

Sterilization Pouches

Medical Device, Class I

TECHNICAL DATA SHEET

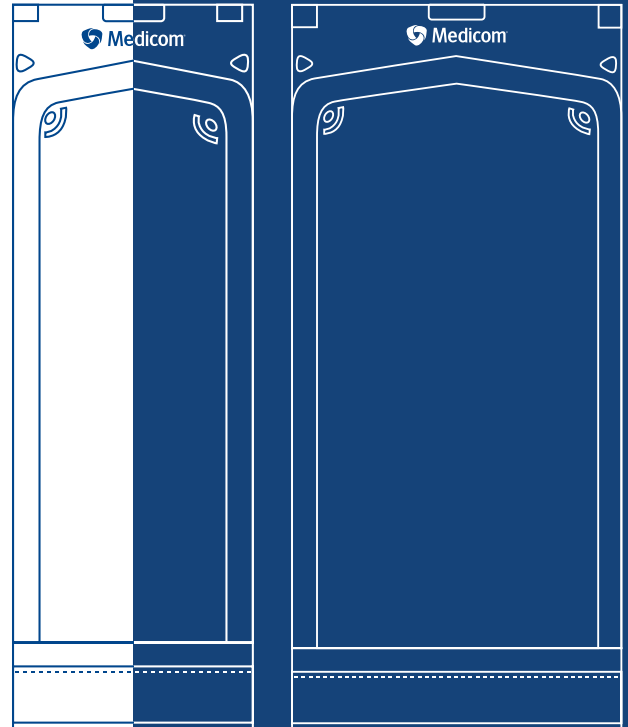
English

FEATURES & BENEFITS

- For use as sterile barrier packaging for terminally sterilized medical devices in sterilization by steam, ethylene oxide gas in healthcare establishments
- Non-tearing, thick multi-layer film made of a combination of polypropylene and polyethylene terphthalates
- Transparent, blue tinted film facilitates both easy instrument viewing and identification of puncture or tears in the film
- Clean, fibre-free separation of paper and film ensures safe presentation of sterile products
- Pouches have a wide adhesive sealing tape which easily and securely seals the pouch providing a reliable seal until pouch is opened
- Permit to keep the sterilization conditions of the contained devices after sterilization: up to 1 year

PRODUCT DESCRIPTION

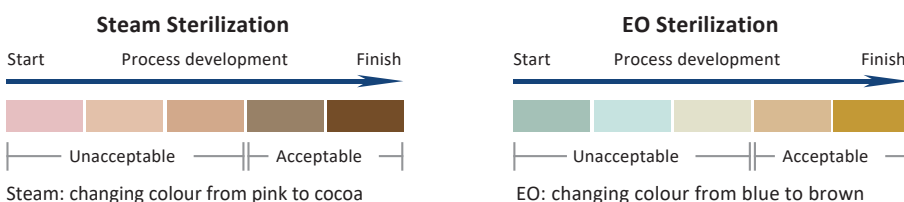
Product name: SafeSeal® Quattro Sterilization Pouches
 Product type: Single use, non-sterile
 Material: Heavy weight medical paper, polypropylene and polyethylene terphthalates film
 Medical grade paper: 60g/m²
 Film: 44 µm
 Origin: Taiwan



Sterilization Cycle Parameter	Gravity Steam		Ethylene Oxide Gas
	30	4	100-120
Time (min)	30	4	100-120
Temperature (°C)	121	134	50
Relative humidity (%)	N/A	N/A	60-85
Sterilant Concentration	N/A	N/A	600
Drying-Aeration time	15-30min	20-30min	12hrs

N/A = Not applicable

Process Indicator Colour Change Guide:



SIZES

REF	Dimensions
88000	70 x 229 mm
88005	89 x 133 mm
88010	89 x 229 mm
88015	57 x 102 mm
88025	133 x 254 mm
88030	191 x 330 mm
88035	254 x 356 mm
88040	305 x 432 mm

Sterilization Pouches

Medical Device, Class I

TECHNICAL DATA SHEET

English

INDUSTRIES

Medical / Dental / Laboratory & Research

STORAGE CONDITIONS

Normal conditions of conservation and storage: not to be exposed to moisture and sun.

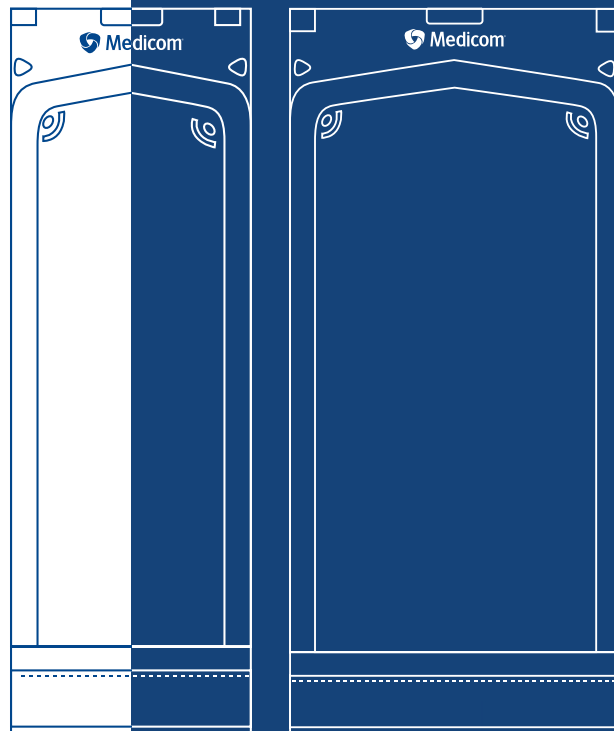
Storage Condition Recommended: Temperature: 15~35°C; RH% below 70%.

STANDARDS & CERTIFICATIONS

Meets the requirement of Regulation (EU) 2017/745 for medical devices. Complies with applicable standards EN ISO 11607 and EN 868-5.

Manufacturing site : ISO 13485 certified.

LOGISTICAL INFORMATION



REF	Outer case specifications Size (W x L x H) mm	Inner box specifications Size (W x L x H) mm	QTY/ Outer case
88000	160 x 268 x 202	76 x 260 x 64	6 packages x 200 pcs.
88005	173 x 483 x 74	95 x 165 x 64	5 packages x 200 pcs.
88010	267 x 298 x 138	95 x 260 x 64	6 packages x 200 pcs.
88015	141 x 333 x 138	64 x 133 x 64	10 packages x 200 pcs.
88025	298 x 307 x 345	140 x 286 x 64	10 packages x 200 pcs.
88030	210 x 328 x 370	197 x 362 x 64	5 packages x 200 pcs.
88035	330 x 400 x 267	260 x 387 x 64	5 packages x 200 pcs.
88040	337 x 476 x 343	311 x 464 x 64	5 packages x 200 pcs.

