

# EU DECLARATION OF CONFORMITY

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

Manufacturer: Boen Healthcare Co., Ltd.  
Unit 602, International Center, No.535, Shenxu Road, 215021  
Suzhou, Jiangsu, China

SRN: Not assigned yet

Trademark: N.A.

European Representative: Humiss Beratung GmbH  
Gneisenaustraße 8. 40477, Duesseldorf, Deutschland

SRN: DE-AR-000023447

Trade Name: Heat sealing Sterilization Flat Roll

Product Name: Heat sealing Sterilization Flat Roll

Basic UDI-DI: /

Classification acc. to MDR Ax. VIII:	Class 1, rule 1	
Applied Standards	EN ISO 14971:2019	EN ISO 15223-1:2016
	EN 1041:2008+A1:2013	ISO 10993-1:2018
	EN ISO 10993-5:2009	EN ISO 10993-10:2013
	EN 868-5:2019	EN ISO 11607-1:2020
	EN ISO 11140-1:2015	

Conformity Assessment Procedure: Annex II + Annex III of MDR

CE Certificate No.: N.A.

Name and ID of the Notified Body: N.A.

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

Jing Zhu

Suzhou, China  
Sep. 22, 2023

## Clarification

WE, BOENMED manufactures Heat sealing Sterilization Flat Roll. The Heat sealing Sterilization Flat Roll made of 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.

Goods offered within the procurement procedure no. 21265769/ocds-b3wdp1-MD-1722602379495, have a sterility retention period of 1 year/12 months, according to the requirements requested in the specifications;

Cat No.	Size (mm x m)
212401	Heat Sealing Sterilization Flat Roll 50x200
212403	Heat Sealing Sterilization Flat Roll 75x200
212404	Heat Sealing Sterilization Flat Roll 100x200
212406	Heat Sealing Sterilization Flat Roll 150x200
212407	Heat Sealing Sterilization Flat Roll 200x200
212408	Heat Sealing Sterilization Flat Roll 250x200
212409	Heat Sealing Sterilization Flat Roll 300x200
212410	Heat Sealing Sterilization Flat Roll 350x200
212411	Heat Sealing Sterilization Flat Roll 400x200

Boen Healthcare Co., Ltd.

Apr. 18, 2025



# BOEN HEALTHCARE CO., LTD.

## Certificate of Analysis

Report No.: GM04-BN24

Product Name	Heat sealing roll	Lot. No.	20241220
Mfg. Date	2024-12	Exp. Date	2029-11
Order Quantity	1579rolls	Inspection Date	2025.01.10
Inspection Standard	Factory Standard	Report Date	2025.01.10
Specification	150mmx200m, 200mmx200m, 250mmx200m, 300mmx200m, 350mmx200m 400mmx200m, 75mmx200m		

Item	Technical Requirement	Result	Conclusion
Size	Tolerance: $\pm 2\text{mm}$	Comply	Qualified
Appearance	The product shall have no holes, cracks, tears, wrinkles that weaken its function, or local thickening or thinning that may affect its function.	Comply	Qualified
Fluorescence	Shall be no fluorescence.	Comply	Qualified
Air permeability	At a pressure of 1.47Kpa, the air permeability shall not be less than $3.4\mu\text{M}/(\text{Pa.s})$ .	Comply	Qualified
Thickness	Thickness not less than $\pm 5\%$ of nominal value.	Comply	Qualified
Leakage	It shall be no leakage.	Comply	Qualified
Sealing and peeling fibers	It should be free of fiber detachment.	Comply	Qualified
Indicator	All chemical indicator color blocks meet the specified color standards.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Tom Li  
Date: 2025.01.10

Checker: Leo Sun  
Date: 2025.01.10



## 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.

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℃ and humidity below 60% is recommended, the valid period will be 6 months after sterilizing.

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

Cat No.	Description	Qty/Case (roll)
212401	Heat Sealing Sterilization Flat Roll 50mmx200m	12
212402	Heat Sealing Sterilization Flat Roll 55mmx200m	12
212403	Heat Sealing Sterilization Flat Roll 75mmx200m	8
212404	Heat Sealing Sterilization Flat Roll 100mmx200m	6
212405	Heat Sealing Sterilization Flat Roll 125mmx200m	4
212406	Heat Sealing Sterilization Flat Roll 150mmx200m	4
212407	Heat Sealing Sterilization Flat Roll 200mmx200m	2
212408	Heat Sealing Sterilization Flat Roll 250mmx200m	2
212409	Heat Sealing Sterilization Flat Roll 300mmx200m	2
212410	Heat Sealing Sterilization Flat Roll 350mmx200m	1
212411	Heat Sealing Sterilization Flat Roll 400mmx200m	1
212412	Heat Sealing Sterilization Flat Roll 500mmx200m	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.