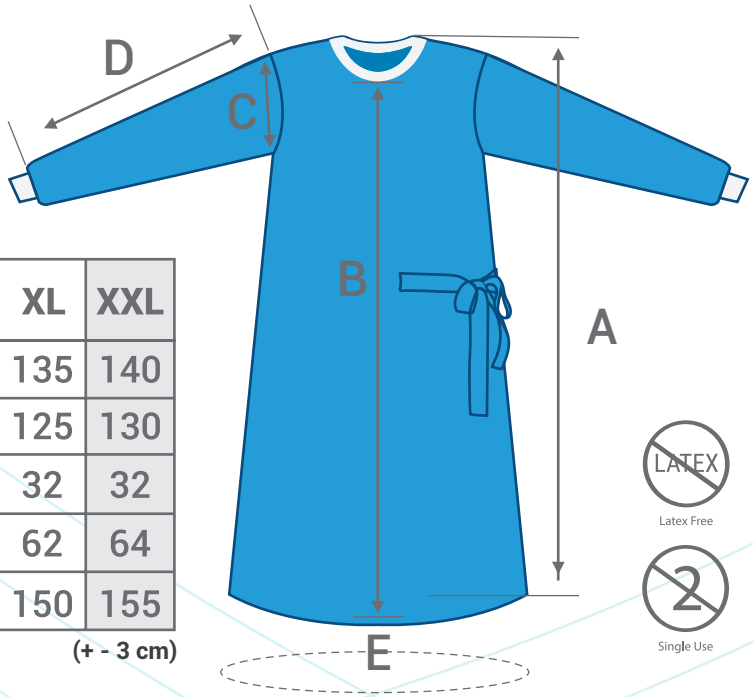
Minimal to Low
Fluid Barrier Protection

LEVEL 2

COMPOSITION

SMMS Hydrophobic (Spunbond, Meltblown, Meltblown, Spunbond) - Polypropylene (PP)

FABRIC WEIGHT	**35 - 45 GSM**
COLOUR	**BLUE**
SIZE EU	**S, M, L, XL, XXL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE ISOLATION GOWN**



SIZE CHART (cm)		S	M	L	XL	XXL
A	Length *(Shoulder to Hem)*	105	115	125	135	140
B	Length *(Collar to Hem)*	103	105	115	125	130
C	Upper Arm	29	29	29	32	32
D	Sleeve Length	56	58	60	62	64
E	Hem Width	140	145	150	150	155

(+ - 3 cm)

PACKING

Each Carton Box Contains: 85 pcs
Each Carton Weight: 9 KG
Carton Box Dimensions: 40 x 60 x 40 cm
ISOLATION GOWNS ARE PACKED IN PE BAGS.

ZAZA MEDICAL

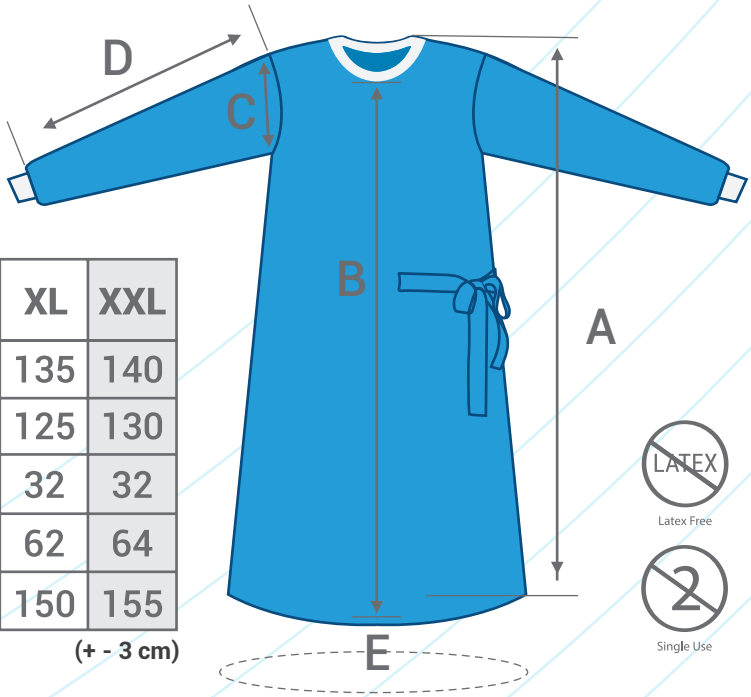
Moderate
Fluid Barrier Protection

LEVEL 3

COMPOSITION

SMMS Hydrophobic (Spunbond, Meltblown, Meltblown, Spunbond) - Polypropylene (PP)

FABRIC WEIGHT	**40 - 45 GSM**
COLOUR	**BLUE**
SIZE EU	**S, M, L, XL, XXL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE ISOLATION GOWN**



SIZE CHART (cm)		S	M	L	XL	XXL
A	Length *(Shoulder to Hem)*	105	115	125	135	140
B	Length *(Collar to Hem)*	103	105	115	125	130
C	Upper Arm	29	29	29	32	32
D	Sleeve Length	56	58	60	62	64
E	Hem Width	140	145	150	150	155

(+ - 3 cm)

PACKING

Each Carton Box Contains: 80 pcs
Each Carton Weight: 9.5 KG
Carton Box Dimensions: 40 x 60 x 40 cm
ISOLATION GOWNS ARE PACKED IN PE BAGS.

