A&Z MED

Personal Protective Equipment

OLI-2023
SURGICAL GOWN

STANDARDS: EN 13795-1

ISO-9001:2015 ISO-13485:2016

MDD - 103

CE

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A&Z A&ZMED
Personal Protective Equipment

OLI-2023
SURGICAL GOWN

TR

KULLANIM TALİMATLARI

Sağlık kurumunun ayakta tedavi ve yatan hasta servisinde.

ÜRÜN BİLEŞENLERİ

İzolasyon önlüklerinin ana hammaddesi olarak Non-woven kumaş, kesme ve dikişle kullanılır.

DİKKAT, UYARI VE TAVSİYE

1. Sadece tek kullanımlık, kullanımdan sonra bertaraf edilmelidir.
2. Paket yıpranmış ya da delinmişse kullanmayın.
3. Uyarıcı yanıtlar veya olumsuz olaylar varsa lütfen kullanmayı bırakın.
4. Boğulma tehlikesini önlemek için, bu plastik torbayı bebeklerden ve çocuklardan uzak tutun. Bu poşeti beşiklerde, yataklarda, arabalarda veya oyun kalemlerinde kullanmayın. Bu çanta oyuncak değil.

KULLANIM İÇİN TALİMATLAR

1. Paketi açın ve ürünü çıkarın.
2. Bu önlüğü takmadan önce bedenini ve manşetleri kontrol edilmelidir.
3. Kullanımdan sonra içeriye dışarı çevirin, daha sonra bir "zararlı çöp" kova içine atın. [Depolama Koşulu]% 80 bağıl nemden az, iyi havalandırılmış, serin ve kuru bir depoda saklanır. Doğrudan güneş ışığından ve aşındırıcı gazdan kaçının.

EN

USE INSTRUCTIONS

Common isolation of outpatient service of medical institution and inpatient ward.

PRODUCT COMPONENTS

Non-woven fabric is used as the main raw material of Isolation Gown, which is made by cutting and sewing.

CAUTION, WARNING AND ADVICE

1. Single use only, disposal after use.
2. Do not use if the package is broken.
3. Please stop using if there are stimulus responses or adverse events.
4. To avoid danger of suffocation, keep this plastic bag away from babies and children. Do not use this bag in cribs, beds, carriages or play pens. This bag is not a toy.

INSTRUCTIONS FOR USE

1. Open the package and take out the product.
2. The seal of each cuff should be checked before wearing this gown.
3. Please flip inside to outside after use, then dispose into a "harmful garbage" bucket. [Storage Condition] Stored in a well-ventilated, cool and dry warehouse, less than 80% relative humidity. Avoid direct sunlight and corrosive gas.

FR

INSTRUCTIONS D'UTILISATION

Isolement commun des services ambulatoires de l'établissement médical et de la salle d'hospitalisation.

COMPOSANTS DU PRODUIT

Le tissu non tissé est utilisé comme matière première principale de la robe d'isolement qui est faite par coupe et couture.

ATTENTION, AVERTISSEMENT ET CONSEILS

1. Usage unique, élimination après utilisation.
2. Ne pas utiliser si l'emballage est brisé.
3. Veuillez cesser d'utiliser s'il y a des réponses de stimulus ou des événements indésirables.
4. Pour éviter tout risque d'étouffement, gardez ce sac en plastique loin des bébés et des enfants. N'utilisez pas ce sac dans des berceaux, des lits, des voitures ou des parcs de jeu. Ce sac n'est pas un jouet.

INSTRUCTIONS D'UTILISATION

1. Ouvrez l'emballage et retirez le produit.
2. L'étanchéité de chaque manchette doit être vérifiée avant de porter cette robe.
3. Veuillez retourner l'intérieur vers l'extérieur après utilisation, puis jeter dans un seau à «déchets dangereux».[Condition de stockage] Stocker dans un entrepôt bien ventilé, frais et sec, à moins de 80% d'humidité relative. Éviter la lumière directe du soleil et les gaz corrosifs.

DE

GEBRAUCHSANWEISUNGEN

Übliche Isolierung des ambulanten Dienstes medizinischer Einrichtungen und der stationären Station.

PRODUKTKOMPONENTEN

Hauptkomponente der Isolierkleidung ist Vliesstoff, der durch Schneiden und Nähen zusammengesetzt wird.

