

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

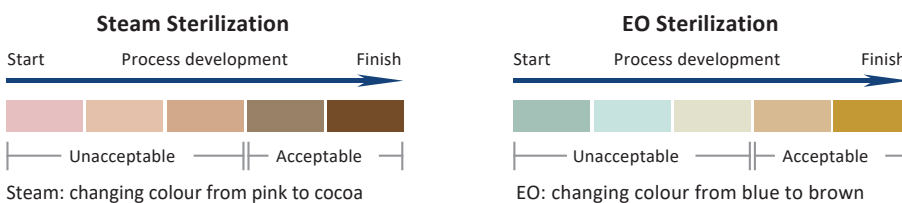
PRODUCT DESCRIPTION

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 | 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 | 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 |

