



## TECHNICAL DATA SHEET

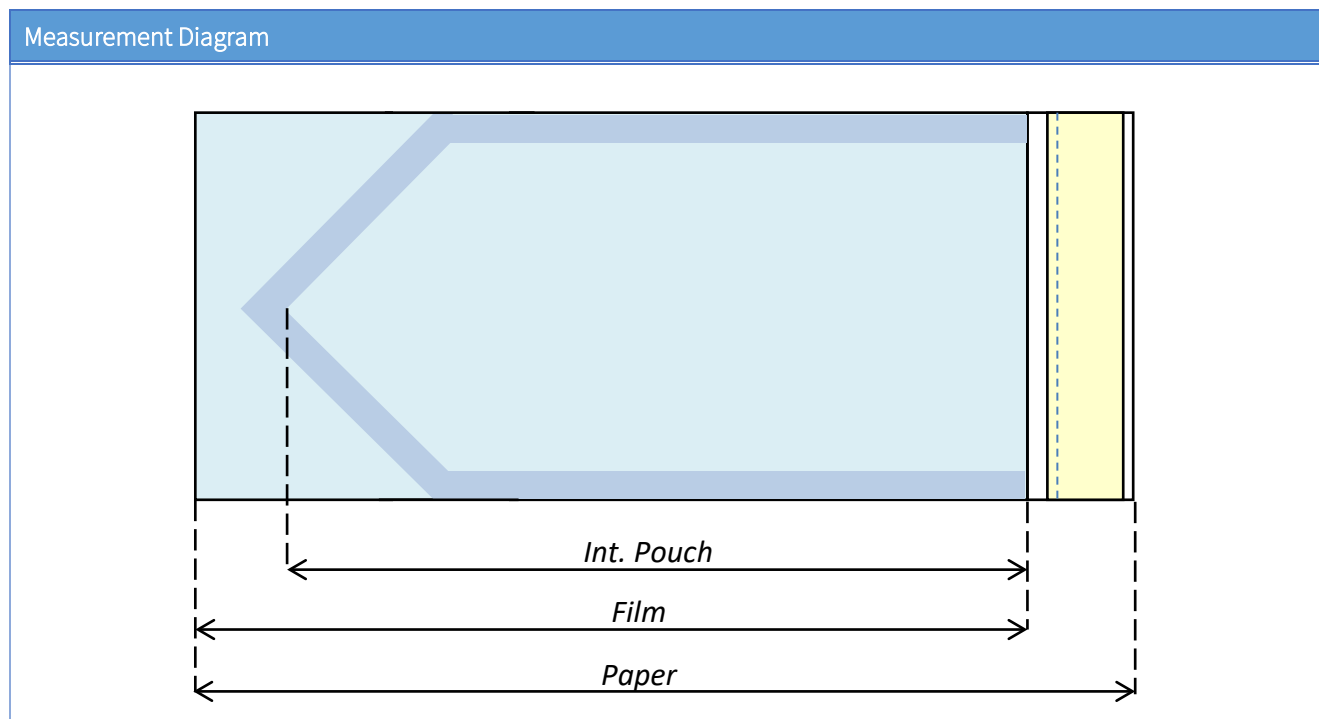
### SELF-SEAL STERILIZATION POUCH

#### Intended Use

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

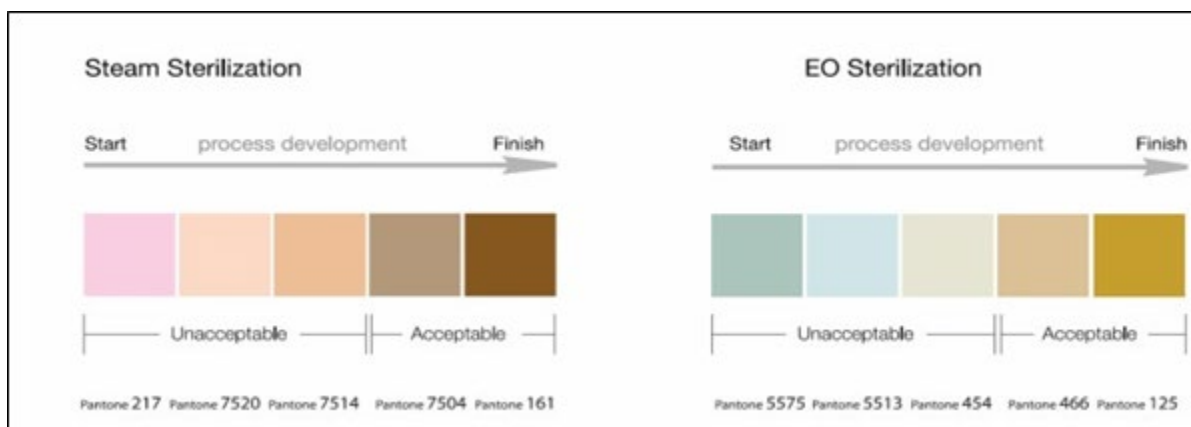
Characteristic	Specification			
Material Composition	Blue tinted film sealed to paper with two sets of indicators and double sides coated adhesive tape.			
Process Indicator Exposure	Steam: Indicators turn from pink to cocoa when processed 30 min. at 121°C or 4 min. at 134°C. EO: Indicators turn from 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 (inch)	Length (inch)
	2 ¼" X 4"	Film	2 ¼	4
		Paper	2 ¼	5
		Int. Pouch	1 ½	2 <sup>61</sup> / <sub>64</sub>
	2 ¾" x 9"	Film	2 ¾	9
		Paper	2 ¾	10
		Int. Pouch	2	8
	3 ½" x 5 ¼"	Film	3 ½	5 ¼
		Paper	3 ½	6 ¼
		Int. Pouch	2 ¾	4 <sup>5</sup> / <sub>16</sub>
	3 ½" x 9"	Film	3 ½	9
		Paper	3 ½	10
		Int. Pouch	2 ¾	8 ¼
	4 ¼" x 11"	Film	4 ¼	11
		Paper	4 ¼	12
		Int. Pouch	3 ½	9 <sup>15</sup> / <sub>16</sub>
	5 ¼" X 6 ½"	Film	5 ¼	6 ½
		Paper	5 ¼	7 ½
		Int. Pouch	4 ½	5 ½

Characteristic		Specification		
Dimension	Size	Part	Width (inch)	Length (inch)
	5 ¼" X 10"	Film	5 ¼	10
		Paper	5 ¼	11
		Int. Pouch	4 ½	8 <sup>15</sup> / <sub>16</sub>
	7 ½" X 13"	Film	7 ½	13
		Paper	7 ½	14
		Int. Pouch	6 ¾	11 <sup>15</sup> / <sub>16</sub>
	10" X 14"	Film	10	14
		Paper	10	15
		Int. Pouch	9 ⅝	12 <sup>51</sup> / <sub>64</sub>
	12" X 17"	Film	12	17
		Paper	12	18
		Int. Pouch	11 ⅝	15 <sup>15</sup> / <sub>16</sub>
	13" X 20"	Film	13	20
		Paper	13	21
		Int. Pouch	12 ⅝	19



## 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.	USA

### Appendix 1 List of Item Codes and Attributes

## Appendix 1 (List of items)

AMD Medicom Inc.

Item Code	Description	Packaging Information	Size	Specific Attribute	Marketed in USA as	Marketed in Canada as
