

Hospital Self Sealing Sterilization Pouches Items# A80305 to A87513

Intended Use

The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices (skin and mucosal tissue contact) intended for sterilization in steam autoclaves and via Ethylene Oxide (EO). The pouch's process indicators are designed to indicate to the user that the pouch has undergone either a Steam or EO sterilization process.

Characteristic	Acceptable Limits				
Description	Blue Tinted Film sealed to Paper with one set of indicator with polyester backed adhesive tape as depicted on page 3. Tape is adhesive on film and paper				
Material	Paper: Medical Grade Craft Paper Laminated film: Polypropylene and Polyester				
Dimension	Label Size	Item Code	Size	Width	Length
	3.5" x 5.25"	A80305	Film	89 mm / 3 1/2"	159 mm / 6 1/4"
			Paper	89 mm / 3 1/2"	191 mm / 7 1/2"
			Int. Pouch	70 mm	132.5 mm
	3.5" x 9"	A83509	Film	89 mm / 3 1/2"	254 mm / 10"
			Paper	89 mm / 3 1/2"	286 mm / 11 1/4"
			Int. Pouch	70 mm	227.5 mm
	3.5" x 22"	A83522	Film	89 mm / (3 1/2"	584 mm / 23"
			Paper	89 mm / (3 1/2"	617 mm / 24 1/4"
			Int. Pouch	70 mm	557.5 mm
	5.25" x 10"	A85210	Film	133 mm / 5 1/4"	279 mm / 11"
			Paper	133 mm / 5 1/4"	311 mm / 12 1/4"
			Int. Pouch	114 mm	252.5 mm
	5.25" x 14"	A85215	Film	133 mm / 5 1/4"	381 mm / 15
			Paper	133 mm / 5 1/4"	413 mm / 16 1/4"
			Int. Pouch	114 mm	354.5 mm
	7.5" x 13"	A87513	Film	190 mm / 7 1/2"	356 mm / 14"
			Paper	190 mm / 7 1/2"	388 mm / 15 9/32"
			Int. Pouch	171 mm	329.5 mm
	8" x 16"	A80816	Film	203 mm / 8 "	432 mm / 17"
			Paper	203 mm / 8"	464 mm 18 9/32"
			Int. Pouch	184 mm	405.5 mm
	12" x 18"	A81218	Film	305 mm / 12"	483 mm / 19"
			Paper	305 mm / 12"	515 mm / 20 9/32"
			Int. Pouch	286 mm	456.5 mm
	16.34" x 22.75"	A81624	Film	415 mm / 16 11/32"	603 mm / 23 3/4"
			Paper	415 mm / 16 11/32"	636 mm / 25"
			Int. Pouch	394 – 398 mm	574.5 – 578.5 mm
Seal Width	Thermal seal:		9/32" – 7/16" (7.5 – 11.5 mm)		
	Adhesive seal:		13/16" – 1" (21 – 25 mm)		
Perforation Location	1 mm to 3 mm above the bottom of the tape backing.				
Adhesive Distribution	Film & Paper: 5/16" – 15/32" (8 – 12 mm)				



TECHNICAL DATA SHEET

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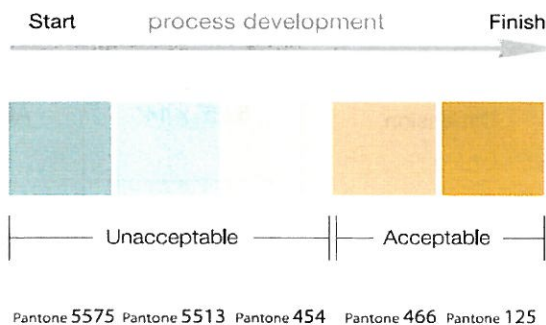
Characteristic	Acceptable Limits			
Process Indicator Performance	Both EO and Steam process indicators complies with class 1 process indicators requirements.			
Process Indicator Exposure	Steam	Indicators turn from pink to cocoa when processed 4 min at 134 °C with 20 to 30 min dry time		
	EO	Indicators turn from blue to golden brown when processed 100-120 min at 50 °C, 60-85%RH, and EtO concentration of 600mg/L		
Skin Irritation	Negligible (Primary Skin Irritation Index 0.0-0.4)			
Cytotoxicity	Mild (Grade 2 for cytotoxicity extracts)			
Sensitization (Buehler Method)	Discrete or patchy erythema (Grade 1, provided grades of less than 1 are seen in control)			
Packaging	Item Code	Unit / Box	Box/ Case	Quantity / Case
	A80305, A83509, A85210, A85215	200	10	2000
	A80816, A81218, A83522, A87513	200	5	1000
	A81624	100	4	400

