

## Technical Data Sheet Multi-parameter Self-Sealing Sterilization Pouches

**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 dual process indicators are designed to indicate to the user that the pouch has undergone either a Steam or EO sterilization process.



Item Code	Description	Measurements of the pouch	# pouches / box	# boxes / case
88000	SafeSeal Duet	2 ¾" X 9" (70mm x 229mm)	200	6
88005	SafeSeal Duet	3 ½" X 5 ¼" (89mm x 133mm)	200	5
88010	SafeSeal Duet	3 ½" X 9" (89mm x 229mm)	200	6
88015	SafeSeal Duet	2 ¼" X 4" (57mm x 100mm)	200	10
88025	SafeSeal Duet	5 ¼" X 10" (133mm x 254mm)	200	10
88030	SafeSeal Duet	7 ½" X 13" (190mm x 330mm)	200	5
88035	SafeSeal Duet	10" X 14" (254mm x 356mm)	200	5
88040	SafeSeal Duet	12" X 17" (305mm x 432mm)	200	5

**Available**

For Canadian Market Only

**Country of Origin**

Made in US and/or Made in Taiwan

**Material components**

Blue tinted film sealed to paper with 2 sets of lead-free indicator inks and a polyester-backed adhesive tape

Pouches are made with high quality porous medical grade Kraft paper and a laminated 2 ply thick blue tinted film made from a combination of polypropylene and polyethylene. These materials are selected to ensure proper sterilant penetration.

Pouches and corresponding packaging is latex free.

## Product Performance

Safe-Seal Duet self-sealing pouches meet CDC guidelines for effective sterilization

Now with Class 4 internal multi-variable indicators and Class 1 external process indicators for steam

Responds to 3 variables: time, temperature and saturated steam

Stated value: 2 minutes @134°C in the presence of saturated steam

Meet CDC guidelines for effective sterilization. Comply with CSA/ISO 11140-1:2005 standard for Class 4 external indicators and Class 1 internal indicators. Comply with ISO 11607 standard for pouch performance

When seals are peeled open: no visual film fracturing, delaminating or fiber tear that can create foreign particulate in the operating room or sterile field is observe

Process indicators respond to multiple sterilization parameters that are essential for sterilization via steam or EO.

- *Steam – Time, Temperature, Presence of Steam.*
- *EO – Time, Temperature, Relative Humidity, EO concentration.*

## Other Product Info

Pouches have a 5/8" wide adhesive tape seal and a 3/8" wide thermal single seal to ensure the pouch maintains sterility after sterilization.

Pouches are compatible with large number of commonly used disinfectants

## Sterility

Pouches maintain sterility of the device for up to one year post sterilization.

## Usage

For Single-use only

### *Some definitions:*

- **ISO 11140 standard:** Process indicators are verified for conformance to ISO 11140-1 class 1 performance characteristics. This ensures the stability of the inks so that there are no issues of process indicators firing prematurely or not at all during sterilization.
- **ISO 11607 standard:** Pouches are manufactured under stringent quality-assurance systems as required by the current version of ISO 13485. 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 of tearing of the film