88000-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 6 Boxes/Case, 1200 Pouches/Case	2 ¾" x 9" (70 x 229 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88005-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 5 Boxes/Case, 1000 Pouches/Case	3 ½" x 5 ¼" (89 x 133 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88010-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 6 Boxes/Case, 1200 Pouches/Case	3 ½" x 9" (89 x 229 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88010-4B	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	500 Pouches/Box 6 Boxes/Case, 3000 Pouches/Case	3 ½" x 9" (89 x 229 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88015-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	2 ¼" x 4" (57 x 102 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88020-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	5 ¼" x 6 ½" (133 x 165 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88025-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 10 Boxes/Case, 2000 Pouches/Case	5 ¼" x 10" (133 x 254 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88030-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 5 Boxes/Case, 1000 Pouches/Case	7 ½" x 13" (190 x 330 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88035-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	100 Pouches/Box, 4 Boxes/Case, 400 Pouches/Case	10" X 14" (254 x 354 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1

Item Code	Description	Packaging Information	Size	Specific Attribute	Marketed in USA as	Marketed in Canada as
88040-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	100 Pouches/Box, 4 Boxes/Case, 400 Pouches/Case	12" X 17" (305 x 430 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1
88045-4	Medicom SafeSeal Quattro Self-Sealing Sterilization Pouches	200 Pouches/Box, 6 Boxes/Case, 1200 Pouches/Case	4 ¼" x 11" (108 x 280 mm)	Process Indicator Exposure with Steam: 30 min. at 121°C or 4 min. at 134°C	Medical Device Class 2	Medical Device Class 1