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Web: [www.baojiechina.com](http://www.baojiechina.com) Email: [sales6@baojiechina.com](mailto:sales6@baojiechina.com) Mobile/Whatsapp: 0086-139 6581 88

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## Declaration

We, Anqing Baojie Packaging Co., Ltd is a manufacture of heat-sealing flat sterilization roll, heat-sealing gusseted sterilization roll

Here we declare that each sterilization roll is packed within a plastic film, and each carton has a big PE pouch to pack all the sterilization roll.

*Gaminiojas teigia, kad sterilizacijos gaminiai supakuoti į Pe plėvelę ir kartono dėžę.*

For and on behalf of  
ANQING BAOJIE PACKAGING CO., LTD

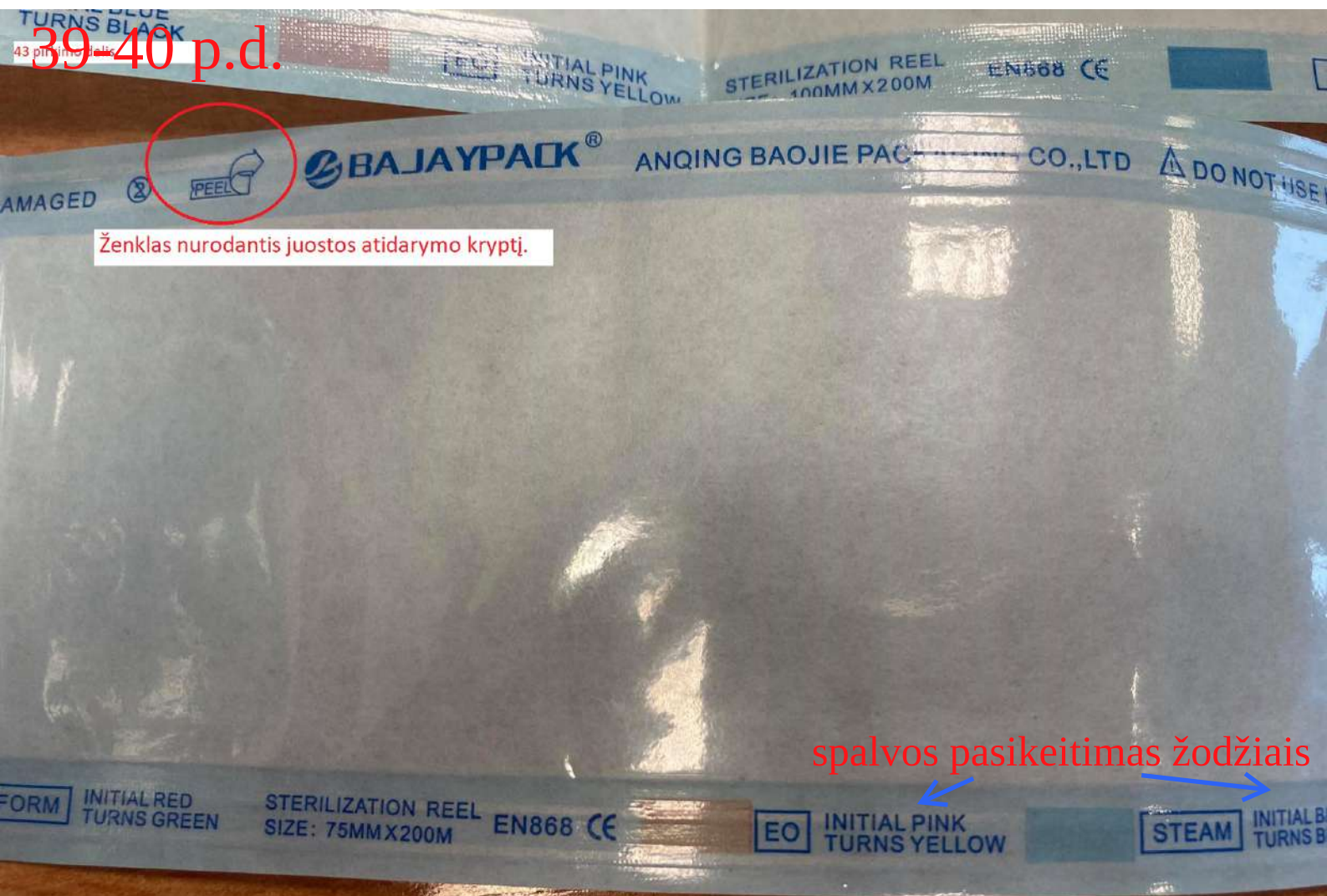
安庆市宝洁包装有限公司  
ANQING BAOJIE PACKAGING CO., LTD

