

Sterilization Reels

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
- Permit to keep the sterilization conditions of the contained devices after sterilization: up to 1 year

PRODUCT DESCRIPTION

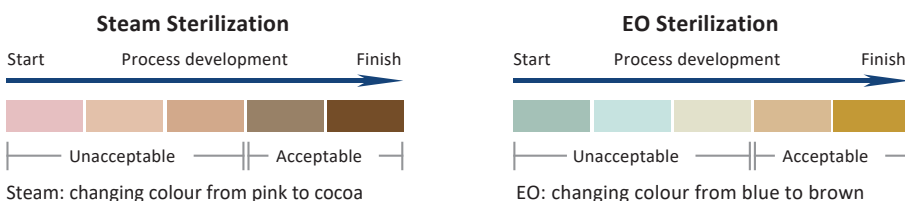
Product name: SafeSeal® Quattro Sterilization Reels
 Product type: Single use, non-sterile
 Material: Heavy weight medical paper, polypropylene and polyethylene terphthalates film
 Medical grade paper: 60g/m²
 Film: 52 µm
 Origin: Taiwan



Sterilization Cycle Parameter	Gravity Steam		Ethylene Oxide Gas
	30	4	
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	12 hrs

N/A = Not applicable

Process Indicator Colour Change Guide:



INDUSTRIES

Medical / Dental / Laboratory & Research



SIZES

REF	Dimensions
9850	50mmx200m
9860	75mmx200m
9870	100mmx200m
9880	150mmx200m
9890	200mmx200m
98100	250mmx200m
98110	300mmx200m

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TERMS OF USE

The sealing temperature recommended is in the range of 165°C up to 210°C (depending on the type of sealing machine and requested seal strength)

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%. Shelf life of the product: 3 years

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

Outer case specifications

REF	Size (W x L x H) mm	QTY/ Outer case
9850	220 x 325 x 220	6 reels
9860	220 x 325 x 220	4 reels
9870	220 x 325 x 220	3 reels
9880	220 x 325 x 220	2 reels
9890	220 x 225 x 220	1 reel
98100	226 x 275 x 230	1 reel
98110	226 x 325 x 230	1 reel