ZAZA MEDICAL

Highest Fluid & Microbial
Reinforced

LEVEL 4

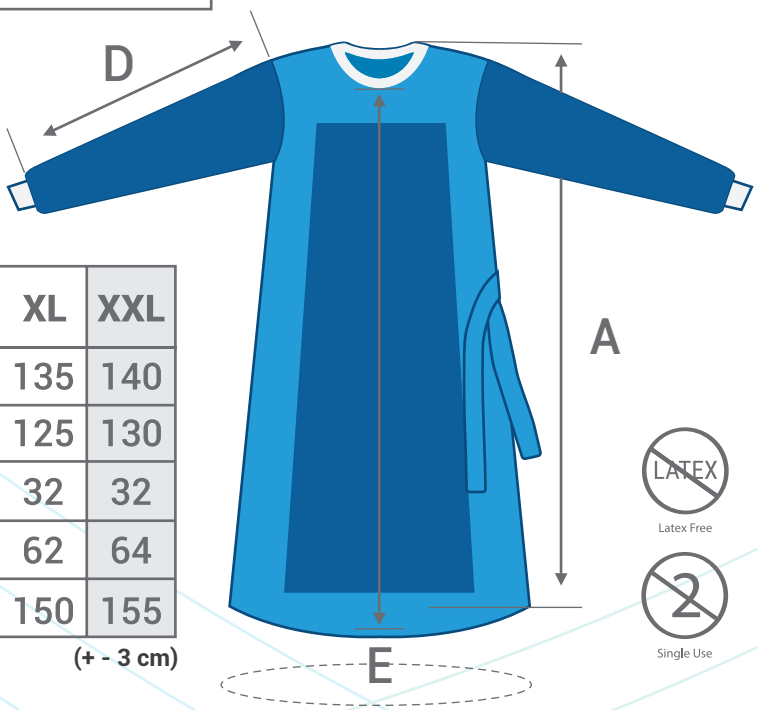
COMPOSITION

SMMS Hydrophobic (Spunbond, Meltblown, Meltblown, Spunbond) - Polypropylene (PP)

FABRIC WEIGHT	**40 - 55 GSM**
COLOUR	**BLUE**
SIZE EU	**S, M, L, XL, XXL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE ISOLATION GOWN**
OTHER OPTIONS	**STERILE / NON-STERILE**

SIZE CHART (cm)		S	M	L	XL	XXL
A	Length *(Shoulder to Hem)*	105	115	125	135	140
B	Length *(Collar to Hem)*	103	105	115	125	130
C	Upper Arm	29	29	29	32	32
D	Sleeve Length	56	58	60	62	64
E	Hem Width	140	145	150	150	155

(+ - 3 cm)



PACKING

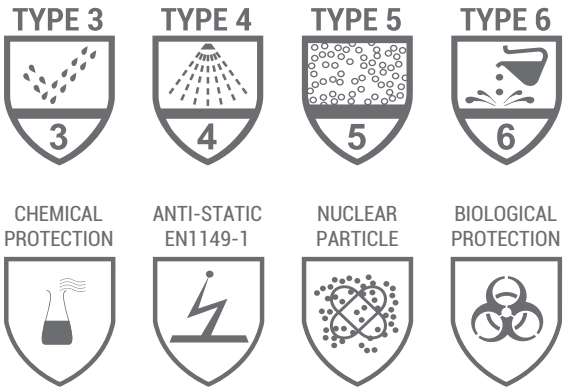
Each Carton Box Contains: 75 pcs
Each Carton Weight: 9 KG
Carton Box Dimensions: 40 x 60 x 40 cm
ISOLATION GOWNS ARE PACKED IN PE BAGS.