杨晓东

Signature

Xiao Dong Yang

39-40 p.d.



ANQING BAOJIE PACKAGING Co. Ltd.  
*Xingye RD 123, Anhui, Kinija*

DEKLARACIJA

Mes, Anqing Baojie Packaging Co.Ltd, plokščių ir su klose juostų gamintojai čia teigiame, kad kiekvienas sterilizacijai skirtas juostos rulonas yra supakuotas į plastiko plėvelę ir vėliau sudedamas į polietileno maišelį bei į kartoninę dėžę.

Anqing Baojie Packaging Co. Ltd. vardu

*/parašas/*

*/ antspaudas /*

Pag 1

ANQING BAOJIE PACKAGING CO., LTD

No.123, Xingye Road, Yixiu District, Anqing, Anhui Province, China

Web: [www.baojiechina.com](http://www.baojiechina.com) Tel: +86-558-5369412 mail: [sales6@baojiechina.com](mailto:sales6@baojiechina.com)

Date: Apr-19TH - 2019

DECLARATION

We, Anqing Baojie Packaging Co., Ltd is a manufacture of heat-sealing flat sterilization roll. Heat-sealing gusseted sterilization roll.

*Tvirtiname, kad mūsų produktai atitinka ISO 868-5, ISO 11607-1 ir ISO 11140-1*

Here we declare that all our products are in conformity with EN ISO 868-5, EN ISO 11607-1, ISO 11140-1

*Mūsų rekomenduojama užlydymo temperatūra 180C, laikas 2 sec., slėgis 0,15kg/cm2*  
Our recommendations for sealing temperature and pressure is 180 °C for  
2 seconds ,the valid pressure should be 0.15kg/cm2.

For and on behalf of

ANQING BAOJIE PACKAGING CO., LTD

安庆市宝洁包装有限公司

ANQING BAOJIE PACKAGING CO., LTD

杨晓东

Signature

*Xiao Dong Yang*

**安庆市宝洁包装有限公司**  
**ANQING BAOJIE PACKAGING CO., LTD**

安徽省安庆市开发区兴业路 123 号 、 NO.123,XINGYE RD, DEVELOPMENT DISTRICT,ANQING, ANHUI  
电话/Tel:0556-5369413 传真/Fax :4008266163\*59008 网址/Web:www.baojiechina.com 邮箱/Mail: sales6@baojiechina.com

Date: Jan. 27th, 2022

## DECLARATION

We, Anqing Baojie Packaging Co., Ltd, as a manufacture of sterilization roll(reel) in China, with address No.123, Xingye Road, Yixiu District, Anqing city, China,

Hereby declare that the printing info on the sterilization flat roll(reel) and gusseted roll(reel) includes following :

Roll size, ETO,Steam,Form Indicators, ISO 11607, tearing of direction, CE, size, manufacture name and other related info

Best regards

Anqing Baojie Packaging Co., Ltd

安庆市宝洁包装有限公司  
ANQING BAOJIE PACKAGING CO.,LTD  
杨晓东

热封型立体卷袋

Heat Sealing Sterilization Gusseted Reel

Atitinka EN11607  
reikalavimus



产品描述

Description

产品材质: 60gsm/70gsm 医用高温透析纸(法国Ajo纸  
+蓝色/绿色/白色医用CPP/PET复合膜  
制造标准: ISO 11607-1 EN868-5 BJ-C-07/E

Materials:60gsm/70gsm Medical Grade  
Paper/France Ajo Paper+blue/white/green medical  
CPP/PET Compound Film.

