HANDEL FÜR
INDIVIDUELLE
MEDIZINPRODUKTE

Technisches Datenblatt Einweg Isolationskittel

Einweg Isolationskittel

LT111FYC, SS, 40 gr/m^2

Produktbeschreibung

- SS Vliesstoff,
- Gewicht: 40g / m^2
- Flüssigkeitsbeständ
- Atmungsaktiv
- Halsgebunden oder Klettverschluss
- Mit gestrickten Manschetten oder Bandmanschetten
- Mit Band an der Taille
- Einzelverpackung

Material

2-lagiger SS Aufbau: Spinnvlies – Spinnvlies

Gewicht: 116 g

Zertifizierung

CE-Zertifikat nach EN13795:2019

P&S Handels GmbH
Auf der Gemarke 1
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Gebrauchsanweisung

HANDEL FÜR
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GEBRAUCHSANWEISUNG

Einweg-Kittel - Stufe 1

Verwendungszweck

Die Kittel können zum Beispiel als persönliche Schutzausrüstung, im Gesundheitswesen verwendet werden. Sie werden verwendet, um den Träger vor der Ausbreitung von Infektionen oder Krankheiten zu schützen, wenn der Träger mit potenziell infektiösem flüssigem und festem Material in Kontakt kommt. Sie können auch verwendet werden, um zu verhindern, dass der Kittelträger Mikroorganismen überträgt, die gefährdeten Patienten, wie z. B. Patienten mit geschwächtem Immunsystem, schaden könnten. Kittel sind ein Teil einer umfassenden Strategie zur Infektionskontrolle

- Stufe 1: Minimales Risiko, das beispielsweise während der Grundversorgung, der Standardisolierung, des Deckmantels für Besucher oder in einer medizinischen Standardeinheit verwendet werden kann
- Wird für minimale Risikosituationen verwendet
- Bietet eine leichte Barriere gegen kleine Mengen des Eindringens von Flüssigkeit
- Anwendbarkeit: Grundversorgung, Standardklinik

Kontraindikationen

KEINE BEKANNT

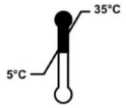
Sicherheitstipps

- Wenn sich an den Kittel Löcher oder Risse befinden, verwenden Sie diese nicht und entsorgen Sie sie.
- Wenn die Haltbarkeit abgelaufen ist, sollten die Kittel nicht verwendet werden.

Lager

Wir empfehlen Lagerbedingungen zwischen 5° C und 35 ° C. Nicht nach Ablaufdatum verwenden.

Grafische Symbole

 Halten Sie zwischen 5 und 35 Grad Celsius	 Chargen-nummer	 Hersteller	 Zertifizierungen
 **Verfallsdatum**	 **Herstellungs-datum**	 **Verwenden Sie den Inhalt nicht falls das Paket beschädigt ist**	 **Nicht wiederverwenden**
SKU-Modell **Katalognummer**		 Nicht waschen	

Hergestellt durch:
INTEGRAS SAVUNMA VE MEDİKAL A.Ş.
Mutlukent Mah. 2001 Sokak No:2 Cankaya, Ankara, TURKEY
Loxtay is the registered Trademark of Integras.