Indicator Color Change Guide

Steam Sterilization



EO Sterilization

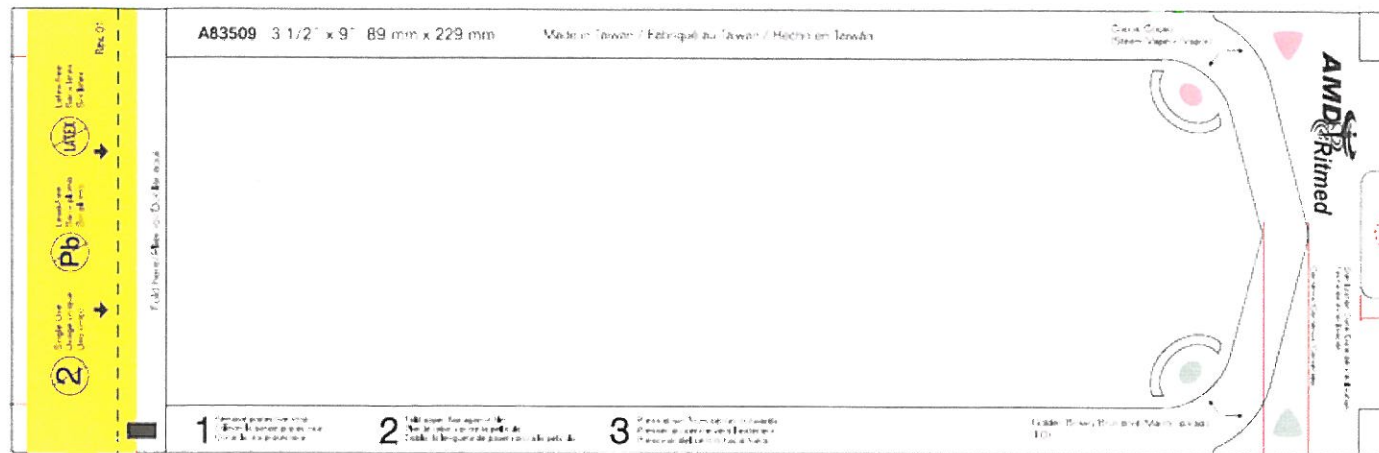




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Visual AMD Self-Sealing Pouch



Performance Standards

The chemical indicator performs according to ISO 11140-1
The pouches are designed in accordance to the ISO 11607-1

Item Code	Description	Color	Specific Attributes
A80305	AMD-Ritmed Self Seal Pouches 3 1/2" x 5 1/4", 200/bx X 10 = 2000/cs	N/A	Non-Sterile
A80816	AMD-Ritmed Self Seal Pouches 8" x 16", 200/bx X 5 = 1000/cs	N/A	Non-Sterile
A81218	AMD-Ritmed Self Seal Pouches 12" x 18", 200/bx X 5 = 1000/cs	N/A	Non-Sterile
A81624	AMD-Ritmed Self Seal Pouches 16.34" x 22 3/4", 100/bx X 4 = 400/cs	N/A	Non-Sterile
A83509	AMD-Ritmed Self Seal Pouches 3 1/2" x 9", 200/bx X 10 = 2000/cs	N/A	Non-Sterile
A83522	AMD-Ritmed Self Seal Pouches 3 1/2" x 22", 200/bx X 5 = 1000/cs	N/A	Non-Sterile
A85210	AMD-Ritmed Self Seal Pouches 5 1/4" x 10", 200/bx X 10 = 2000/cs	N/A	Non-Sterile
A85215	AMD-Ritmed Self Seal Pouches 5 1/4" x 14", 200/bx X 10 = 2000/cs	N/A	Non-Sterile
A87513	AMD-Ritmed Self Seal Pouches 7 1/2" x 13", 200/bx X 5 = 1000/cs	N/A	Non-Sterile

Storage Conditions

Keep away from light, heat and humidity. Store at temperature between 15-35°C (59-95 °F) with a relative humidity of <70%.

