

SMARTDENT

Sterilisationsfolienrollen

Technical Data Sheet

A special film with characteristics of resistance and good peelability, sealed to a medical paper with high anti-bacterial protection are the main components of our flat reels.

Medical Paper:

- density 60 g/m²

Laminated Bi-Component Film (PP-PET):

- PET thickness 12 nm
- PP thickness 30 nm
- Color: Blue

Release of fibers of paper:

- None

Lacerations of the plastic material:

- None

Welding:

- 3 weld lines equally spaced
- Span of the welding from the edge: 11 mm
- Seal the open end(s) with a thermostealing machine at:
 - T: 170-180 °C/338-356 °F
 - P: 70-90 N/cm²
- follow the instructions of the sealing machine manufacturer

Chemical Indicators on the product:

- STEAM from pink to brown (121°C for 15' or 134°C for 3')
- EO from green to Ochre
- Toxicity: not toxic, water based

Regulatory Framework

- Regulation MDR 745/2017 on Medical Device
- Class I medical device
- Reach regulation: not applicable

Compliance with following relevant standards:

- Reels and Pouches: EN 11607-1
- Final testing: EN 868-5
- Medical paper: EN 868-3
- Chemical Indicators: EN 11140-1 class 1

Storage Environmental conditions (to be met only before use):

- T min: + 5 °C
- T max: +35 °C
- RH min: 30%
- RH max: 70%

Expiring time

- 5 years from the welding date

Traceability:

- Batch number

Models and UDI-DI

REF	Description	UDI DI
111349	Roll 50 mm x 200 m	0803402839803
111350	Roll 75 mm x 200 m	0803402839804
111351	Roll 100 mm x200 m	0803402839805