


CAMICE MONOUSO
DISPOSITIVO
MEDICO SANITARIO
Surgical Gown
93 / 42 / EE MDD Clas 1
TS EN ISO 141262003/AC:2004
EN ISO 13982 - 1:2004/A:1:2010
EN 13034:2005+A1:2009
EN 1149-5:2018
SS
NONSTERIL
Bu ürün ÖZBERİM Tekstil ve Sanayi TİC. LTD. ŞTİ. tarafından üretilmiştir.

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Scheda Tecnica

Versione No.: 12 **Data Revisione: Ott 16,2018**

Nome Prodotto: Camice chirurgico sterile con rinforzo

1. Descrizione Generale Prodotto

Camice chirurgico fatto di SMS (tessuto non tessuto spunbond meltblown), con polsini in maglia, con cartone ai lacci della vita, libro pieghevole, avvolti in drappo PE, con velcro sul collo. Camice chirurgico con rinforzo sono rivestiti in PE con SMS nella parte anteriore del corpo e delle maniche per la resistenza ad acqua, sangue e alcol.

Camice chirurgico con marchio CE secondo la direttiva UE 93/42/CEE per i dispositivi medici. Il prodotto, dopo la sterilizzazione, è classificato come dispositivo medico di classe I.

Una valutazione della conformità è stata eseguita ed ha dimostrato di essere in regola con tutti i requisiti applicabili della direttiva di cui sopra.

Corrisponde ai requisiti della Norma Europea per abiti chirurgici DIN EN 13795(1-3)

2. Applicazione/ Indicazione

Monouso soltanto in procedure chirurgiche; esattamente adattate alle diverse esigenze a seconda del tipo di intervento chirurgico, varie misure sono disponibili per gli utenti.

3. Presentazioni

Camice chirurgico: apertura posteriore, si lega dietro, con polsino in maglia e velcro sul collo
Misure: M, L, XL, XXL
Colore: blu
Confezionato singolarmente in busta a strappo , sterilizzato ETO.

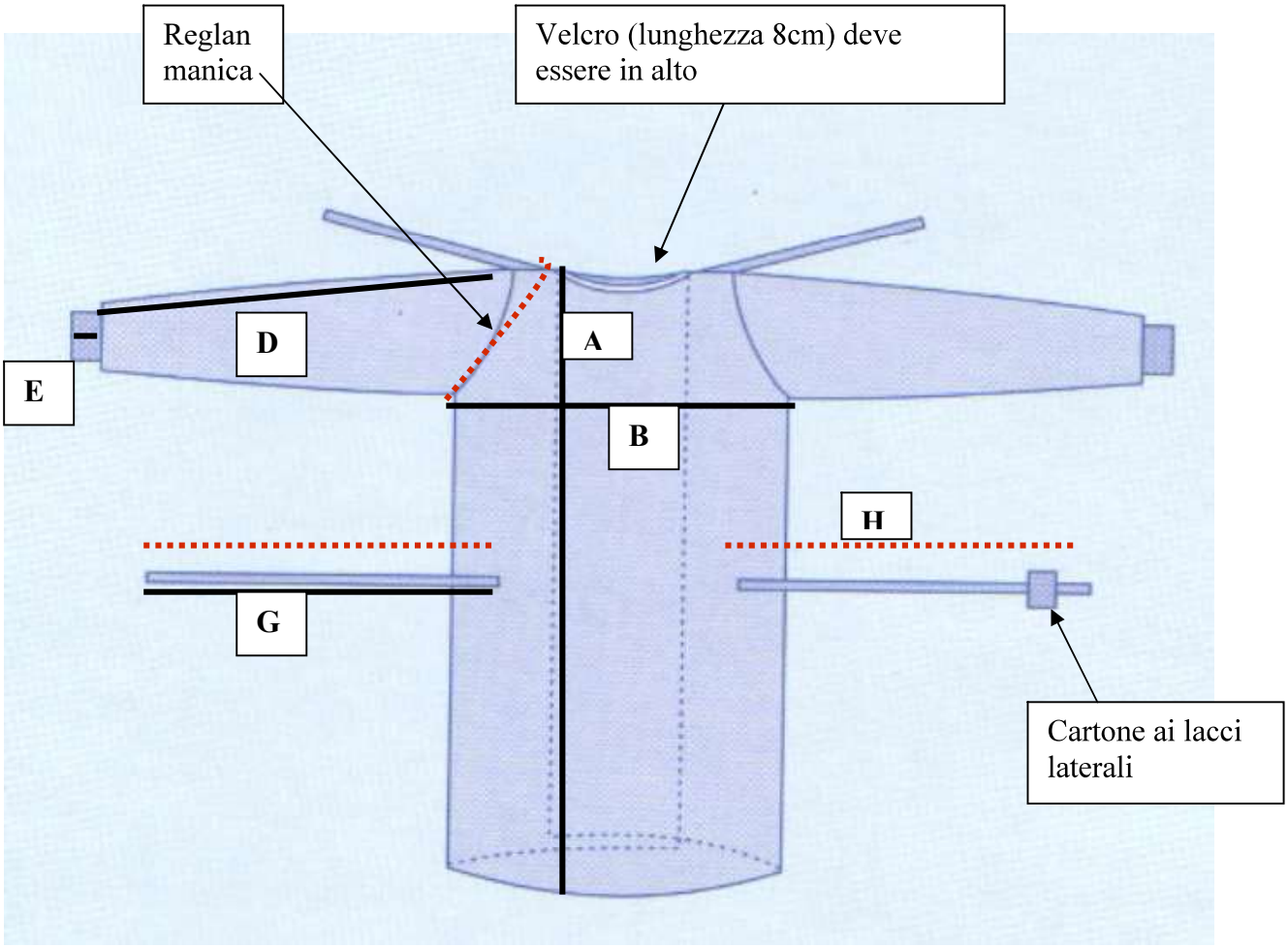
4. Charatteristiche Prodotto:

Composizione:
Camice chirurgico non contiene lattice di gomma naturale
- Materiale Principale: SMS (60g/m2 +/-5%), blu
- Rinforzo: PP+PE rivestito, bianco
- Polsini: cotone, bianco
- Cuciture: poliestere, bianco
- Salviette: spunlace tessuto non tessuto (65g/m2 +/-5%), 40x40cm (+/-5%), bianco
- Telo per il confezionamento camice chirurgico: PE (9g/pc, + / -5%), bianco

5. Requisiti Prodotto

5. 1. Dimensioni prodotto camice chirurgico

	A	B	D	E	G	H
M	125cm	70cm	59cm	6.5cm	2x75cm	2x75cm
L	130cm	72.5cm	62cm	6.5cm	2x75cm	2x75cm
XL	135cm	75cm	63cm	6.5cm	2x75cm	2x75cm
XXL	140cm	80cm	64cm	6.5cm	2x75cm	2x75cm
Tolleranza(±)	3cm	2.5cm	2cm	0.5cm	3cm	3cm



5.2. <u>Requisit materiale: SMS</u>

Proprietà	Test Data
Peso unità	60 g/m2(min.55g/m2; max 65g/m2)
Spessore	≧0.6mm
Resistenza trazione(MD)	≧120 N/5cm
Resistenza trazione (CD)	≧70 N/5cm
Allungamento (MD)	≧87%

Allungamento (CD)	≧75%
Repellenza alcol	conforme
Repellenza acqua	conforme
Repellenza sangue	conforme
Bioburden	<100cfu/g
Pressione Idrostatica testata(cm. H2O)	≧3 3.5

5.3. Quantità per confezione

Codice	Misura	Quantità/sacca	Quantità/cartone	Misure cartone -cm
13963	L	1 pz	20 sacche	40x28x56cm
13964	XL	1 pz	20 sacche	40x28x56cm

6. Imballaggio e Stampa

Etichetta include le seguenti informazioni: importatore e distributore, fabbricante, rappresentante europeo, il numero lotto, data di produzione, data di scadenza; marchio CE, simbolo del metodo di sterilizzazione, simbolo di smaltimento, simbolo di stoccaggio
Imballato individualmente, sigillato nella busta a strappo (carta/stagnola) e in scatola di colore marrone (3 strati di carta kraft + carta ondulata a 2 veli) adatta per il trasporto con una sola etichetta (12x14cm) incollata su un lato; la confezione viene sigillata con i nastri adesivi.

7. Conservazione

Conservare in un luogo ventilato, asciutto e pulito e tenere lontano dalla luce del sole e pioggia.

8. Sicurezza Prodotto

I prodotti non hanno alcun rischio per l'utente o il paziente se utilizzati secondo le norme e per l'uso previsto.

EU DECLARATION OF CONFORMITY

MANUFACTURER

ÖZBERİM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
M. Nesihi Özmen Mahallesi Ladin Sokak No:6 Kat 1 Güngören ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: LENASSO
Model: AB-K78000LNS

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 by Natıonal Protectıve Testıng LLC
- 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.

Özcan YILMAZ
General Manager
27/05/2020

CE

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CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD - 127

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

ÖZBERİM TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

M. Nesihi Özmen Mahallesi Ladin Sokak No:6 Kat 1 Güngören ISTANBUL / TURKEY

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

Brand Name: LENASSO
Model: AB-K78000LNS
(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 27/05/2020 and valid until 26/05/2021 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.

ISTANBUL –27/05/2020

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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.