

TECHNICAL DATA SHEET

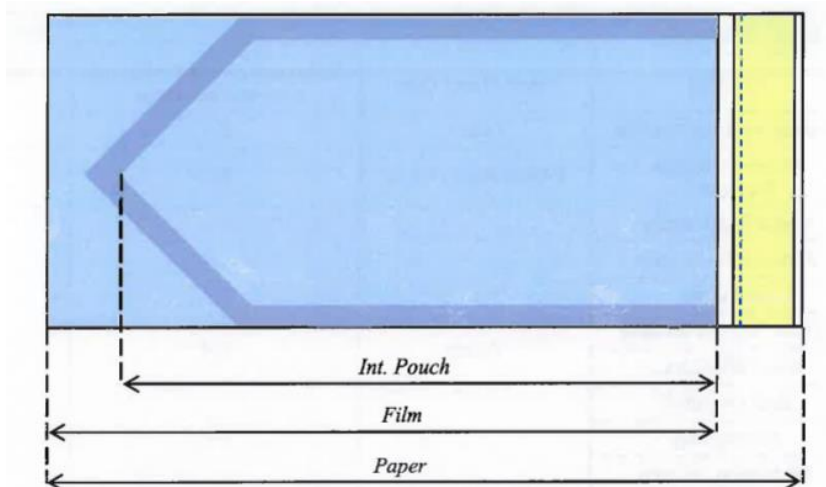
Self-Seal Sterilization Pouch

Intended Use

The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices intended to 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.

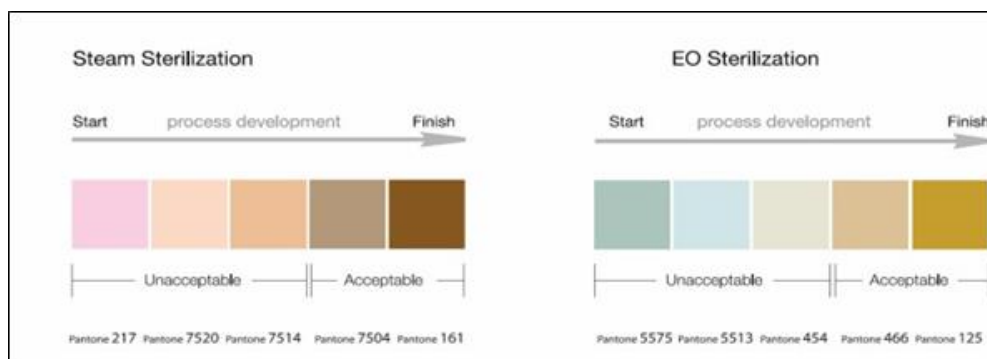
Characteristic	Specification			
Device Components	Blue tinted film sealed to paper with one set of indicators and double-sided coated adhesive tape.			
Process Indicator Exposure	Steam: Indicators turn from pink to cocoa when processed 30 min. at 121°C. EO: Indicators turn from blue to golden brown when processed 100-120 min at 50°C, 60-85% RH, and EO concentration of 600 mg/L.			
Dimension	Size	Part	Width (mm)	Length (mm)
	3 ½" x 5 ¼"	Film	89	159
		Paper	89	191
		Int. Pouch	70	132,5
	3 ½" x 9"	Film	89	254
		Paper	89	286
		Int. Pouch	70	227,5
	5 ¼" x 10"	Film	133	279
		Paper	133	311
		Int. Pouch	114	252,2
	7 ½" x 13"	Film	190	356
		Paper	190	388
		Int. Pouch	171	329,5

Measurement Diagram



Process Indicator Color Change Guide

As a reference we have included this color change guide to help in the interpretation of the color change when the pouches are processed in an autoclave, or ethylene oxide sterilization chamber. Caution: the chemical indicators are to be used as sterilization process indicators only.



Additional Information

Storage Condition	Post Sterilization Shelf Life	Country of Origin
Keep away from light, heat, and humidity. Store at temperature between 15 – 35°C (59 – 95°F) with a relative humidity of <70%	The sterilization pouch maintains the enclosed devices sterile up to one year post-sterilization.	Taiwan

Appendix 1 List of Item Codes and Attributes

Appendix 1 (List of items)

AMD Medicom Inc.

Item Code	Description	Packaging Information	Size	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
A80305	AMD-Ritmed Self Seal Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	3 1/2" x 5 1/4"	Process Indicator Exposure with Steam: 4 min. at 134°C	Non-Sterile	Medical Device Class 2	Medical Device Class 1
A83509	AMD-Ritmed Self Seal Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	3 1/2" x 9"	Process Indicator Exposure with Steam: 4 min. at 134°C	Non-Sterile	Medical Device Class 2	Medical Device Class 1
A85210	AMD-Ritmed Self Seal Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	5 1/4" x 10"	Process Indicator Exposure with Steam: 4 min. at 134°C	Non-Sterile	Medical Device Class 2	Medical Device Class 1
A87513	AMD-Ritmed Self Seal Pouches	200 Pouches/Box, 5 Boxes/Case, 1000 Pouches/Case	7 1/2" x 13"	Process Indicator Exposure with Steam: 4 min. at 134°C	Non-Sterile	Medical Device Class 2	Medical Device Class 1