VORSICHTSMAßNAHMEN UND WARNHINWEIS

1. Nur zum einmaligen Gebrauchgeeignet. Nach Gebrauch zu entsorgen.
2. Nicht verwenden, wenn die Verpackung beschädigt ist.
3. Nicht mehr verwenden, wenn Reizreaktionen oder unerwünschten Ereignisse auftreten.
4. Um Erstickungsgefahr zu vermeiden, halten Sie diese Plastiktüte von Babys und Kindern fern. Verwenden Sie diesen Beutel nicht in Kinderbetten, Betten, Kinderwagen oder Laufställen. Diese Tüte ist kein Spielzeug.

GEBRAUCHSANWEISUNG

1. Öffnen Sie die Verpackung und nehmen Sie das Produkt heraus.
2. Das Siegel jeder Manschette sollte vor dem Tragen dieses Kittels überprüft werden.
3. Bitte nach Gebrauch von innen nach außen stülpen (auf links drehen) und dann im medizinischen Abfall entsorgen. Lagerbedingungen: in einem gut belüfteten, kühlen und trockenen Lagerhaus, weniger als 80% relative Luftfeuchtigkeit. Vermeiden Sie direkte Sonneneinstrahlung und korrosive Gase.

ES

INSTRUCCIONES DE USO

Aislamiento común del servicio ambulatorio de la institución médica y la sala de pacientes hospitalizados.

COMPONENTES DEL PRODUCTO

La tela no tejida se utiliza como materia prima principal de la Bata de Aislamiento, que está hecha por corte y costura.

PRECAUCIÓN, ADVERTENCIA Y CONSEJOS

1.Este material es para un solo y tiene que ser desechado después de cada uso.
2.No lo use si el paquete está roto.
3.Deje de usar si hay respuestas de estímulo o eventos adversos.
4.Para evitar el peligro de asfixia, mantenga esta bolsa de plástico lejos de bebés y niños. No use esta bolsa en cunas, camas, carruajes o corrales. Esta bolsa no es un juguete.

INSTRUCCIONES DE USO

1.Abra el paquete y tome el producto.
2.El sello de cada mangito debe verificarse antes de usar esta bata.
3.Voltee de adentro hacia afuera después del uso, luego deséchelo en la "basura dañina". [Condición de Almacenamiento] Debe almacenarse en un almacén bien ventilado, fresco y seco, con una humedad relativa inferior al 80%. Evite la luz solar directa y el gas corrosivo.

IT

ISTRUZIONI PER L'USO

Isolamento comune del servizio ambulatoriale di istituto medico e reparto di degenza.

COMPONENTI DI PRODOTTO

Tessuto "non tessuto" viene utilizzato come materia prima principale del camice da isolamento che viene prodotto tagliando e cucendo.

CAUTELA, AVVERTENZA E CONSIGLI

1. Esclusivamente monouso, smaltimento dopo l'uso.
2. Non utilizzare se il pacchetto è rotto.
3. Interrompere immediamente l'uso se ci sono risposte allo stimolo o eventi avversi.
4. Per evitare rischi di soffocamento, tenere fuori dalla portata dei bambini questo sacchetto di plastica. Non utilizzare questa borsettina in lettino, carrozze o box. Questa borsettina non è un giacottolo.

ISTRUZIONI PER L'USO

1. Aprire il pacchetto e estrarre il prodotto.
2. Il sigillo di ciascun bracciale dovrebbe essere controllato prima di indossare questo camice.
3. Rovesciare dall'interno all'esterno dopo l'uso, quindi smaltire in un secchiello "rifiuto nocive".
[Condizioni di conservazione] Conservato in un magazzino ben aerato, fresco e asciutto all'umidità inferiore all'80%. Evitare la luce solare diretta e la presenza di gas corrosivi.

PT

INSTRUÇÕES DE USO

Isolamento comum do serviço ambulatorial da instituição médica e da enfermaria.

COMPONENTES DO PRODUTO

O tecido não tecido é usado como principal matéria-prima da Bata de Isolamento, que é feita por corte e costura.

ATENÇÃO, AVISO E CONSELHOS

1. Este material é apenas para um uso e deve ser descartado após cada uso.
2. Não use se o pacote estiver quebrado.
3. Interrompa o uso se houver respostas de estímulo ou eventos adversos.
4. Para evitar o risco de asfixia, mantenha este saco plástico longe de bebês e crianças. Não use esta bolsa em berços, camas, carruagens ou brinquedos. Esta bolsa não é um brinquedo.