Pagaminta iš medicininio popieriaus ir skaidraus plastiko.

产品特点

Features

- 100米/卷, 可以依据被灭菌物品的尺寸任意取长, 方便实用;
- 展开后呈立体状有效增加容积, 能够轻松装入较大的被灭菌物品;
- 印有灭菌变色指示标识, 灭菌前后变色显著、无逆反; 蒸汽灭菌前为蓝色, 灭菌后呈灰黑色; 环氧乙烷灭菌前为粉红色, 灭菌后呈褐色;
- 采用三条防爆边工艺, 可以有效防止爆裂;
- 通过透明复合膜可以直接观察内装物品, 有效防止差错。

- 100m/roll, size can be cut according to different kind of sterilizing goods, easy to use.
- Large sterilizing goods can be easily loaded due to gusseted design;
- The indicator's color has significant change and no change back; the initial blue will turn into black based on steam sterilization method;
- turn brown from initial pink based on ETO sterilization method;
- The three sided explosion proof can efficiently prevent the pouch from bursting;
- The transparent compound film can show what inside the pouch clearly in order to reduce errors.



Informacija pateikta ant juostos

使用说明

How to use

- 适用于医院、社区诊所、实验室的灭菌包装, 美容用品的消毒包装, 家庭高温消毒包装;
- 适用于环氧乙烷(ETO)灭菌, 高温高压蒸汽(STEAM)灭菌;
- 器械尖銳部位的摆放方向与剥离方向相反, 以确保使用安全;
- 用封口机封好袋口, 标明灭菌时间、内容、用途等相关信息
- 建议灭菌后储存于温度低于25℃、湿度低于60%的洁清区域, 并于灭菌后6个月内使用;
- Apply to hospital, clinic and laboratory's sterilization;and also apply to the disinfection of beauty products or family high-temperature;
- Apply to both ETO sterilization and STEAM 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

Tinka sterilizacijai garais ir FO dujomis. Juostų vidiniame laminuotos

规格参数

SPECIFICATION

| 产品<br>ITEM   | 规格(宽x长)<br>SIZE(WxL) |         | 包装<br>ROLL/CTN | 外箱尺寸<br>SIZE OF CTN | 毛重<br>G.W. | 净重<br>N.W. |
|--------------|----------------------|---------|----------------|---------------------|------------|------------|
|              | 英寸<br>INCH           | mmxm    |                |                     |            |            |
| LTJD.075-100 | 2.75 "               | 75X100  | 8              | 400X210X320         | 10         | 9.5        |
| LTJD.100-100 | 4 "                  | 100X100 | 6              | 400X210X320         | 10         | 9.5        |
| LTJD.150-100 | 6 "                  | 150X100 | 4              | 400X210X320         | 10         | 9.5        |
| LTJD.200-100 | 8 "                  | 200X100 | 2              | 400X210X220         | 7.5        | 7          |
| LTJD.250-100 | 10 "                 | 250X100 | 2              | 400X210X270         | 8          | 7.5        |
| LTJD.300-100 | 12 "                 | 300X100 | 2              | 400X210X320         | 10         | 9.5        |
| LTJD.350-100 | 14 "                 | 350X100 | 2              | 400X210X370         | 11         | 10.5       |
| LTJD.400-100 | 16 "                 | 400X100 | 2              | 400X210X420         | 12         | 11         |

