



**SCIENTIFIC
LABORATORY
SUPPLIES**

DISPOSABLE ISOLATION GOWN

ONE SIZE | NON STERILE

BAYTEKS 1422A FABRIC | TOLERANCE: +/-1g

| | | |
|----------|------------------|-------|
| A | Length | 115cm |
| B | 1/2 Chest | 71cm |
| C | Width | 68cm |
| D | Sleeve Width | 58cm |
| E | Sleeve Length | 28cm |
| F | Top to the Waist | 45cm |
| G | Waist Tie Length | 150cm |
| H | Neck Tie Length | 110cm |
| I | Cuff (RIB) | 6,5cm |



1 PIECE PER BAG

ISO 13485-KPR0242001

PRODUCT CODE: COV2020

England & Wales: 0115 982 1111
Scotland: 01236 431 857

slsinfo@scientific-labs.com
www.scientificlabs.co.uk

CERTIFICATION(S)

CERTIFICATE OF CE

NVA QUALITY CERTIFICATION



TECHNICAL REVIEW FILE DECLARATION

We hereby declare ,Manufacturer, Distributor /EU Representative:

MİNATEKS TEKSTİL MEDİKAL SAN.VE TİC.LTD.ŞTİ.
PETROLSB MAH. 4 CAD. KURTOĞLU YAPI NO: 8 A / 8 MERKEZ/ ADIYAMAN / TÜRKİYE

that the following described product in our delivered version complies with appropriate basic safety and health requirements based Medical Devices Directive 93/42/EC on its design and type as brought into circulation by us. In case of alteration of the product not agreed upon by us, this declaration will lose its validity.

Teslim edilen versiyonumuzda aşağıda açıklanan ürünün, tarafımızdan delayama sorumluluğuyle sağlıya tasarımı ve tipine ilişkin Tıbbi Cihazlar Direktifi 93/42/EC uygun temel güvenlik ve sağlık gerekliliklerine uygun olduğunu. Üzerinde anlaşılmaya varılmayan ürünün değiştirilmesi halinde, bu beyan geçerliliğini yitirecektir.

Description Of The Product/Product Part : DISPOSABLE SURGICAL MASK
QUARANTINE DRESS AND OVERALLS
ÜRÜNÜN / ÜRÜNÜN TANIMI : TEK KULLANIMLIK CERRAHİ MASKE
KARANTİNA ELBİSESİ VE TULUMU

Product Type / Ürün Tipi : 1 LAYER SURGICAL MASK / 1 KATLI CERRAHİ MASKE
3 LAYER SURGICAL MASK / 3 KATLI CERRAHİ MASKE
LAMINATED DISPOSABLE / LAMİNELİ TULUM
NON-LAMINATED DISPOSABLE / LAMİNESİZ TULUM

Product Commercial Brand / Marka : MİNATEKS

Applicable EC Directives : MEDICAL DEVICES DIRECTIVE 93/42/EC
Geçerli AT Direktifleri : TIBBİ CİHAZLAR DİREKTİFİ 93/42/EC

Applicable Harmonised Standards : TS EN 14683+AC
Geçerli AT Direktifleri

Applicable National Technical Standards and Specifications

Uygulanabilir Ulusal Teknik Standartlar ve Özellikler

| | |
|--|--------------|
| Classifications / Sınıflandırmaları | : CLASS-1 |
| Certificate Number / Sertifika Numarası | : 20040634 |
| Certificate Code / Sertifika Kodu | : MİNATEKS |
| Certificate Issue Date / Sertifika Yayın Tarihi | : 06.04.2020 |
| Certificate Validity Date / Sertifikanın Geçerlilik Tarihi | : 06.04.2021 |
| EU Representative / AB Temsilcisi | |

(Authorized Signature and Title) / (Yetkili İmza ve Ünvan)



System effectively and timely surveillance audits this document is valid as long as the 1-years. NVA control the conduct of standards. Although due competence, including gross negligence will not accept responsibility. This document or proprietary rights owned by NVA and must be returned upon request. Sistem etkin ve zamanında denetimler bu belgeyi geçerli tutar. NVA kontrol standartların uygulanmasını. Yeterli yeterlilik, dâhil olmak üzere, bu belgeyi 1 yıl geçerli tutar. NVA kontrol yetkileri NVA'ya aittir ve istenildiğinde iade edilmelidir.