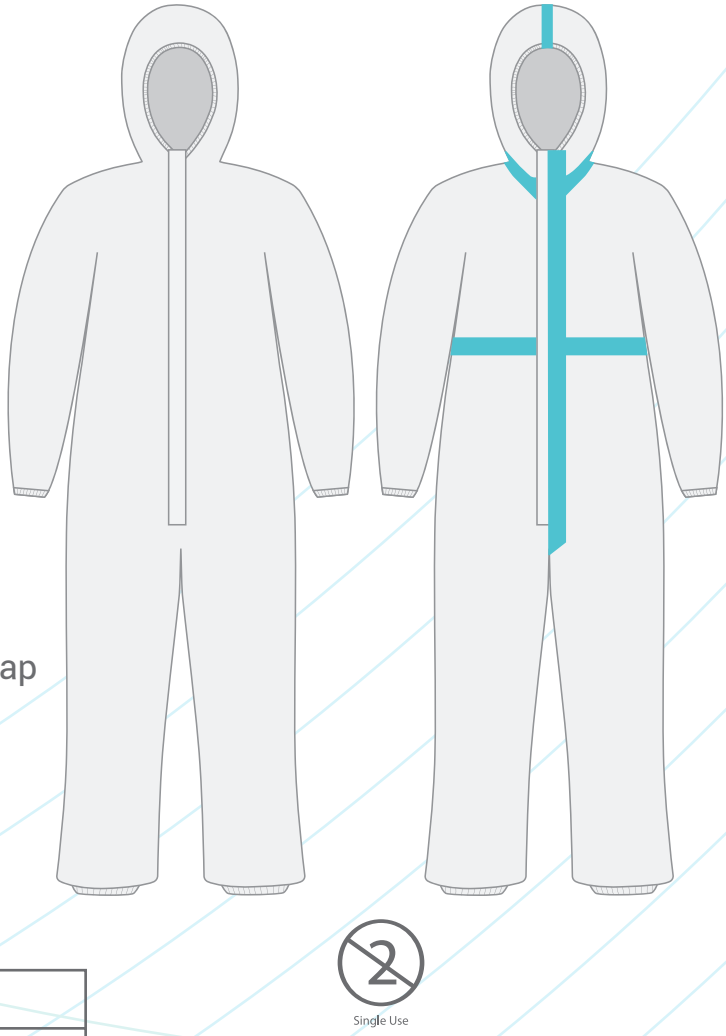
ZAZA MEDICAL

DISPOSABLE COVERALLS

TECHNICAL DETAILS

Premium protection against airborne particles and fibres. Limited protection against chemical spray **(Type 4)** , airborne particles **(Type 5)** and splashes of LOW RISK chemicals **(Type 6)**. Zip front with adhesive backed cover flap. Elasticated hood with a solid knit wristing, ankle closures to limit dust ingress. CE Category III, types 3, 4, 5 & 6. Anti-static to EN1149-5.





KEY FEATURES

- Elasticated hood and self-adhesive chin flap
- Stitched and overtaped seams
- Elasticated cuffs and ankles
- Zipper with self-adhesive double zip flap

FABRIC WEIGHT	**55 GSM**
COLOUR	**WHITE**
SIZE EU	**S, M, L, XL, XXL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE COVERALL**

ZAZA MEDICAL

DISPOSABLE WARM-UP JACKET

KEY FEATURES

- Long sleeves
- A gentle knit collar
- Front snap closures
- Knit cuffs
- Elastic waist

FABRIC WEIGHT	**40 GSM - SMS / SMMS**
COLOUR	**BLUE**
SIZE EU	**M, L, XL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE WARM-UP JACKET**

SIZE (cm)	M	L	XL
Chest	63	68	72
Length	74	81	87

(+ - 3 cm)

Single Use

PACKING

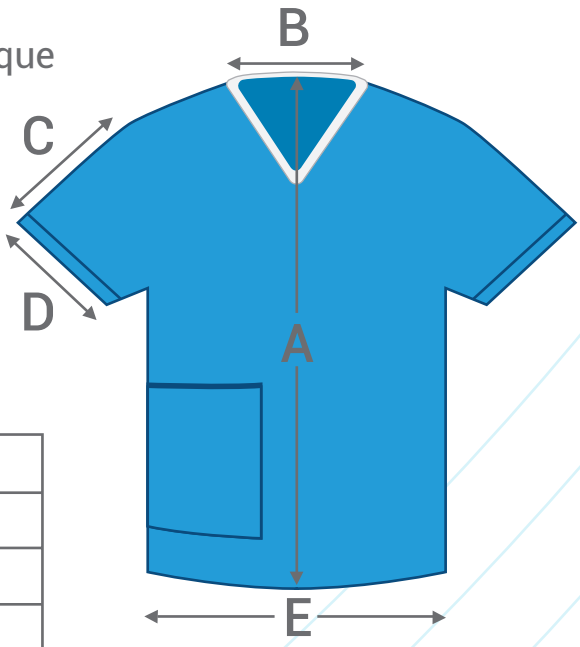
Each Carton Box Contains: 50 pcs
Each Carton Weight: 7.5 KG
Carton Box Dimensions: 30 x 60 x 39 cm
WARM-UP JACKETS ARE PACKED IN PE BAGS.

ZAZA MEDICAL

DISPOSABLE SCRUB SUIT

KEY FEATURES

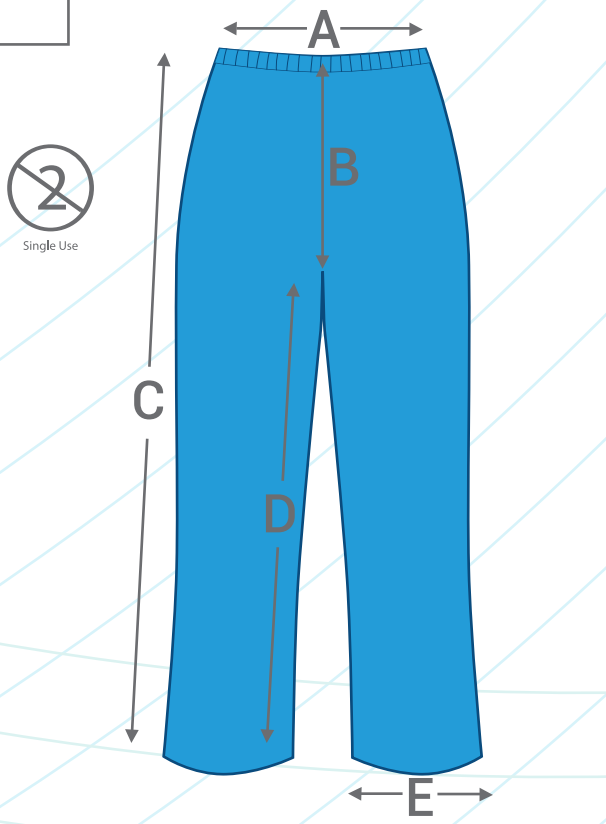
- Set includes a shirt and trouser made of an opaque SMS material
- Shirt with a bell-shaped design for a perfect fit
- Convenient pocket on the shirt
- Adjustable waist ties on the trouser



