

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices



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China
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Product name: Sterilization Pouch/Roll

Model No.: /

Basic UDI DI: /

EMDN codes: S0102-STERILISATION REELS

Intended Purpose: Used to enclose other medical devices for sterilization and subsequent storage until used

Classification: Class I, in accordance with Annex VIII, Rule [1] of Regulation (EU) 2017/745

Applicable Regulation: Regulation (EU) 2017/745 on medical devices

Applicable Standards / CS: ISO 10993-10:2021; ISO 10993-5:2009; ISO 10993-23:2021;
EN ISO 15223-1:2021; EN ISO 14971: 2020; ISO 20417: 2021;
EN ISO 13485: 2016;

We, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Regulation (EU) 2017/745 on the Medical Devices (MDR). All supporting documentation is retained under the premises of the manufacturer.

Place, Date
Suzhou, June-16, 2026

Zhu Jing, General Manager
BOEN HEALTHCARE CO., LTD.

Heat sealing Sterilization Flat Roll



Apply to hospital, clinic and laboratory's sterilization; and also apply to the disinfection of beauty products or family high-temperature;

Made of transparent, polyester-polypropylene film coupled to medical grade paper which permit steam and gas penetration during sterilization.

Apply to STEAM sterilization, ETO sterilization and FORM sterilization.

The sharp part of equipment should be put contrary to the peel side to ensure safety use;

Using sealing machine to seal and mark the sterilization time, contents and usage etc.

The clear area with temperature below 25°C and humidity below 60% is recommended.

Sterility preservation period – 1 year;

The product corresponds to the standard of ISO11140-1 in conformity with EN868-5.

Cat No.	Size (mm x m)	Qty/Case (roll)
212401	Heat Sealing Sterilization Flat Roll 50x200	12
212402	Heat Sealing Sterilization Flat Roll 55x200	12
212403	Heat Sealing Sterilization Flat Roll 75x200	8
212404	Heat Sealing Sterilization Flat Roll 100x200	6
212405	Heat Sealing Sterilization Flat Roll 125x200	4
212406	Heat Sealing Sterilization Flat Roll 150x200	4
212407	Heat Sealing Sterilization Flat Roll 200x200	2
212408	Heat Sealing Sterilization Flat Roll 250x200	2
212409	Heat Sealing Sterilization Flat Roll 300x200	2
212410	Heat Sealing Sterilization Flat Roll 350x200	1
212411	Heat Sealing Sterilization Flat Roll 400x200	1
212412	Heat Sealing Sterilization Flat Roll 500x200	1

User Manual for Sterilization Roll

Product Name: Heat Sealing Sterilization Flat Roll

Specification: 50mmx200m, 55mmx200m, 75mmx200m, 100mmx200m, 150mmx200m, 200mmx200m, 250mmx200m, 300mmx200m, 350mmx200m, 400mmx200m

Intended Use: it is widely used in sterilization and preservation of medical instruments in hospital supply room, operating room and stomatology department, etc.

Structure: Composed of a layer of medical dialysis paper resistant to high temperature and high-pressure steam and a layer of high temperature resistant transparent composite film. On the paper, it is with EO and steam sterilization indicator.

Instruction for Use:

1. Cut the appropriate size according to the medical device.
2. Put the clean and dry medical instrument into the sterilization bag.
3. Seal the bag with heat sealing machine.
4. Put the sterilization bag into STEAM sterilization machine or ETO sterilization machine, Sterilize according to conventional methods.
5. Mark the sterilization time and other information on the bag, confirm that the sterilization indicator has changed color.
6. When needed, tear open the sterilization bag and take it out for use.
7. DO NOT USE A SECOND TIME.

Suitable for Sterilization

1. The sterilization condition of the lower row pressure steam sterilizer by the sterilization bag is 102.9 kPa, the temperature reaches 121 °C, the sterilization time is 30 minutes, and biological monitoring is carried out regularly.
2. The sterilization condition of the sterilization bag to the pre vacuum pressure steam sterilizer is 205.8kpa, the temperature reaches 134 °C, the sterilization time is 4 minutes, and biological monitoring is carried out regularly.
3. The sterilization bag is also suitable for ETO ethylene oxide sterilization. Or packaging materials with other sterilization methods can be selected.
4. The sterilization bag is not suitable for dry heat sterilization.

Use Suggestions

1. After standard sterilization, the sterilized instruments and articles stored in the sterilization bag are stored in a qualified environment. When the temperature, humidity and cleanliness are appropriate, it is recommended to use them within 12 months after steam or ETO ethylene oxide sterilization.
2. Before use, check the integrity of the sterilization bag. Do not use it if it is damaged.
3. The shelf life of the sterilization bag is 5 years.