NVA QUALITY CERTIFICATION



SERTİFİKA / CERTIFICATE

MİNATEKS TEKSTİL MEDİKAL SAN.VE TİC.LTD.ŞTİ.
PETROLSB MAH. 4 CAD. KURTOĞLU YAPI NO: 8 A / 8 MERKEZ/ ADIYAMAN / TÜRKİYE

Kuruluşunun "44 Dış Giyim Eşyası İmalatı, Dokuma, Örmek (Trikotaj) Ve Tiğ İşleri (Kroşe) Kumandan Olanlar (Kaban, Palto, Çeket, Pantolon, Takım Elbise, Döpiyes, Anorak, Yağmurluk, Gece Kıyafetleri) (Terzilerin Faaliyetleri Hariç) Her Türü Tıbbi Ve Cerrahi Alet Ve Malzemelerini Medikal Malzemelerini (Korse, Koruyucu Yüz Maskesi Ve Cerrahi Maske, Koruyucu Tulum, Bone, Bandana, Hasta Yatığı, Yastık, Minder, Çarşaf, Nevresim, Sodye Örtüsü, Uyku Bandı, Önlük, Güloz) Toptan Ve Perakende Alım Satımı Ve İmalatını Yapmak İhali Ve İhracatı "44 Kapsamı için

For scope "44 Outerwear Manufacturing, Weaving, Knitting (Knitting) and Crochet (Crochet) Fabric (Coats, Coats, Jackets, Pants, Suits, Doubles, Anorak, Raincoats, Nightwear) (Excluding the Activities of the Tailors) All Kinds of Medical and Surgical Instruments and Materials, Medical Materials) (Corset, Protective Face Mask and Surgical Mask, Protective Apron, Bone, Bandana, Bed, Pillow, Cushion, Bed Sheet, Duvet Cover, Stretcher Cover, Sleeping Band, Apron, Shoe Covers) Import And Export Of Wholesale And Retail Buying And Selling "44

ISO 13485 : 2016

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ Medical Devices Quality Management System

Kuruluşunu ve uyguladığını belgelemek ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standartın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number : 20040635
Sertifika Kodu / Certificate Code : MİNATEKS
Sertifika Yayın Tarihi / Certificate Issue Date : 06.04.2020
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 06.04.2021
Sertifika Periyodu / Certificate Period : 1 Yıl / 1 Year



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Sistem etkin ve zamanında denetimler bu belgeyi geçerli tutar. NVA kontrol standartların uygulanmasını. Yeterli yeterlilik, dâhil olmak üzere, bu belgeyi 1 yıl geçerli tutar. NVA kontrol yetkileri NVA'ya aittir ve istenildiğinde iade edilmelidir.

www.nva.com.tr info@nva.com.tr

CERTIFICATE OF MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM



2020

CERTIFICATE OF REGISTRATION

This certifies that:

MINATEKS TEKSTIL MEDI LTD STI
Petrol OSB Mah. 4
Cad Kurtoglu Yapi No. 8A 8 Merkez
Adiyaman , TR

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number: **10074572**
Device Classification Name: **FACE MASK (EXCEPT N95 RESPIRATOR)**
FOR GENERAL PUBLIC/HEALTHCARE
PERSONNEL PER IIE GUIDANCE
QKR
Product Code: **Registrar Corp**
Official Correspondent and U.S. Agent: **144 Research Drive, Hampton, Virginia, 23666, USA**
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
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David Lenfanz
Executive Director
Registrar Corp
Dated: June 1, 2020

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2020

CERTIFICATE OF REGISTRATION

This certifies that:

MINATEKS TEKSTIL MEDI LTD STI
Petrol OSB Mah. 4
Cad Kurtoglu Yapi No. 8A 8 Merkez
Adiyaman , TR

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number: **10074572**
Device Classification Name: **SUIT, SURGICAL**
Product Code: **FXO**
Regulation Number: **878.4040**
Official Correspondent and U.S. Agent: **Registrar Corp**
144 Research Drive, Hampton, Virginia,
23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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David Lenfanz
Executive Director
Registrar Corp
Dated: June 1, 2020

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2020

CERTIFICATE OF REGISTRATION

This certifies that:

MINATEKS TEKSTIL MEDI LTD STI
Petrol OSB Mah. 4
Cad Kurtoglu Yapi No. 8A 8 Merkez
Adiyaman , TR

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number: **10074572**
Device Classification Name: **NON-SURGICAL ISOLATION**
GOWN
Product Code: **OEA**
Regulation Number: **878.4040**
Official Correspondent and U.S. Agent: **Registrar Corp**
144 Research Drive, Hampton, Virginia,
23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Lenfanz
Executive Director
Registrar Corp
Dated: June 1, 2020

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SERTİFİKA / CERTIFICATE

MİNATEKS TEKSTİL MEDİKAL SAN. VE TİC. LTD. ŞTİ.
PETROLOSB MAH. 4 CAD. KURTOĞLU YAPI NO: 8 A / 8 MERKEZ/ ADIYAMAN / TURKEY

Kuruluşunun " Diş Giyim Eşyası İmalatı, Dokuma, Örne(Trikota) Ve Tığ İşi (Kroşe) Kumaktan Olanlar (Kaban, Paltó, Çeket, Pantolon, Takım Elbise, Döpiyes, Anorak, Yağmurluk, Gece Kıyafetleri) (Terzilerin Fasliyeleri Hariç) Her Türlü Tıbbi Ve Cerrahi Alet Ve Malzemelerini Medikal Malzemelerini (Korse, Koryucu Yüz Maskesi Ve Cerrahi Maske ,Koryucu Tulum, Bone, Bandana, Hasta Yatağı, Yastık, Minder, Çarşaf, Nevresim, Sedyer Örtüsü, Uykü Bandı, Önlük, Galos) Toptan Ve Perakende Alım Satımı Ve İmalatını Yapmak İhali Ve İhraatı " **Kapsamı için**

For scope " *Outerwear Manufacturing, Weaving, Knitting (Knitting) and Crochet (Crochet) Fabric (Coats, Coats, Jackets, Pants, Suits, Doubles, Anorak, Raincoats, Nightwear) (Excluding the Activities of the Tailors) All Kinds of Medical and Surgical Instruments and Materials, Medical Materials) (Corset, Protective Face Mask and Surgical Mask, Protective Jumpsuit, Bone, Bandana, Bed, Pillow, Cushion, Bed Sheet, Dixet Cover, Strucher Cover, Sleeping Band, Apron, Shoe Covers) Import And Export Of Wholesale And Retail Buying And Selling "*

ISO 9001:2015

KALİTE YÖNETİM SİSTEMİ
Quality Management System

Kurduğunu ve uyguladığını belgelemek ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standartın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number : 20040633
Sertifika Kodu / Certificate Code : MİNATEKS
Sertifika Yayın Tarihi / Certificate Issue Date : 06.04.2020
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 06.04.2021
Sertifika Periyodu / Certificate Period : 1 Yıl / 1 Year


Certification Manager
Belgeleme Müdürü

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www.nva.com.tr nva@nva.com.tr

CERTIFICATE
OF QUALITY
MANAGEMENTCERTIFICATE OF
MASK AND OVERALL
QUALITY AND TEST

CERTIFICATE

| | |
|-----------------------------|--|
| CERTIFIED PRUCTS | : TEK KULLANIMLIK CERRAHİ MASKE KARANTİNA ELBİSESİ VE TULUMU DISPOSABLE SURGICAL MASK QUARANTINE DRESS AND OVERALLS |
| KIND OF SAMPLE | : 55 GSM NEFES ALABİLİR LAMİNASYON ÜRÜNÜ 55 GSM BREATHABLE NONPRINTED LAMINATION PRODUCT |
| MANUFACTURER / DISTRIBUTOR | : MİNATEKS TEKSTİL MEDİKAL SAN.VE TİC.LTD.ŞTİ. PETROLOSB MAH. 4 CAD. KURTOĞLU YAPI NO: 8 A / 8 MERKEZ ADIYAMAN / TURKEY |
| NUMBER OF CERTIFICATE | : KPR 042001 |
| TEST PROGRAM | : Tested On Hazardous Materials And Components Tehlikeli Madde Ve Bileşenler Üzerinde Test Edilmiştir |
| TEST RESULT | : The products fulfill the NVA test criteria. For further details see the reports. Ürünler NVA Test Kriterlerini Karşılar. ISO 13027 Hijyen Ve Sanitasyon |
| VALIDITY OF THE CERTIFICATE | : 04.2020 |


Certification Manager
Belgeleme Müdürü

System effectively and timely surveillance audits this document is valid as long as the 1-year, NVA control the conduct of standards, Although due care and compliance, including gross negligence will not accept responsibility. This document or proprietary rights owned by NVA and must be returned upon request.

