



Visitor Gown 20g



- Nowoven Spunbond Material 20 gr/m²
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Single Use
- Shape: Long Sleeves, Men Collar, Velcro Strips Front Side, Double Seam Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BATVIS20	Visitor Gown 20g	Individual – 100 units/master

DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

STANDARDS

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

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

OPTIONS

SIZES

M – L – XL

COLORS (more options available)



PACKAGE

NON STERILE



Apex
nonwovens

CE EC DECLARATION OF CONFORMITY

We APEX Teknik Tekstil ve Sağlık Ürünleri San. Tic. Ltd. Şti.

Herewith declare that the following described product meets the provisions of the following directives. All supporting documentation is retained under the permises of the manufacturer.

PRODUCTS

20G VISITOR GOWN
30G VISITOR GOWN

STANDARDS

93/42/ECC MEDICAL DEVICES REGULATION (CLASS I ANEX VII)

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

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

EN ISO 9001:2000 Quality Management System – Requirements

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

CONTACT INFORMATIONS

APEX Teknik Tekstil ve Sağlık Ürünleri San. Tic. Ltd. Şti.
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Date: 23/04/20

Apex TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ
SANAYİ TİCARET LİMİTED ŞİRKETİ
Hacı Sabancı Organize Sanayi Bölgesi
Ordu Cad. No: 23 Sarıçam / ADANA
Tel: 0322 394 44 70 (Pbx) Fax: 0322 394 44 73
Yüreğir V.D. 619 014 6555



VERSION: BZ-9/2013

DATA SHEET

Product : Polypropylene SB Nonwoven Fabrics				
Product Description		:ENDLESS FILAMENTS SPUNBOND, THERMALLY BONDED		
Raw Material		:100 % POLYPROPYLENE		
Application on Fabric		:NORMAL		
Treatment		:		
Fabric Colour		:WHITE		
Weight		:20 G / SQM		
Width		:		
Production Line		:Line A		
PROPERTIES	TEST METHOD	UNIT	TARGET	ACTUAL VALUE
WEIGHT	Edana 40.3-90	g/sqm	20	20
THICKNESS	Edana 30.4-89	mm	0,24	0,24
TENSILE STRENGTH	Edana 20.2-89	N/5 cm	MD	50
			CD	40
			CV	52
ELONGATION AT BREAK	Edana 20.2-89	%	MD	68
			CD	40
			CV	67
			71	72

MD means Machine Direction
 CD means Cross Direction

For any complaints regarding
 quality please kindly inform us barcode
 number written on labels

Tolerances For Results	
Weight Per Unit Area.....	+/- 10 %
Thickness.....	+/- 10 %
Tensile Strength.....	+/- 15 %
Elongation.....	+/- 15 %
Tear Strength.....	+/- 15 %
Air Permeability.....	+/- 20 %

Preparation Date
 18.02.2017

Prepared By
 Quality control
 INCI VARKAL

CERTIFICATE of Registration



*This is to Certify that the
Medical Devices – Quality Management System
of*

APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.

**MERKEZ ADRESİ: ACIDERE OSB MAH. ORDU CD. NO:23
SARIÇAM / ADANA / TÜRKİYE**

**ŞUBE ADRESİ: ORUC REİS MAH. BARBAROS CAD. GİYİM KENT SİTESİ 16.
SOK.NO:102-104 ESENLER / İSTANBUL / TÜRKİYE**

**has been independently assessed and is compliant
with the requirements of**

ISO 13485:2016

**This Certificate is applicable to the following product or service ranges:
PRODUCTION AND SALES OF SINGLE USE MEDICAL CONSUMABLES
(MASK, CAPS, SHOE COVER, SLEEVE COVER, COVERALL, GOWN,
SHEET, DRAPE AND SURGICAL SETS)**

**TEK KULLANIMLIK SAĞLIK ÜRÜNLERİ (MASKE, BONE, KEP, GALOŞ, KOLLUK,
TULUM, ÖNLÜK, ÖRTÜ VE AMELİYAT SETLERİ) ÜRETİMİ VE SATIŞI**

:: Certificate No :: TR51529H

Date of initial registration 07 February 2020

Date of this Certificate 07 February 2020

Surveillance audit on or before 06 February 2021

Recertification Due / Certificate expiry 06 February 2023

**This Certificate is property of Staunchly Management & System Services Ltd. and remains valid
subject to satisfactory surveillance audits.**

Director

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SMS/F109A/17/REV02

For precise and updated information concerning the present certificate mail to info@staunchlyservices.com

This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded

