Sterilization Flat Reels

Product Features

- Medical Paper provides maximum safety.
- All imprint are located outside the packaging area to prevent ink pigment migration to the product.
- Transparent , multilayer co-polymer film allows easy identification.
- Reinforced film to avoid tear during opening.
- Superior barrier and quality with 60gsm or 70gsm medical kraft paper.
- Indicators which are water based, non toxic and give accurate result for steam, EO Gas and Formaldehyde (FO).
- Strong seal-strength, visible sealing lines.
- Clean fibre-free opening.
- All materials comply with international standards.
- Opening direction marked.
- Conformity with EN 868-5.

TECHNICAL DATA SHEET

STERILIZATION FLAT/GUSSET REEL, 60gsm

	PRODUCT CODE	**:**	**4AFR (Flat Reel) - 4AGR (Gusset Reel)**
TEHNICALDATA SHEET	**RELATED STANDARDS**	**:**	4A Medical flat and gusseted reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the reel production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. 4A Medical Reels meet the requirements of 93/42/EEC Medical Device Directive regulations
	INTENDED USE	**:**	4A Medical reels are designed to provide excellent barrier for sterile medical device packaging purposes. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. 4A Medical reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices. Sterilized material in sterilization package is storable for up to 5 years after the sterilization in a clean room conditions.
	FILLING VOLUME	**:**	According to DIN 58953-7 (German national standard): Seleable paper bags and seleable pouches and reals shall be filled up to 3/4 max of their volume. This limits avoids too high stress / burdon to the seals. Belowe the buttom seal there must be space of minimum 30 mm between load and sealing area. There is no known limit bu standarts for weight and it is based on experience. However, it is suggested to follow the 3/4 rule. In terms of solid, heavy load (metal instruments), it is the weight itself, in case of any sharp objects which could demage the material, and the volume of condensate (directly related to mass=weight) which is created during the steam sterilization.
	OPERATION CONDITIONS	**:**	4A Medical reels are used for steam, ethylene oxide, formaldehyde sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.
	SPECIFICATIONS	**:**	

	PROPERTIES	**UNITS**	**STANDARD**	**TYPICAL VALUE**
MEDICAL PAPER	SUBSTANCE	g/m²	ISO 536	60,0
	THICKNESS	µm	ISO 534	76
	BENDTSEN POROSITY	ml/min	ISO 5636-3	650
	AIR PERMEANCE	µm (Pa*s)	ISO 5636-3	7,4
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	250
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	250
	PORE SIZE	µm	EN 868-2 (app.D)	17
	TENSILE STRENGTH, MD	kN/m	EN ISO 1924-2	5,9
	TENSILE STRENGTH, CD	kN/m	EN ISO 1924-2	2,9
	WET TENSILE STRENGTH, MD	kN/m	ISO 3781	1,6
	WET TENSILE STRENGTH, CD	kN/m	ISO 3781	0,9
	BURST STRENGHT	kPa	ISO 2758	300
	WET BURST	kPa	ISO 3689	100
	TEARING STRENGHT MD	mN	ISO 1974	600
	TEARING STRENGHT CD	mN	ISO 1974	650
	COBB TEST (60s)	g/m²	ISO 535	15,0
	WATER REPELLENCY	s	EN 868-2 (app.E)	30,0
	FLOUORESCENCE	pts/dm²	EN 868-2 (app.B)	0,0
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

TECHNICAL DATA SHEET

STERILIZATION FLAT/GUSSET REEL, 60gsm

TECHNICAL DATA SHEET

	PROPERTIES	UNIT	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	Micron	LAM.FILM	52 ± 5
			PE	40 ± 5
			PET	12 ± 2
	BREAKING FACTOR	N/15mm	35	
	TEAR STRENGTH MD/CD	mN	300	
	BOND STRENGHT	N/m	265	
	ELONGATION	%	70	
	TEMPERATURE DURABILITY	min/degrees	30 min/140C	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

PRODUCT SPECIFICATION :