FABRIC WEIGHT	**40 GSM - SMS or TELA**
COLOUR	**BLUE**
SIZE EU	**M, L, XL**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE SCRUB SUIT**

SIZE CHART (cm)		M	L	XL
SCRUB TUNIC	A	75	76	77
	B	18	19	19
	C	29	30	31
	D	19	20	21
	E	55	57	59
SCRUB TROUSER	A	50	52	54
	B	35	37	39
	C	106	107	108
	D	82	84	85
	E	22	24	25

(+ - 3 cm)



ZAZA MEDICAL

DISPOSABLE

Caps and Shoe Covers

DISPOSABLE MOB CAP

KEY FEATURES

- High breathability
- Polypropylene
- Anti-Static
- Lightweight
- Spunbond Nonwoven
- Elastic edge
- Moisture resistant
- Reduce risk of infection

FABRIC WEIGHT	**10 GSM**
COLOUR	**WHITE, BLUE, GREEN**
SIZE (COLOUR:CM)	**W : 40x40cm B&G : 45x52cm**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE MOB CAP**

PACKING

Each Bag Contains: 100 pcs
Each Carton Box Contains: 2000 pcs
Each Carton Weight: 4.5 KG
Carton Box Dimensions: 35 x 48 x 41 cm

ZAZA MEDICAL

DISPOSABLE SURGICAL CAPS

KEY FEATURES

- Spunbond Nonwoven
- Elastic Edge
- Tie Back
- Polypropylene
- Lightweight

FABRIC WEIGHT	**40 GSM**
COLOUR	**BLUE, GREEN**
SIZE	**33 CM DIAMETER**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE SURGICAL CAP**

PACKING

Each Bag Contains: 200 pcs
Each Carton Box Contains: 1000 pcs
Each Carton Weight: 6 KG
Carton Box Dimensions: 40 x 60 x 40 cm

ZAZA MEDICAL

DISPOSABLE SURGICAL CAP

KEY FEATURES

- Laminated Spunbond
- Adjustable ties
- Non-Sterile

FABRIC WEIGHT	**57 GSM**
COLOUR	**WHITE**
SIZE EU	**ONE SIZE**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE SURGICAL CAP**

ZAZA MEDICAL

DISPOSABLE SHOE COVER

KEY FEATURES

- Spunbond Nonwoven
- Polypropylene
- Elastic edge
- Lightweight

FABRIC WEIGHT	**25 GSM**
COLOUR	**BLUE**
SIZE	**ONE SIZE**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE SHOE COVER**

PACKING

Each Bag Contains: 100 pcs
Each Carton Box Contains: 1600 pcs
Each Carton Weight: 5.8 KG
Carton Box Dimensions: 40 x 60 x 40 cm

ZAZA MEDICAL

DISPOSABLE SHOE COVER

KEY FEATURES

- Polyethylene
- Single Elastic
- Lightweight
- Double Elastic

COLOUR	**BLUE**
SIZE	**ONE SIZE**
MADE IN	**TURKEY**
CARE INSTRUCTION	**DISPOSABLE SHOE COVER**

PACKING

Each Bag Contains: 1000 pcs
Each Carton Box Contains: 5000 pcs
Each Carton Weight: 9.30 KG
Carton Box Dimensions: 40 x 60 x 40 cm

ZAZA MEDICAL

CERTIFICATES

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KIOSCERT®

CERTIFICATE

Bu Sertifika / This certificate is granted to the organization

PRATİK İSTANBUL İÇ VE DIŞ TİCARET LTD. ŞTİ.

Sarıdemir mah. Ragıp Gümüşpala Cad. Ahenk İş Hanı No : 29 A Fatih / İstanbul / Türkiye

KIOSCERT Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu
Kalite Yönetim Sisteminin
Is audited by KIOSCERT Certification and applied
Quality Management System meet the requirements of

ISO 9001:2015

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
Standard for the following activities.

Belgelendirme Kapsamı / Certification Scope

TULUM, ÖNLÜK, CERRAHİ ÖNLÜK, İZOLASYON ÖNLÜĞÜ, ZİYARETÇİ ÖNLÜĞÜ, AMELİYAT ÖNKÜĞÜ, DOKTOR ÖNLÜĞÜ, BOX ÖNLÜĞÜ, BONE GALOŞ, SEDYE ÖRTÜSÜ, KOLLUK, SAKAL KORUYUCU, ISITICI CEKET VE İKİLİ SET ÜRÜNLERİNİN İMALATI VE SATIŞI, MEDİKAL CİHAZLARIN SATIŞ HİZMETLERİ

COVERALLS, GOWNS, APRONS, SURGICAL GOWN, ISOLATION GOWN, VISITOR GOWN, SURGICAL FOREARM, DOCTOR'S APRON, BOX GOWN, MOB CAPS, BOUFFANT CAPS, SHOE COVERS, SURGICAL CAPS, WARM UP JACKETS, STRETCHER COVER, BEARD COVER, MANUFACTURE AND SALE OF HEATER JACKET AND DOUBLE SET PRODUCTS, MEDICAL DEVICES SALES SERVICES