Sistem etkin bir şekilde süratle ve zamanında denetimler bu belge 1 yıl geçerlidir. NVA denetim yürütülmesinde gerekli özen ve titizlikle çalışırken yine de dikkatsizlikler dahil sorumluluk kabul etmeyebilir. Bu belgenin mülkiyeti NVA aittir ve istenildiğinde iade edilebilir.
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CERTIFICATE OF CUSTOMER SATISFACTION MANAGEMENT

NVA QUALITY CERTIFICATION



SERTİFİKA / CERTIFICATE

MİNATEKS TEKSTİL MEDİKAL SAN.VE TİC.LTD.ŞTİ.
PETROLOSB MAH. 4 CAD. KURTOĞLU YAPI NO: 8 A / 8 MERKEZ/ ADIYAMAN / TURKEY

Kuruluşunun “ Dış Giyim Eşyası İmalatı, Dokuma, Orme(Trikotaj) Ve Tiğ İşi (Kroşe) Kumaşın Olanlar (Kaban, Palto, Çeket, Pantolon, Takım Elbise, Döpiyes, Anorak, Yağmurluk, Gece Kıyafetleri) (Terzilerin Faaliyetleri Hariç) Her Türlü Tıbbi Ve Cerrahi Alet Ve Malzemelerini Medikal Malzemelerini (Korse, Koruyucu Yüz Maskesi Ve Cerrahi Maske ,Koruyucu Tulum, Bone, Bandana, Hasia Yatağı, Yastık, Minder, Çarşaf, Nevresim, Sedyeye Ortusu, Uykü Bandı, Önlük, Galoş) Toplan Ve Perakende Alım Satımı Ve İmalatını Yapmak İhtali Ve İhracatı ” **Kapsamı için**

For scope “ *Outerwear Manufacturing, Weaving, Knitting (Knitting) and Crochet (Crochet) Fabric (Coats, Coats, Jackets, Pants, Suits, Doubles, Anorak, Raincoats, Nightwear) (Excluding the Activities of the Tailors) All Kinds of Medical and Surgical Instruments and Materials, Medical Materials) (Corset, Protective Face Mask and Surgical Mask, Protective jumpsuit, Bone, Bandana, Bed, Pillow, Cushion, Bed Sheet, Duvet Cover, Stretcher Cover, Sleeping Band, Apron, Shoe Covers) Import And Export Of Wholesale And Retail Buying And Selling* ”

ISO 10002:2018

MÜŞTERİ MEMNUNİYETİ YÖNETİM SİSTEMİ Customer Satisfaction Management System

Kurduğunu ve uyguladığını belgelemek ve NVA tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standartın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by NVA it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number : 20040632
Sertifika Kodu / Certificate Code : MİNATEKS
Sertifika Yayın Tarihi / Certificate Issue Date : 06.04.2020
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 06.04.2021
Sertifika Periyodu / Certificate Period : 1 Yıl / 1 Year



Sistem etkin bir şekilde uygulanmış ve denetim sonuçları bu belgeyi doğrulamıştır. NVA denetim sonuçlarında yer alan ve yetkililer tarafından sağlanan bilgilerle ilgili sorumluluk kabul etmezler. Bu belgenin etkinliği sadece NVA tarafından kontrol edilebilir.

Sistem etkin bir şekilde uygulanmış ve denetim sonuçları bu belgeyi doğrulamıştır. NVA denetim sonuçlarında yer alan ve yetkililer tarafından sağlanan bilgilerle ilgili sorumluluk kabul etmezler. Bu belgenin etkinliği sadece NVA tarafından kontrol edilebilir.

| HÜNER NANO TEKSTİL PLASTİK SAN. VE TİC. LTD. ŞTİ. | | ANALİZ SERTİFİKASI (CERTIFICATE OF ANALYSIS) | | FOC DAKKS | |
|---|---|---|-------------------------|---------------------------------|------------------------------|
| URETİM KODU (PRODUCT CODE) | B2021300157 | | | | |
| URETİM İSMİ (PRODUCT NAME) | 55 GSM BREATHABLE NONPRINTED LAMINATION PRODUCT | | | | |
| MÜŞTERİ (CUSTOMER) | | | | | |
| TARİH (DATE) | 14.02.2020 | | | | |
| TEST SONUÇLARI (TEST RESULTS) | | | | | |
| TEST (REQUIREMENT) | BİRİM (UNIT) | HEDEF (TARGET) | TOLERANS (TOLERANCE) | TEST ORTALAMASI (AVERAGE) | TEST METODU (TEST METHOD) |
| Nonwoven Gramajı (Nonwoven Grammage) | [g/m ²] | 35 | ± 1 | 35,8 | EDANA 40.3-90 |
| PE Gramajı (PE Grammage) | [g/m ²] | 18 | ± 1 | 18,1 | EDANA 40.3-90 |
| Tutkal Gramajı (Hotmelt Grammage) | [g/m ²] | 2 | ± %20 | 2,15 | EDANA 40.3-90 |
| Toplam Gramajı (Total Grammage) | [g/m ²] | 55 | ± 5 | 56,05 | EDANA 40.3-90 |
| Gerilme Direnci MD (Tensile Strength MD) | [N/25mm] | 60 | ± %20 | 67,5 | EDANA 20.2.89 |
| Gerilme Direnci TD (Tensile Strength TD) | [N/25mm] | 30 | ± %20 | 28,8 | EDANA 20.2.89 |
| MD Kopmada Uzama (Elongation at Break MD) | % | 70 | ± %20 | 77,5 | EDANA 20.2.89 |
| TD Kopmada Uzama (Elongation At Break TD) | % | 80 | ± %20 | 88,0 | EDANA 20.2.89 |
| MD Yırtılma Dayanımı (Tearing Resistance MD) | gf | 1100 | ± %20 | 1150,0 | ASTM B 1424 |
| TD Yırtılma Dayanımı (Tearing Resistance TD) | gf | 1800 | ± %20 | 1840,0 | ASTM B 1424 |
| Su Buharı Geçirgenlik (Water Vapour Transfer Rate) | g/(m ² .6 hours) | > 1500 | ± %20 | - | ASTM E 398 |
| Yapışma (Lam. Peeling Strength) | [N/25mm] | 2 | ± %20 | 2,15 | EDANA 401.0.R0 |
| Renk Analizi D50/2° (Spectrophotometry) | ΔE | < 2.5 | ± %20 | - | ISO 13655 |
| Opasite (Opacity) | % | - | ± %20 | - | ASTM D 1748 |
| Su Sütunu (Hydro Head) | [mmSS] | > 900 | ± %20 | (+2500) | DIN-EN 20811 |
| Aşınma Dayanımı (Abrasion Resistance Martindale) | [EMPA Standard] | 1_5 | ± 1 | 5 | EDANA 020.5.R0 |
| Baskı Toleransı (Printing Tolerance) | mm | < 0.5 | ± %20 | - | HNR |
| Kontrol Edilen (Controlled By) | | | | | |
| Onaylayan (Approved By) | | | | | |
| ABDULKADİR ÜÇPİNER | | | | | |


CERTIFICATE OF FABRIC ANALYSIS


IMAGES




TEK KULLANIMLIK CERRAHİ ÖNLÜK

DISPOSABLE SURGERY GOWN
EINWEG CHIRURGIE KLEIDER

 Cildin Nefes Almasını Sağlayan medikal özellikte spunlance malzemedir. (Nonwoven)
Önlüklerin kumaşı SS 40 gr materyali kumaş
Önlükler Uzun kollu, sırt bölgesi açık, diz altına kadardır.

 It is a medical spunlance material that allows the skin to breathe. (Nonwoven)
Apron fabric SS 40 g fabric
Aprons Long sleeves, open back, below the knee.

 Es ist ein medizinisches Spunlance-Material, das die Haut atmen lässt. (Nicht gewebt)
Stoff aus Schürzen SS 40 g-Stoff
Schürzen Lange Ärmel, offener Rückenbereich, unterhalb des Knies.

S M L XL

