


**MESTRA®**

TECHNICAL DATE SHEET

Reference:	Ref. 080448, 080449, 080450, 080451, 080452, 080454, 080456, 080457, 080458, 080459	Foto: 																																								
Name:	SELF SEAL POUCHES																																									
Standard:	CE 2017/745 MDR																																									
	TALLERES MESTRAITUA S.L. Txori-Erri Etorbidea, 60 Tel. + 34 944530388 Fax + 34 944711725 mestra@mestra.es www.mestra.es 48150 SONDIKA – BILBAO SPAIN																																									
Intended use:	<p>Pouches are designed to provide an excellent barrier for the packaging of sterile medical devices. They meet the requirements of the medical industry for high quality, hygiene and safety levels. They are used for packaging medical devices prior to sterilization and maintain the sterility of the products after sterilization. They are easy to package and the indicator used for sterilization provides information on the sterilization status. The sterilized material in the sterilization package can be stored for up to 5 years after sterilization under clean room conditions.</p>																																									
Use conditions:	<p>Pouches are used for steam, ethylene oxide, formaldehyde sterilization methods. The sterilization conditons should be determined by the end user regarding to material to be sterilized.</p>																																									
Sizes:	<table border="0"> <tr><td>Ref. 080448</td><td>5 cm</td><td>x</td><td>24 cm</td></tr> <tr><td>Ref. 080449</td><td>7 cm</td><td>x</td><td>26 cm</td></tr> <tr><td>Ref. 080450</td><td>9 cm</td><td>x</td><td>26 cm</td></tr> <tr><td>Ref. 080451</td><td>5 cm</td><td>x</td><td>9 cm</td></tr> <tr><td>Ref. 080452</td><td>14 cm</td><td>x</td><td>28 cm</td></tr> <tr><td>Ref. 080454</td><td>19 cm</td><td>x</td><td>36 cm</td></tr> <tr><td>Ref. 080456</td><td>25 cm</td><td>x</td><td>40 cm</td></tr> <tr><td>Ref. 080457</td><td>30 cm</td><td>x</td><td>40 cm</td></tr> <tr><td>Ref. 080458</td><td>30 cm</td><td>x</td><td>45 cm</td></tr> <tr><td>Ref. 080459</td><td>5,7 cm</td><td>x</td><td>13 cm</td></tr> </table>		Ref. 080448	5 cm	x	24 cm	Ref. 080449	7 cm	x	26 cm	Ref. 080450	9 cm	x	26 cm	Ref. 080451	5 cm	x	9 cm	Ref. 080452	14 cm	x	28 cm	Ref. 080454	19 cm	x	36 cm	Ref. 080456	25 cm	x	40 cm	Ref. 080457	30 cm	x	40 cm	Ref. 080458	30 cm	x	45 cm	Ref. 080459	5,7 cm	x	13 cm
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Medical paper specifications.

PROPERTIES	UNIT	STANDARD	TYPICAL VALUE
Substance	g/m ²	ISO 536	60
Thickness	µm	ISO 534	83
Bendtsen porosity	ml/mn	ISO 5636-3	1000
Air permeance	mm/(Pa.s)	ISO 5636-3	11,4
Bendtsen toughness FS	ml/mn	ISO 8791-2	375
Bendtsen toughness WS	ml/mn	ISO 8791-2	375
Tensile strength /MD	kN/m	EN ISO 1924-2	6,4
Tensile strength /CD	kN/m	EN ISO 1924-2	3,4
Wet tensile strength /MD	kN/m	ISO 3781	2,1
Wet tensile strength /CD	kN/m	ISO 3781	1,1
Burst strength	kPa	ISO 2758	350
Tearing strength /MD	mN	ISO 1974	600
Tearing strength /CD	mN	ISO 1974	650
Wet burst	kPa	ISO 3689	150
Water repelency	s	EN 868-2 (app.D)	35
Pore size	µm	EN 868-2 (app.E)	21
Cobb test (60 s)	g/m ²	ISO 535	15
Fluorescence	pts/dm ²	EN 868-2 (app.B)	0
pH: between 5.0 and 8.0 (OSO 6588-2)			
Chloride content < 0, 5% (ISO 9197)			
Sulphate content < 0,25% (ISO 9198)			
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

Laminated film specifications:

PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
Thickness	µm	ASTM D 374	Film lam.	53 ± 5
			PP	40 ± 5
			PET	12 ± 2
COF	F/M	ASTM F 1894	0,30-0,35	
	M/M		0,35-0,40	
Termal seal	°C	ASTM F 88	150 ± 5	
Tear	G	D1922	MD	40 ± 5
			TD	50 ± 5
Gloss	%	ASTM 2457	150 ± 5	
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

Bag specifications:	PROPERTIES				UNIT		STANDARD		TYPICAL VALUE	
	Seal strength	Cm		ASTM F 88	< 25		≥ 25			
		Sellado de borde			250 ≤		300 ≤			
	Bubble test			ASTM F2096-04		None				
	Pinole determination			EN 868-5 Anexo C		None				
	Dimensión control	cm o mm		ASTM F2203-02		Desired dimensions				
	Leakage test			ASTM F1929-98		None				
	Peel direction			EN 686-5 Anexo E		Must not break the particle				
	Indicator control			ISO 11140-1		Must return the specified color				
Indicator specifications:	STERILIZATION METHOD			BEFORE STERILIZATION		AFTER STERILIZATION				
	STEAM			Blue		Black				
	EO			Pink		Yellow				
	FORMALDEHYDE			Red		Green				