Importiert und vertrieben durch:
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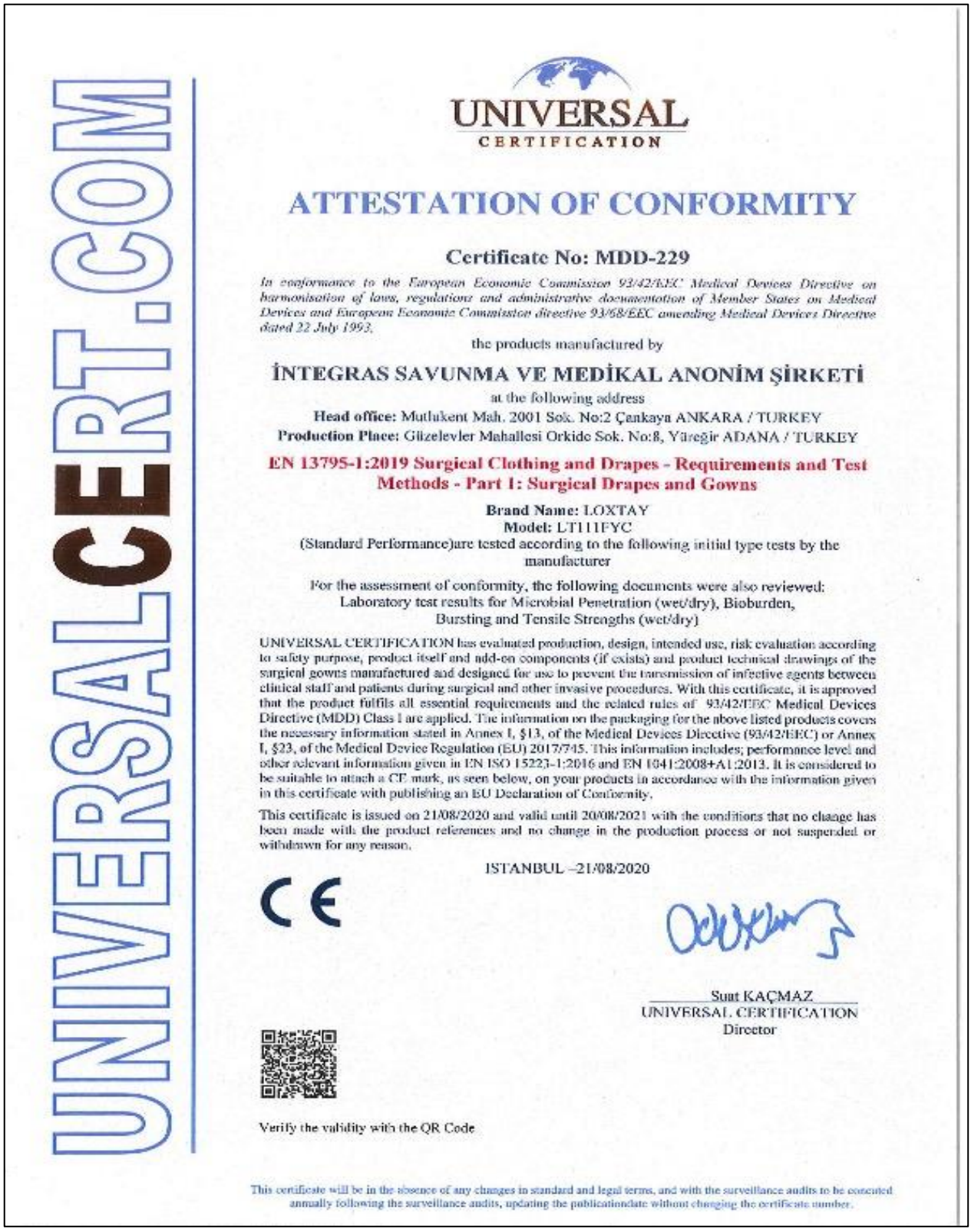
Zertifikat



UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-229

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

İNTEGRAS SAVUNMA VE MEDİKAL ANONİM ŞİRKETİ

at the following address

Head office: Mutlukent Mah. 2001 Sok. No:2 Çankaya ANKARA / TURKEY
Production Place: Güzelevler Mahallesi Orkide Sok. No:8, Yüreğir ADANA / TURKEY

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

Brand Name: LOXTAY
Model: LT111FYC
(Standard Performance)ure 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 21/08/2020 and valid until 20/08/2021 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.

ISTANBUL –21/08/2020

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 executed annually following the surveillance audits, updating the publicationdate without changing the certificate number.

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EU DECLARATION OF CONFORMITY

MANUFACTURER

İNTEGRAS SAVUNMA VE MEDİKAL ANONİM ŞİRKETİ

Head office: Mutlukent Mah. 2001 Sok. No:2 Çankaya ANKARA / TURKEY
Production Place: Güzelevler Mahallesi Orkide Sok. No:8, Yüreğir ADANA / TURKEY

PRODUCT DESCRIPTION

Brand Name: LOXTAY
Model: LT111FYC

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 - 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.

General Manager
21/08/2020

CE

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