Sertifika Yayın Tarihi / 19.01.2021
Certificate Date

Sertifika Geçerlilik Tarihi / 18.01.2022
Certificate validity Date

Sertifika Son Basım Tarihi / 19.01.2021
Certificate Last Issue Date

Sertifika No / QMS-21-1901-PRA
Certificate No

Belge Periyodu / 3 Yıl (Years)
Certificate Period

NAC MANAGEMENT SYSTEM ISO/IEC 17021-1:2015 NAC-004-MS

Kioscert Uluslararası Sistem Ürün Belgelendirme Denetim ve Eğitim Hizmetleri Ltd. Şti.
İmbatlı Mah. 6076/3 Sk. No: 9 K:2 D:4 Family Park-2 Sitesi Karşıyaka - İZMİR • Tel: 0232 570 08 89 • www.kioscert.com • info@kioscert.com
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Medikal Cihaz Yönetim Sisteminin
Is audited by KIOSCERT Certification and applied
Medical Devices Management System meet the requirements of

ISO 13485:2016

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
Standard for the following activities

Belgelendirme Kapsamı / Certification Scope

TULUM, ÖNLÜK, CERRAHİ ÖNLÜK, İZOLASYON ÖNLÜĞÜ, ZİYARETÇİ ÖNLÜĞÜ, AMELİYAT ÖNKÜĞÜ, DOKTOR ÖNLÜĞÜ, BOX ÖNLÜĞÜ, BONE GALOŞ, SEDYE ÖRTÜSÜ, KOLLUK, SAKAL KORUYUCU, ISITICI CEKET VE İKİLİ SET ÜRÜNLERİNİN İMALATI VE SATIŞI, MEDİKAL CİHAZLARIN SATIŞ HİZMETLERİ

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Certificate validity Date

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Certificate Last Issue Date

Sertifika No / MDMS-21-1901-PRA
Certificate No

Belge Periyodu / 3 Yıl (Years)
Certificate Period

NAC MANAGEMENT SYSTEM ISO/IEC 17021-1:2015 NAC-004-MS

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İmbatlı Mah. 6076/3 Sk. No: 9 K:2 D:4 Family Park-2 Sitesi Karşıyaka - İZMİR • Tel: 0232 570 08 89 • www.kioscert.com • info@kioscert.com
Sertifikaların geçerlilik bilgisini **www.kioscert.com** adresinden kontrol edebilirsiniz.

IFC

CE

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress
SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone
+90 532 546 21 21
Mail:
info@zazamedical.com

Ürün İsmi / Product Name
İZOLASYONLU ÖNLÜK/ INSULATED GOWN

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğumuz altında, yukarıda ismi ve modeli geçen ürünlerin, (EU)2016/425 Kişisel Koruyucu Ekipmanlar Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, under the responsibility of the EU Classified Manufacturer, Distributor / Representative, it is declared that the products mentioned above are manufactured in accordance with the (EU) 2016/425 Personal Protective Equipment Directive and Turkhish regulations.

Direktif ve Yönetmelikler / Directives and Regulations
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive

Ürün Ticari Markası / Product Commercial Brand

ZAZA MEDICAL ZAZAMED MEDICAL

Harmonize Standartlar / Harmonized Standards
TS EN 14126 Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları /Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
TS EN ISO 13688 Koruyucu giyecekler-Genel özellikler- Protective clothing - General requirements
TS EN 14605+A1 Koruyucu giyecekler - Sıvı kimyasal maddelere karşı - Vücudun sadece bir kısmına koruma sağlayanlar (tip pb [3] ve tip pb [4]) dâhil, bağlantı yerleri sıvı geçirmez (tip 3) veya sprey geçirmez (tip 4) giyecekler için performans özellikleri- Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
TS EN 13034+A1 Sıvı kimyasal maddelere karşı koruyucu giyecekler - Sıvı kimyasal maddelere karşı sınırlı koruma sağlayan koruyucu giyecekler için performans kuralları (tip 6 ve tip pb [6] donanımı)- Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
TS EN 1149-5 Koruyucu giysi - Elektrostatik özellikler - Bölüm 5: Malzeme performansı ve tasarım gereksinimleri- Protective clothing – Electrostatic properties – Part 5: Material performance and design requirements

Sertifika No/ Certificate No: 2020-13239
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

IFC

CE

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone +90 532 546 21 21
Mail: info@zazamedical.com

Ürün İsmi ve Tipleri / Product Name and Types
Level 1/2/3/4/5 Önlük / Level 1/2/3/4/5 Gown
KORUYUCU ÖNLÜK / PROTECTIVE GOWN –İZOLASYONLU ÖNLÜK/ INSULATED GOWN-CERRAHİ ÖNLÜK / SURGICAL GOWN HASTA ÖNLÜĞÜ / PATIENT GOWN - ZİYARETÇİ ÖNLÜĞÜ / VISITOR GOWN - AMELİYAT ÖNLÜĞÜ / SURGERY GOWN- BOX ÖNLÜĞÜ / BOX GOWN -DOKTOR ÖNLÜĞÜ / DOCTOR GOWN

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici,Dağıtıcı/Temsilci olarak kendi sorumluluğumuz altında, yukarıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ve yönetmeliklerine ve EK-1 Temel Gerekere uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under our own responsibility as a Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and regulations.

