



# **GESPRIN**

## **MATERIAL SANITARIO**



## **BATA POLIPROPILENO 20g**

Polígono Espíritu Santo  
Parcela 12  
Oviedo - 33010

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# Surgical Gown 20G



## DESCRIPTION

Nowoven Spunbond Material 20 gr/m<sup>2</sup>

Overlock Seam

Antiallergic, Air Permeable

Does Not Contain Latex, Fiberglass

Suitable for Sterilization

Single Use

Shape: Long Sleeves, Zero Collar, Open Back Side,, With Belt, Knitted

CODE	DESCRIPTION	PACKAGE
AMET20G	Surgical Gown 20G	1-5 Piece/Pack, 100 Pcs./Carton



#### Surgical Gown

\*Nonwoven Spunbond Material 40 gr/m<sup>2</sup>

\*Overlock Seam

\*Antiallergic, Air Permeable

\*Does Not Contain Latex, Fiberglass

\*Suitable for Sterilization

\*Single Use

\*Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms

Code	Description	Package
7030	Surgical Gown M - L - XL Size	1-5 Piece/Pack, 100 Pcs./Carton
7040	Surgical Gown With Reinforced, P.E. Reinforced At Front Side M - L - XL Size	1-5 Piece/Pack, 100 Pcs./Carton

#### POLYPROPYLENE SPUNBOND NONWOVEN FABRICS

PROPERTIES	TEST METHOD	UNIT	FABRIC ACTUAL VALUE														
				12	15	18	20	30	40	50	60	70	80	90	100	120	140
WEIGHT	ERT 40.3---90	G/SQ.M		12	15	18	20	30	40	50	60	70	80	90	100	120	140
THICKNESS	ERT 30.4---89	MM		0,12	0,15	0,18	0,2	0,28	0,33	0,38	0,43	0,46	0,49	0,53	0,6	0,7	0,7
TENSILE STRENGTH	ERT 20.2---89	N/5 CM	MD	32	34	38	73	105	128	153	163	172	174	19	203	212	225
			CD	22	25	31	36	56	76	82	84	103	107	123	184	196	201
ELONGATION AT BREAK	ERT 20.2---89	%	MD	62	67	65	60	65	84	79	69	72	76	77	73	79	68
			CD	65	70	71	70	63	89	83	78	68	70	88	78	84	72
TEAR STRENGTH	ERT 70.3---96	N	MD	20	22	29	35	39	43	58	72	74	76	77	78	91	102
			CD	22	25	27	41	43	46	68	80	82	88	90	90	99	106

MD Machine Direction

CD Cross Direction

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

APEX TEKNİK TEKSTİL VE SAĞLIK URUNLERİ TICARET LIMITED SİRKETİ

Head Office / Factory :

Hacı Sabancı Organize Sanayi Bölgesi Ordu Caddesi No: 23 Yüreğir / Adana

Phone : +90 322 394 44 70 (Pbx) Fax : +90 322 394 44 73 info@amet.com.tr

## EC DECLARATION OF CONFORMITY



We, APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ LTD ŞTİ.

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

**PRODUCT : DISPOSABLE APRON / OVERALLS**

**MODEL : X-RAY, PATIENT, SURGICAL, VISITOR / STANDARD,  
WITH HOOD**

**CLASS : CLASS 1**

**APPLICABLE EC DIRECTIVES :**  
93/42/EEC MEDICAL DEVICE DIRECTIVE

**APPLICABLE STANDARDS :**  
TS EN ISO 9001:2000 QUALITY MANAGEMENT SYSTEM  
TS EN ISO 10993 series BIOCOMPATIBILITY

**CONTACT INFORMATIONS :**  
H.Sabancı Org. San. Böl. Ordu Cad. No:23  
Yakapınar / ADANA / TURKEY  
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**DATE OF ISSUE :** 26.08.2019

**SIGNATURE :** HİMMET ATİK  
General Manager

# CERTIFICATE

## The company

**Apex Teknik Tekstil Ve Saglik Ürünleri  
San. Tic Ltd. Sti.**  
Haci Sabanci Organize Sanayi Bölgesi.  
Ordu Cad. No. 23  
01350 Saricam - Adana, TURKEY

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use  
the STANDARD 100 by OEKO-TEX® mark, based on our test report  
**19.0.97581**



## for the following articles:

### White and masterbatch dyed spunbonded nonwoven produced from polypropylene.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

**The certificate 12.HTR.08445 is valid until 31.12.2020**

Boennigheim, 30.12.2019

*Schramm*

Dipl.-Ing. (FH) Ivonne Schramm  
Head of Certification Body OEKO-TEX®



# 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**

**STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.**

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SMS/F109A/17/REV02

For precise and updated information concerning the present certificate mail to [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

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