	PROPERTIES	UNIT	TYPICAL VALUE
POUCH	SEAL STRENGTH	N/15mm	2,5
	BUBBLE TEST		None
	PINHOLE DETERMINATION		None
	DIMENSION CONTROL	cm or mm	Desired dimensions
	LEAKAGE TEST		None
	PEEL DIRECTION		None
	INDICATOR CONTROL		Returns the specified color

	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
INDICATOR	**STEAM**	**BLUE**	**GREEN**
	EO	**PINK**	**ORANGE**
	FORMALDEHYDE	**PURPLE**	**GREEN**

PACKAGING:	4A Medical reels are packaged in carton boxes as below: Flat Reels are 200m long and Gusset Reels are 100m long.

Product dimensions	Pieces in carton
50mm X 200m /	10
75mm X 200m / 75mm X 100m	8
100mm X 200m / 100mm X 100m	8
120mm X 200m / 120mm X 100m	4
150mm X 200m / 150mm X 100m	4
200mm X 200m / 200mm X 100m	4
250mm X 200m / 250mm X 100m	2
300mm X 200m / 300mm X 100m	2
350mm X 200m / 350mm X 100m	2
400mm X 200m / 400mm X 100m	2
420mm X 200m / 420mm X 100m	2
450mm X 200m / 450mm X 100m	2
500mm X 200m /500mm X 100m	2

MANIFACTURER : **DORT-A TIP MALZEMELERI SAN. ITH. IHR. TIC. LTD. STI.**
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SANİTER®
GIDA - ÇEVRE BİLİMİ GÖZETİM VE MÜHENDİSLİK HİZMETLERİ TURİZM TİCARET ANONİM ŞİRKETİ

Test
TS EN ISO/IEC 17025
AB-0009-T

ANALYSIS REPORT

AB-0009-T	
2154037-25	
07-25	

Digitally signed by Cojocaru Vera
Date: 2025.12.19 09:31:13 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Report No./Revision No.	: 2154037-25
Contract / Offer No	: 20856-25
The Purpose of the Analysis	: SPECIAL REQUEST
Customer Name	: DÖRT-A TIP MALZ.SAN.İTH.İHR.TİC.LTD.ŞTİ
Address	: BALIKHİSAR MAH. KÖYİÇİ SERPMELERİ NO:795 06750 AKYURT/ANKARA
Project Name	: -

Sample's ;

The location of sampling	: -
Type	: STERİLİZATİON REEL/POUCH (GAUZE İN THE PACKAGE)
Serial-Batch/ Number	: 4A-0125
Sample Code Number	: -
Packing Shape/Type	: MEDICAL PACKAGING
Amount of Sample	: 2 pcs
Producing	: -
Sampling Temperature	: -
Ambient Temperature	: 21°C
Acceptance Temperature	: -
Date of Manufacture	: -
Expiration Date	: -

Date Received	: 29.05.2025
Date of analysis	: 29.05.2025
Date of report	: 11.07.2025
Date of Sampling	: -

Operating as a test laboratory, Saniter Food- Env. Sci. Inc. has been accredited by TÜRKAK with the accreditation number AB-0009-T, according to TS EN ISO 17025-2017 standards.

The Turkish Accreditation Agency (TÜRKAK) has signed a Multilateral Agreement with the European Accreditation Association (EA) and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC) on the recognition of test reports.

The results of the analysis of "STERİLİZATİON REEL/POUCH (GAUZE İN THE PACKAGE)" sample that you have sent on May 29 2025 are given below.

