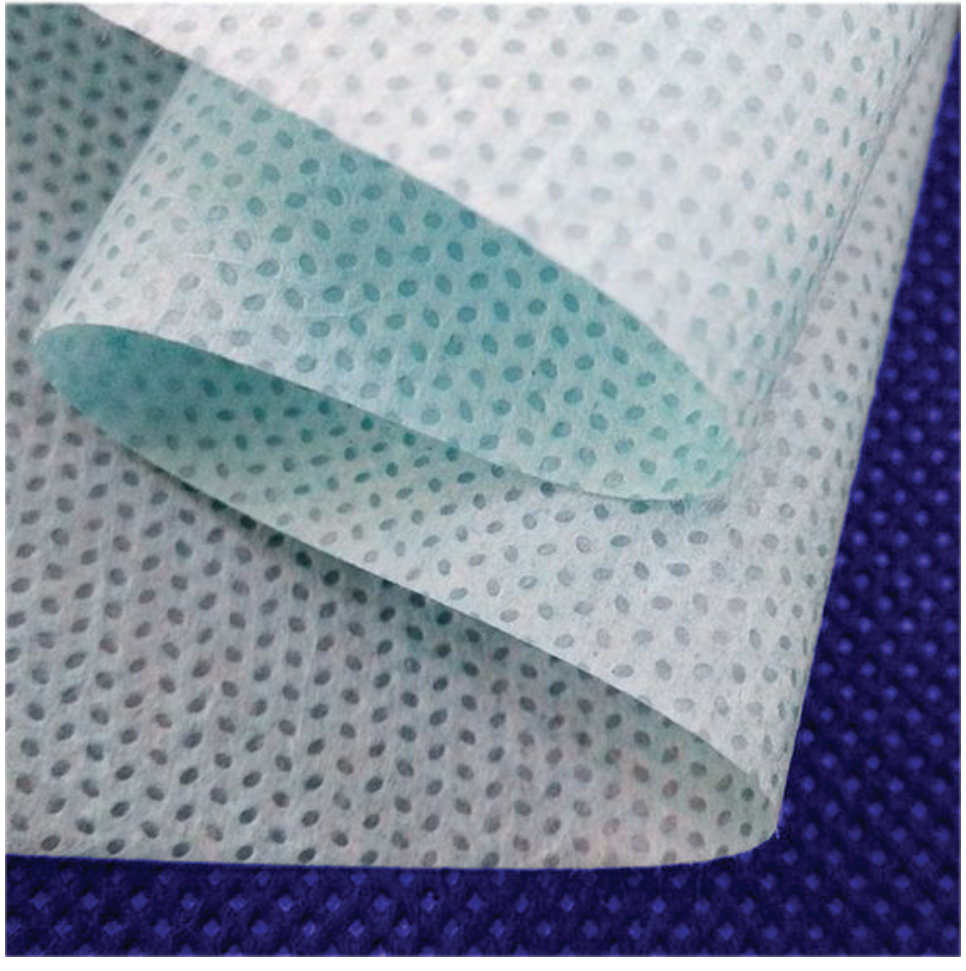
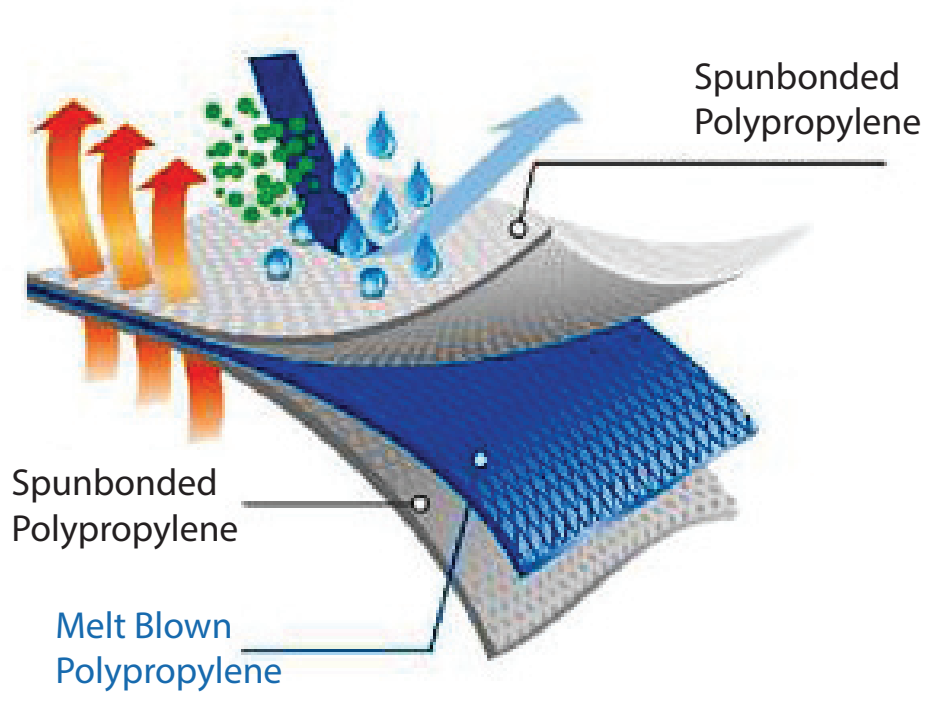
DISPOSABLE MEDİCAL GOWN

MM801

Fabric

The gown is made in SMS Fabric which is produced Polypropylene Spunmelt production technology that contains multiple Spunbond and Meltblown types in single production line.
It is waterproof quality , anti-static, UV Stabilizer , Flame Reterdant





Production

The closure is at back with 4 tie strings at waist and velcro at neck.
The cuffs are made with internal elastic for protection.

ÜRÜN ANALİZ SERTİFİKASI CERTIFICATE OF ANALYSIS

Malzeme : (Material)	43 GSM SMS FOBIK WHITE SPUNBOND	Malzeme Numarası : (Material Number)	107001209

Özellikler (Characteristics)	Test Metodu (Test Method)	Birim (Units)	Hedef (Target)	Minimum (Minimum)	Maksimum (Maximum)	Sonuç (Average)
Gramaj Basis Weight	WSP130.1	g/m²	43,0	41,0	45,0	43,0
Cd Sünme @ Peak CD Elongation @ Peak	WSP110.4	%	-	60,0	120,0	60,5
Cd Mukavemet @ Peak CD Tensile @ Peak	WSP110.4	N	70,0	55,0	-	55,4
Md Mukavemet @ Peak MD Tensile @ Peak	WSP110.4	N	115,0	90,0	-	91,0
Md Sünme @ Peak MD Elongation @ Peak	WSP110.4	%	-	60,0	120,0	60,7
Su Sütunu Hydrostatic Head	WSP80.6	mmWC	320,0	280,0	-	405,7
Rulo Eni Slit Width	Gülsan	mm	1600	1590	1610	1602

1 piece in 1 polybag
60 pcs in 1 box
Box dimension :40*60*40
Gross weight : 8,30 kg

EU DECLARATION OF CONFORMITY

MANUFACTURER

MADAMMODE KONFEKSİYON SANAYİ VE TİCARET ANONİM ŞİRKETİ
Karaduvar Mahallesi Serbest Bölge Bulvarı No:21 Akdeniz MERSIN / TURKEY

PRODUCT DESCRIPTION

MM 801 Model coded, 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:

- Government Regulation no. 93/42/EEC Medical devices 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
- Other relevant local, national and community 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 medical face mask is supplied. The information is 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.

Ekrem SAĞLAM
General Manager
Istanbul 29/04/2020

CE