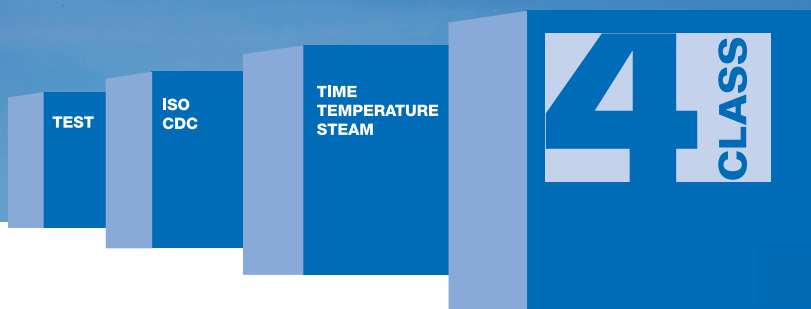


# MEDICOM<sup>®</sup> SAFE-SEAL duet



## Can your pouch say the same?

To assure a high quality product, effective sterilization and comply with ISO Standards, Safe-Seal Duet was put through a series of tests and validations.



## Features

- Now with a Class 4 internal multi-variable indicator and a Class 1 external process indicator for steam sterilization
  - Responds to all variables: time, temperature & saturated steam
  - Stated value of 2 minutes @134°C in the presence of saturated steam
- Class 1 internal and external process indicators for EO sterilization
- Meet CDC guidelines for effective sterilization
- Comply with ISO 11140-1:2005 standard for Class 4 and Class 1 indicators
- Comply with ISO 11607 standard for pouch performance

The following characteristics are routinely verified in accordance with ISO 11607-1

- Seal integrity - uniform seal width, no over sealed areas, leaks, channels, wrinkles, cracks, folds, tears, pinholes in the sealed area.
- Seal Strength - uniform seal strength ensures an aseptic opening without delamination or tearing of the film



### ISO 11140-1:2005 Standard

**1** Class 1 external process indicators (that are located outside the instrument area) are intended to indicate that the unit has been directly exposed to the sterilization process and to distinguish between process and unprocessed units.

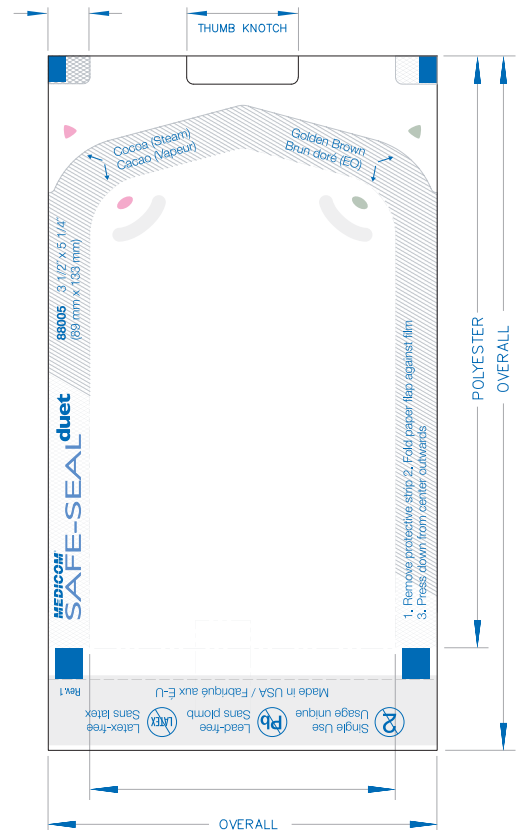
**2** Class 4 internal multi-variable indicators (that are located inside the instrument area) shall be designed to react to 2 or more of the critical variables and is intended to indicate exposure to a sterilization cycle at a stated value of the chosen variables.

### Safe-Seal Benefits

- Gives the user the assurance of confirming sterilization variables in one easy step: time, temperature & presence of saturated steam with internal & external indicators printed directly on the pouch
- Provides convenience and economy
- Maintains sterility of the device for up to 1 year post sterilization
- Tested and certified by an independent laboratory

# Safe-Seal Duet Main Characteristics

- ISO 11140-1:2005 compliant indicators
  - Class 4 internal multi-variable indicators and Class 1 external process indicators for steam sterilization
  - Class 1 internal and external process indicators for EO sterilization
- Strong seal with extra wide chevron seal protects against instrument breaching
- High quality porous medical grade paper that meets medical standard
- Lightly blue tinted film facilitates both easy instrument viewing and identification of punctures or tears in the film. The peeling of the film is equally easy because of clean separation of paper and film due to high grade materials
- Wide self-seal adhesive strip easily and securely seals the pouch and provides reliable seal until pouch is opened
- Perforated fold facilitates easy and accurate folding of adhesive strip to form airtight seal until pouch is opened
- Thumb notch assures easy opening of pouch



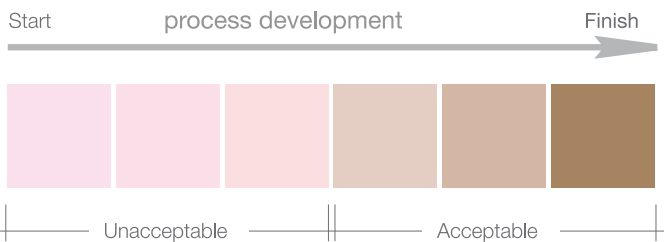
## Did you know?

- The Alberta Dental Association recommends the use of Class 4 indicators:
  - To comply with this recommendation, manufacturers must comply with ISO 11140-1:2005 (or the Canadian equivalent CAN/CSA Z11140-1)
  - Must state the critical variables and declare a stated value on the packaging
  - The reference Standard must be identified
- Steam is not a sterilant, only saturated steam is
- There is no such thing as Class 4 external multi-variable indicators - there are only Class 4 internal multi-variable indicators
- Any product and its packaging that does not reference the Standard and that does not declare stated values are simply not compliant
- Any product and its packaging that misuses terms are also not compliant

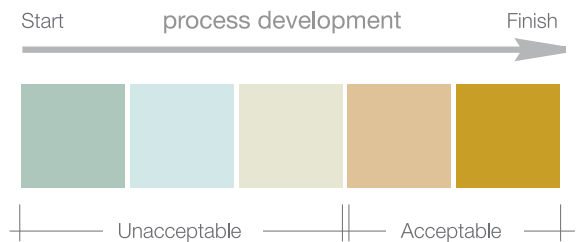
item code	description	units/pkg	pkg/case
88000	2 3/4" x 9" (70mm x 229mm)	200	6
88005	3 1/2" x 5 1/4" (89mm x 133mm)	200	5
88010	3 1/2" x 9" (89mm x 229mm)	200	6
88015	2 1/4" x 4" (57mm x 100mm)	200	10
88025	5 1/4" x 10" (133mm x 254mm)	200	10
88030	7 1/2" x 13" (190mm x 330mm)	200	5
88035	10" x 14" (254mm x 356mm)	200	5
88040	12" x 17" (305mm x 432mm)	200	5

# Colour Change Guide

## Steam Sterilization



## EO Sterilization



To order samples, please use code number: SP-88000  
 Questions? 1-800-361-2862 [www.medicom.com](http://www.medicom.com)