E-Signed
Cansu FİL
Chemical/Physical Department Chief

E-Signed
Cansu KÖLOĞLU
Microbiology Department Chief

E-Signed
Yasemin AKBIYIKOĞLU
Sample Acceptance and Reporting Department Chief

Confirmable
E-signed
Gül KELLECİ ÇAKMAK
Lab.Technical Manager

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ANALYSIS REPORT

AB-0009-T
2154037-25
07-25

Analysis	Results	Limits	Compl. Legislation	**Compl. Status	Meas. Limits	Recovery	MU(%)	Analysis Method
1- Stability Test (1 years,60°C, 26 days)	As a result of the examinations, no physical deformation was detected in the product.	-	-	C	-	-	-	ASTM F 1980
2- * Aerobic mesophilic bacteria (30°C 14 d Tryptone soy broth)	No Growth	No Growth	ISO 11737-2	C	-	-	-	ISO 11737-2
3- * Anaerobic mesophilic bacteria (30°C 14 d Fluid thioglycollate medium)	No Growth	No Growth	ISO 11737-2	C	-	-	-	ISO 11737-2
4- * Positive Control :Bacillus atropheus (30 °C 14 d TSB and FTM)	Growth	Growth	ISO 11737-2	C	-	-	-	ISO 11737-2
5- * Negative Control (30°C 14 d TSB and FTM)	No Growth	No Growth	ISO 11737-2	C	-	-	-	ISO 11737-2

* Accredited by TÜRKAK.
The results of the analysis are given above.
**Compliance Status: C: Conformed, NC: Non Conformed, NE: No evaluation for not having limit value.

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ANALYSIS REPORT

AB-0009-T
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Descriptions:

Test amacı, hızlandırılmış yaşlandırma yöntemi ASTM F 1980 kullanılarak raf ömrünün belirlenmesidir.
İlk olarak "STERİLİZASYON RULOSU/ZARFI (PAKET İÇERİSİNDE GAZLI BEZ)" örnekleri 60 ^{0}C de bekletilmiştir. Bu örnekler daha sonra görsel inceleme ile değerlendirilir.
/The test objective is to determine the shelf life using the accelerated aging method ASTM F 1980.
First, samples of "STERİLİZATİON REEL/POUCH (GAUZE İN THE PACKAGE)" were kept at 60 ^{0}C. These samples are then evaluated by visual inspection.

SONUÇ/RESULTS: Üründe herhangi bir fiziksel deformasyon tespit edilmemiştir./ Product stability test is suitable.

GERÇEK ZAMANLI YAŞLANDIRMA/REAL TIME AGING(RT)	: 1 YIL (365 GÜN)/1 YEAR (365 DAYS)
% BAĞIL NEM/% RELATIVE HUMIDITY	: 40
ORTAM SICAKLIĞI(T_{RT})/AMBIENT TEMPERATURE (T_{RT})	: 22 ^{0}C
HIZLI YAŞLANDIRMA SICAKLIĞI(T_{AA})/ACCELERATED AGING TEMP. (T_{AA})	: 60 ^{0}C
ARRHENIUS SABİTİ Q_{10} / ARRHENIUS EQUATION Q_{10}	: 2
HIZLI YAŞLANDIRMA ZAMANI (AAT)/ACCELERATED AGING TIME (AAT)	: 26 gün/26 days

*** The limit value is valid for the Total Number of Aerobic Mesophilic Microorganisms (Aerobic mesophilic bacteria+mold+yeast). The sum of aerobic mesophilic bacteria and mold-yeast must not exceed the relevant value.

1-Any part of this analysis report in all or separately.
2- Analysis results are valid for the received sample.
3- Where necessary,uncertainty of measurement and recovery rate are given together with the analysis result, Measurement uncertainty is not considered for microbiological analysis.Measurement uncertainty is not considered for chemical and physical analysis.If the measurement uncertainty is used in the calculation; it is defined in the descriptions.
4-This report cannot be copied or reproduced in whole or in part without the written permission of the laboratory.
5-Uncertainty of measurement is calculated using K=2 in the %95 percent confidence internal.
6-Official analysis report are invalid without a cover letter and signature.
7-Special request reports are invalid unsigned.
8- Additional information given by the customer is indicated in the descriptions.
9- The results which are expressed in the descriptions about analysis without asterisk (*) are not related to the scope of accreditation.
10- Simple decision rule is applied in the Saniter Laboratory. Wrong rejection, wrong acceptance rule can be applied upon customer request. Saniter's decision rule is explained on the website www.saniter.com.tr.
11-Where necessary, the waiver statement is tracked with a tracking number.
12- 'Saniter' is not responsible for the information provided by the customer

This report created on www.saniter.com.tr

END OF REPORT

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