Direktif ve Yönetmelikler / Directives and Regulations
93/42/EEC Tıbbi Cihaz Direktifi / 93/42/EEC Medical Device Directive

Ürün Ticari Markası / Product Commercial Brand

ZAZA MEDICAL ZAZAMED MEDICAL

Harmonize Standartlar / Harmonized Standards
93/42/EEC- Tıbbi Cihaz Yönetmeliği /SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
TS EN ISO 13485 Tıbbi Cihazlar – Kalite Yönetim Sistemleri – Düzenleyici Amaçlar İçin Gereklilikler
Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes
EN 13795-1 Cerrahi giysiler ve örtüler – Gereklilikler ve deney yöntemleri – Bölüm 1: Cerrahi örtüler ve önlükler / Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
TS EN 14126 Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları /Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
TS EN ISO 13688 Koruyucu giyecekler-Genel özellikler- Protective clothing - General requirements
TS EN 14605+A1 Koruyucu giyecekler - Sıvı kimyasal maddelere karşı - Vücudun sadece bir kısmına koruma sağlayanlar (tip pb [3] ve tip pb [4]) dâhil, bağlantı yerleri sıvı geçirmez (tip 3) veya sprey geçirmez (tip 4) giyecekler için performans özellikleri- Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
TS EN 13034+A1 Sıvı kimyasal maddelere karşı koruyucu giyecekler - Sıvı kimyasal maddelere karşı sınırlı koruma sağlayan koruyucu giyecekler için performans kuralları (tip 6 ve tip pb [6] donanımı)- Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
TS EN 1149-5 Koruyucu giysi - Elektrostatik özellikler - Bölüm 5: Malzeme performansı ve tasarım gereksinimleri- Protective clothing – Electrostatic properties – Part 5: Material performance and design requirements
TS EN ISO 15223-1 Tıbbi Cihazlar - Tıbbi Cihaz Etiketlerinde Etiketlemede Ve Sunulacak Bilgide Kullanılacak Semboller - Bölüm 1: Genel Gereklilikler / Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied - Part 1: General Requirements
TS EN 1041+A1 Tıbbi Cihaz İmalatçıları Tarafından Sağlanan Bilgiler / Information Supplied By The Manufacturer Of Medical devices
TS EN 1073-2 Radyoaktif bulaşmasına karşı koruyucu giysi-Kısım 2: Radyoaktif bulaşmasının ayrılmasına karşı havalanmayan koruyucu giysi için gerekliliker ve deney metotları- Protective clothing against radioactive contamination - Part 2: Requirements and test methods for airtight protective clothing against separation of radioactive contamination

Sertifika No/ Certificate No: 2020-13240
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

CERTIFICATES

CERTIFICATE

SERTİFİKA
CERTIFICATE OF REGISTRATION

Bu sertifika aşağıdaki kuruluşa
This certificate has been awarded to the company

PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A
FATİH / İSTANBUL / TÜRKİYE

ZAZA MEDICA ZAZAMED MEDICAL

TS EN 13795+A1 :2013

Hastalar, klinik personeli ve donanımı için tıbbi cihaz olarak kullanılan cerrahi örtüler, önlükler ve temiz hava giysileri-Üreticiler, işlemciler ve ürünleri için deney yöntemleri performans gereksinimleri ve performans düzeyi için genel özellikler

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

Üretilmekte olan ürünlerin TS EN 13795+A1:2013 standardına uygunluğunu belgelendirmek amacı ile aşağıdaki kapsamda verilmiştir.
To document the conformity of the products produced to the TS EN 13795+A1:2013 standard are given in the following scope for the purpose.

CERRAHİ ÖNLÜK ,ÖRTÜ SETİ , KORUYUCU TULUM, ÖNLÜK SETİ, TEK KULLANIMLIK ÇEKET, BONE,CERRAHİ BONE VE GALOŞ
SURGICAL GOWN, SURGICAL DRAPE SET, PROTECTIVE COVERALLS, SCRUB SUIT ,WARM UP JACKET, MOB CAPS, BOUFFANT CAPS, SURGİCAL CAPS, SHOE COVERS

Sertifika No. / Certificate No.:PC-2020-11400
İlk Belgelendirme Tarihi / Initial Certification Date : 18.01.2021
Sertifika Tarihi / Date of Certificate :18.01.2021
Bitiş Tarihi / Expiry Date :18.01.2022
Belgelendirme Periyodu / Certification Period :1 Yıl / Years

System Certification Approval
Certification Manager

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE

SERTİFİKA
CERTIFICATE OF REGISTRATION

Bu sertifika aşağıdaki kuruluşa
This certificate has been awarded to the company

PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A
FATİH / İSTANBUL / TÜRKİYE

ZAZA MEDICA ZAZAMED MEDICAL

TS EN 14126/AC:2004

Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları- Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Üretilmekte olan ürünlerin TS EN 14126/AC:2004 standardına uygunluğunu belgelendirmek amacı ile aşağıdaki kapsamda verilmiştir.

To document the conformity of the products produced to the TS EN 14126/AC:2004 standard are given in the following scope for the purpose.