INSTRUÇÕES DE USO

1. Abra a embalagem e retire o produto.
2. O selo de cada manga deve ser verificado antes de usar esta Bata.
3. Vire de dentro para fora após o uso, depois descarte-o no "lixo prejudicial".
[Condição de Armazenamento] Deve ser armazenado em um armazém bem ventilado, fresco e seco, com umidade relativa do ar inferior a 80%. Evite luz solar direta e gás corrosivo.

RU

ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ

Общая изоляция амбулаторной службы медицинского учреждения и стационарного отделения.

КОМПОНЕНТЫ ПРОДУКТА

В качестве основного сырья Isolation Gown используется нетканный материал, который изготавливается путем резки и сшивания.

МЕР ПРЕДОСТОРОЖНОСТИ, ПРЕДУПРЕЖДЕНИЯ И СОВЕТЫ

1.Только для одноразового использования. Утилизация после использования.
2. Не использовать в случае повреждения упаковки.
3. Прекратите использование в случае появления стимул-реакции или побочного воздействия.
4. Для того, чтобы избежать опасности удушья, держите пластиковый пакет подальше от младенцев и детей. Не используйте эту сумку в креслах, кроватях, колясках или манежах. Эта сумка не игрушка.

УКАЗАНИЯ ПО ИСПОЛЬЗОВАНИЮ

1.Откройте упаковку и извлеките продукт.
2. Перед ношением этого медицинского халата необходимо проверить уплотнение на каждом манжете.
3. Пожалуйста, выверните внутреннюю часть наружу после использования, а затем выбросьте в контейнер "опасных отходов".
[Условия хранения] Хранить в хорошо проветриваемом, прохладном и сухом месте при относительной влажности менее 80%. Избегайте прямых лучей солнца и агрессивных газов.

AR

تعليمات الاستخدام

العزلة المشتركة لخدمة العيادات الخارجية للمؤسسة الطبية وجناح المرضى الداخليين

مكونات المنتج

يتم استخدام الأقمشة غير المنسوجةكمواد خام رئيسية لثوب العزل، والتي تتم صناعتها عبر تقطيع الأقمشة ومن ثم خياطتها

الإحتياطات الاحتياطية أو التحذيرية والإرشادات

1.للاستخدام الفردي فقط، يتم التخلص منها بعد الاستخدام
2.لا تقم باستخدام المنتج إذا كانت الحزمة أو العلبة متضرّرة
3.يرجى التوقف عن الاستخدام إذا كانت هناك تفاعلات محفزة أو تفاعلات ضارةسلبية
4.لتجنب خطر الاختناق، احتفظ بهذه الحقيبة البلاستيكية بعيدًا عنالأطفال والرضع
لا تستخدم هذه الحقيبة في أسرة الأطفال أو الأسرّة أو العربات أو أقفاصاللعب المخصصة للأطفال. هذه الحقيبة ليست لعبة

تعليمات الاستخدام

1.افتح العبوة وأخرج المنتج
2.يجب فحص الختم الموجود على كل طرف قبل استعمال ثوب العزل
3.بعد الاستخدام، يرجى قلب داخل ثوب العزل إلى الخارج ثم التخلص منه في حاويات "القمامة الضارة". [في حال التخزين] تخزّن في مستودع جيّد التّهوية،بارد وجاف، تكون الرطوبة النسبية فيه أقل من 80%. تجنب تعرض المنتج لأشعة الشمس المباشرة أو الغازات المسببة للتآكل

MANUFACTURER:
İBİŞLER TEKSTİL A.Ş.
Orhangazi Mah Tunç Cad. No:5
Esenyurt / Istanbul - TURKEY
Phone: +90 212 602 04 05
Website : www.ibisler.com
email : info@ibisler.com

Do not wash.	Do not dry clean.	Single use.
Do not iron.	Do not machine dry.	Do not bleach.
		NON STERILE

Made in Turkey

8 682742 370720

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD - 103

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ

at the following address

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt / İSTANBUL

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name : A&Z MED, **Model:** OLI - 2023
(Standard Performance)are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/dry), Bioburden, Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 08/05/2020 and valid until 07/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL –08/05/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

MANUFACTURER
İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ
Gürsel Mahallesi Tümleç Caddesi No:1 Kağıthane ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name : A&Z MED, **Model:** OLI - 2023

Surgical Gowns with standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Class I)

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetration (Dry/Wet) and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

İlhan İBİŞ
General Manager
ISTANBUL 08/05/2020

CE