

TECHNICAL DATA SHEET

STERILIZATION REINFORCED REELS/POUCHES

PRODUCT CODE	:	4ASRR / 4ASRP
RELATED STANDARDS	:	4A Medical reinforced sterilization reels/pouches are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices.
INTENDED USE	:	4A Medical Reinforced Reels/Pouches are designed to provide excellent barrier for sterile medical device packaging purposes. Reels/Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. 4A Medical pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical Pouches are easy 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 6 month after the sterilization in a clean room conditions.
OPERATION CONDITIONS	:	4A Medical reels/pouches 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	:	

TECHNICAL DATA SHEET

PROPERTIES	UNITS	STANDARD	TYPICAL VALUE
SUBSTANCE	g/m ²	ISO 536	60,0
HIGH POROSITY	l/min/dm ²	EN 868-2:1999 (app. F)	18,0
THICKNESS (BULKY MATERIAL)	µm	ISO 12625-3	220
TENSILE STRENGTH, MD	kN/m	EN ISO 1924-2	2,2
TENSILE STRENGTH, CD	kN/m	EN ISO 1924-2	0,9
WET TENSILE STRENGTH, MD	kN/m	ISO 3781	2,0
WET TENSILE STRENGTH, CD	kN/m	ISO 3781	0,8
BURST STRENGTH	kPa	ISO 2758	230
WET BURST	kPa	ISO 3689	200
TEARING STRENGTH MD	mN	ISO 1974	1250
TEARING STRENGTH CD	mN	ISO 1974	1900
STRETCH MD	%	ISO 1924-2	11,0
STRETCH CD	%	ISO 1924-2	10
DRAPE CUISICK TEST	%	ISO 9073-9	77
HYDROSTATIC TEST (100 cm ² - 10 mbar/min)	mbar	ISO 811	29
MASON JAR	min	WPS 80-11	130
ALCOHOL REPELLENCY	-	EN 868-2:1999 (app. A)	8,0
FLOUORESCENCE	pts/dm ²	EN 868-2:2009 (app. B)	0,0
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

REINFORCED STERILIZATION FLAT REEL / POUCH

TECHNICAL DATA SHEET

LAMINATED FILM	PROPERTIES	UNIT	TYPICAL VALUE		
	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 :

POUCH	PROPERTIES	UNIT	TYPICAL VALUE
	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

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	BLUE	GREEN
	EO	PINK	ORANGE
	FORMALDEHYDE	PURPLE	GREEN
PACKAGING:		4A Medical reels are packed in carton boxes. 4A Medical Rainforced pouches are packaged laminated film and then in cartons boxes. Quantity in packing depend on size of pouches.	

MANUFACTURER : **DORT-A TIP MALZEMELERI SAN. ITH. IHR. TIC. LTD. STI.**
 Bahkhisar Mahallesi, Köyiçi Serpmeleri, No:795 Akyurt, Ankara, Turkey
 Tel: +90 312 363 50 52 / 53 Fax: +90 312 363 52 10
 Web: <http://www.4amedical.com> E-mail: export@4amedical.com