CERRAHİ ÖNLÜK ,ÖRTÜ SETİ , KORUYUCU TULUM, ÖNLÜK SETİ, TEK KULLANIMLIK ÇEKET, BONE,CERRAHİ BONE VE GALOŞ
SURGICAL GOWN, SURGICAL DRAPE SET, PROTECTIVE COVERALLS, SCRUB SUIT ,WARM UP JACKET, MOB CAPS, BOUFFANT CAPS, SURGİCAL CAPS, SHOE COVERS

Sertifika No. / Certificate No.:PC-2020-11401
İlk Belgelendirme Tarihi / Initial Certification Date : 18.01.2021
Sertifika Tarihi / Date of Certificate :18.01.2021
Bitiş Tarihi / Expiry Date :18.01.2022
Belgelendirme Periyodu / Certification Period :1 Yıl / Years

System Certification Approval
Certification Manager

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CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
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Mail: info@zazamedical.com

Ürün İsmi / *Product Name*
TEK KULLANIMLIK KORUYUCU TULUM / DISPOSABLE PROTECTIVE COVERALL

Ürün Tipi / Types of Product
TİP 1/2/3/4/5/6, LAMİNASYONLU ve LAMİNASYONSUZ / TYPE 1/2/3/4/5/6, LAMINATED and NON-LAMINATED

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğumuz altında, yukarıda ismi ve modeli geçen ürünlerin, (EU)2016/425 Kişisel Koruyucu Ekipmanlar Direktifi, 2001/95/EC (GPSD) Ürün Güvenliği Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, under the responsibility of the EU Classified Manufacturer, Distributor / Representative, it is declared that the products mentioned above are manufactured in accordance with the (EU) 2016/425 Personal Protective Equipment Directive, 2001/95 / EC (GPSD) Product Safety Directive and Turkhish regulations.

Direktif ve Yönetmelikler / Directives and Regulations
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive
2001/95/EC (GPSD) Ürün Güvenliği Direktifi / Product Safety Directive

Ürün Ticari Markası / Product Commercial Brand

ZAZA MEDICA ZAZAMED MEDICAL

Harmonize Standartlar / Harmonized Standards
TS EN 14126 Koruyucu giyecekler - Enfektif ajanlara karşı koruyucu giyecekler için performans kuralları ve deney metotları- Protective clothing – Performance requirements and tests methods for protective clothing against infective agents
TS EN ISO 13982-1 Katı parçacıklara karşı kullanılan koruyucu giyecekler - Bölüm 1: hava ile yayılan katı parçacıklı kimyasal maddelere karşı vücudun tamamında koruma sağlayan kimyasal koruyucu giyecekleri için performans kuralları -Protective clothing for use against solid particulate chemicals – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airbone solid particulate chemicals
TS EN 13034+A1 Sıvı kimyasal maddelere karşı koruyucu giyecekler - Sıvı kimyasal maddelere karşı sınırlı koruma sağlayan koruyucu giyecekler için performans kuralları (tip 6 ve tip pb [6] donanımı)- Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
TS EN 1149-5 Koruyucu giysi - Elektrostatik özellikler - Bölüm 5: Malzeme performansı ve tasarım gereksinimleri- Protective clothing – Electrostatic properties – Part 5: Material performance and design requirements
TS EN ISO 13688 Koruyucu giyecekler-Genel özellikler- Protective clothing - General requirements
TS EN 14605+A1 Koruyucu giyecekler - Sıvı kimyasal maddelere karşı - Vücudun sadece bir kısmına koruma sağlayanlar (tip pb [3] ve tip pb [4]) dâhil, bağlantı yerleri sıvı geçirmez (tip 3) veya sprey geçirmez (tip 4) giyecekler için performans özellikleri- Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
DIN 32781:2010-08 Schutzkleidung - Schutzanzüge gegen Pflanzenschutzmittel / DIN 32781: 2010-08
Koruyucu kıyafetler - pestisitlere karşı koruyucu giysiler.
TS EN 1073-2 Radyoaktif bulaşmasına karşı koruyucu giysi-Kısım 2: Radyoaktif bulaşmasının ayrılmasına karşı havalanmayan koruyucu giysi için gereklilikler ve deney metotları- Protective clothing against radioactive contamination - Part 2: Requirements and test methods for airtight protective clothing against separation of radioactive contamination
ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices
TS EN 1041+A1 Tıbbi cihazlarla birlikte imalatçı tarafından sağlanan bilgiler/ Information supplied by the manufacturer of medical devices

AGAINST INFECTIVE AGENTS EN 14126 | NUCLEAR PARTICLE EN 1073-2 | ANTI-STATIC EN 1149-5 | REDUCED SPRAY EN 13034 | DRY PARTICLES ISO 13982-1 | CHEMICAL PROTECTION EN 13795

Sertifika No/ Certificate No: 2020-13241
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress
SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone
+90 532 546 21 21
Mail:
info@zazamedical.com

Beyan / *Declaration*
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğu altında, aşağıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ,2001/95/EC (GPSD) Ürün Güvenliği Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under responsibility of categorized as Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and 2001/95 / EC (GPSD) Product Safety Directive and Turkish regulations.

Ürün İsmi / *Product Name*
ISINMA CEKETİ / WARM UP JACKET

Ürünün Markası/ Product Brand

ZAZA MEDICA ZAZAMED MEDICAL

Direktifler / *Directives*
2001/95/EC (GPSD) Ürün Güvenliği Direktifi - 2001/95 / EC (GPSD) Product Safety Directive
93/42/EEC Tıbbi Cihaz Direktifi / 93/42/EEC Medical Device Directive

Harmonize Standartlar / Harmonized Standards
93/42/EEC Tıbbi Cihaz Yönetmeliği /SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
EN ISO 9001:2015 Kalite Yönetim Sistemi-Quality Management System
EN ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices

Sertifika No/ Certificate No: 2020-13245
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

European Commission
IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATES

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress
SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone
+90 532 546 21 21
Mail:
info@zazamedical.com

Beyan / *Declaration*
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğu altında, aşağıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under responsibility of categorized as Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and Turkish regulations.

Ürün İsmi / *Product Name*
CERRAHİ BONE / SURGICAL CAP

Ürünün Markası/ Product Brand

Direktifler / *Directives*
93/42/EEC Tıbbi Cihaz Direktifi / 93/42/EEC Medical Device Directive

Harmonize Standartlar / Harmonized Standards
93/42/EEC Tıbbi Cihaz Yönetmeliği / 93/42/EEC Medical Devices Regulation
EN ISO 9001:2015 Kalite Yönetim Sistemi-Quality Management System
EN ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices

Sertifika No/ Certificate No: 2020-13244
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress
SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone
+90 532 546 21 21
Mail:
info@zazamedical.com

Beyan / *Declaration*
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğu altında, aşağıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ,2001/95/EC (GPSD) Ürün Güvenliği Direktifi, (EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under responsibility of categorized as Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive, (EU) 2016/425 Personal Protective Equipment Directive and 2001/95 / EC (GPSD) Product Safety Directive and Turkish regulations.

Ürün İsmi / *Product Name*
BONE / BOUFFANT CAPS

Ürünün Markası/ Product Brand

Direktifler / *Directives*
2001/95/EC (GPSD) Ürün Güvenliği Direktifi - 2001/95 / EC (GPSD) Product Safety Directive
93/42/EEC Tıbbi Cihaz Direktifi / 93/42/EEC Medical Device Directive
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive

Harmonize Standartlar / Harmonized Standards
93/42/EEC Tıbbi Cihaz Yönetmeliği /SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
EN ISO 9001:2015 Kalite Yönetim Sistemi-Quality Management System
EN ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices

Sertifika No/ Certificate No: 2020-13242
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
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CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

EC DECLARATION OF CONFORMITY
AT UYGUNLUK BEYANI

Üretici/ Manufacturer
PRATİK İSTANBUL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ
Adres /Adress
SARIDEMİR MAH. RAGIP GÜMÜŞPALA CAD. AHENK İŞ HANI NO: 29 A FATİH/ İSTANBUL / TÜRKİYE
Telefon / Phone
+90 532 546 21 21
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info@zazamedical.com

Beyan/Statement
Burada, AB tarafından sınıflandırılan Üretici, Dağıtıcı / Temsilci olarak kendi sorumluluğu altında, aşağıda ismi ve modeli geçen ürünlerin, 93/42/EEC Tıbbi Cihaz Direktifi ,2001/95/EC (GPSD) Ürün Güvenliği Direktifi, (EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi ve yönetmeliklerine uygun olarak üretildiğini beyan ederiz.
Here, we declare that the products listed above are manufactured under responsibility of categorized as Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive, (EU) 2016/425 Personal Protective Equipment Directive and 2001/95 / EC (GPSD) Product Safety Directive and Turkish regulations.

Ürün İsmi / Product Name
GALOŞ / SHOE COVERS

Ürün Tipi / Types of Product
HİJYENİK - LASTİKLİ - SIVI GEÇİRMEZ - TEK KULLANIMLIK - ZEMİNDE KAYMA YAPMAZ
HYGIENIC - ELASTIC - LIQUID PROOF - DISPOSABLE –P.E-NONWOVEN -DOESN'T SLIP ON THE GROUND

Ürünün Markası / Brand Of The Product

Direktif ve Yönetmelikler / Directives and Regulations
2001/95/EC (GPSD) Ürün Güvenliği Direktifi / Product Safety Directive
93/42/EEC Tıbbi Cihaz Direktifi / 93/42/EEC Medical Device Directive
(EU) 2016/425 Kişisel Koruyucu Ekipmanlar Direktifi / Personal Protective Equipment Directive

Harmonize Standartlar / Harmonized Standards
93/42/EEC Tıbbi Cihaz Yönetmeliği /SINIF I (Steril Olmayan) Medical Devices Regulation / Class I (Non Sterile)
EN ISO 9001:2015 Kalite Yönetim Sistemi-Quality Management System
EN ISO 13485:2016 Tıbbi Cihazlar İçin Kalite Yönetim Sistemi / Quality Management System for Medical Devices

Sertifika No/ Certificate No: 2020-13243
Sertifika Tarihi /Certificate *Date*: 18.01.2021
Sertifika Bitiş Tarihi /Certificate Expiration *Date*: 18.01.2022

Accredited System Certification Approval

IFC Global Certification Inspection & Training Services GmbH
Hohenzollernring 50 / 50672 Köln / Germany
info@ifcglobal.de

CERTIFICATE / ZERTIFIKAT / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFIKÁ

ZAZA
MEDICAL

LONDON, UNITED KINGDOM

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Company registered in England No: 06958087
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Phone : +44 203 488 0031 / +44 770 248 0316
Address : 2 Meyrick Road, NW10 2EJ, London, UK

ISTANBUL, TURKEY

Pratik Istanbul Import & Export Ltd.
VKN : 7330674060
Phone : +90 532 546 2121
Address : Demirtas Mah. Hayriye Hanim Sk.
No:7/3-4 Fatih, Istanbul, TR

www.zazamedical.com