40.1

40.2

40.3

40.4

40.5

40.6

40.7

DECLARATION

We, Anqing Baojie Packaging Co., Ltd, as a manufacture of sterilization gusseted roll/reel, with address No.123, Xingye Road, Yixiu District, Anqing city, China, Hereby we declare that we can manufacture the sterilization gusseted roll according to the following standard

|      |                                |
|------|--------------------------------|
| 40.1 | 75mm±10mm x 25mm x 100 m       |
| 40.2 | 100mm±10mm x 50mm x 100 m      |
| 40.3 | 150mm ±10mm x 50/65 mm x 100 m |
| 40.4 | 200mm ±10mm x 50/65 mm x 100 m |
| 40.5 | 250mm ±10mm x 60/65 mm x 100 m |
| 40.6 | 300 mm x 65/80 mm x 100 m      |
|      | 350 mm x 70/80 mm x 100 m      |
| 40.7 | 400 mm x 70/80 mm x 100        |

klostès plotis

Best regards

Anqing Baojie Packaging Co., Ltd

安庆市宝洁包装有限公司

ANQING BAOJIE PACKAGING CO.,LTD

杨晓东

**ANQING BAOJIE PACKAGING CO., LTD**

No.123, Xingye Road, Yixiu District, Anqing, Anhui Province, China

Web: [www.baojiechina.com](http://www.baojiechina.com) Tel: +86-556-5369412 mail: [sales6@baojiechina.com](mailto:sales6@baojiechina.com)

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Date: Apr-19TH - 2019

## DECLARATION

We, Anqing Baojie Packaging Co., Ltd is a manufacture of heat-sealing flat sterilization roll. Heat-sealing gusseted sterilization roll.

Here we declare that all our products are in conformity with EN ISO 868-5, EN ISO 11607-1, ISO 11140-1

Our recommendations for sealing temperature and pressure is 180°C for 2 seconds ,the valid pressure should be 0.15kg/cm2.

For and on behalf of

ANQING BAOJIE PACKAGING CO., LTD

安庆市宝洁包装有限公司

ANQING BAOJIE PACKAGING CO., LTD

杨晓东

Signature

*Xiao Dong Yang*

**Anqing Baojie Packaging Co Ltd**  
**No. 123, Xingye Road, Yixiu District, Anqing Province, Kinija**

Data: 2019.04.19

## **D E K L A R A C I J A**

Mes, Anqing Baojie Packagong Co., Ltd esame užlydomų sterilizacijos plokščių ir su klose juostų gamintojai.

Mes tvirtiname kad visi mūsų produktai atitinka ISO 868-5, ISO 11607-1 ir ISO 11140-1.

Rekomenduojame 180 C užlydymo temperatūrą 2 s bei slėgį 0,15kg/cm<sup>2</sup>.

**ANQING BAOJIE PACKAGING CO LTD**

/Antspaudas/

/Parašas/



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

### Applicable 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

### Remark

The declaration of conformity is valid in connection  
with the release technical document  
CE/MDR-BJ01.

All the supporting documentation is retained at the  
premises of the manufacturer.

The Declaration of Conformity is exclusively under  
the sole responsibility of the manufacturer.

## Manufacturer

Name: Anqing Baojie Packaging Co., Ltd.  
Address: No.123, XingYe RD, Development  
District, Anqing City, Anhui, China

## Product Information

Name: Sterilization pouch/roll  
Model: ZFD SERIES, RFD SERIES, PMJD  
SERIES, LTJD SERIES  
GMDN: 13735  
Basic UDI-DI: /  
Classification: Class I, According to Rule 1, Annex  
VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned  
products meet the requirements of Medical Device  
Regulation (EU) 2017/745 and the applicable  
standards above.

Signature: Yang Xiao Dong Date: 2021.5.21

Position: GM



## Atitikties deklaracija

Remiantis EU medicinos priemonių direktyva 2017/745

Gamintojas: Anqing Baojie Packaging Co., Ltd

Adresas: No. 123 Xingye Road, Decelopment rajonas, Anqing miestas, Anhui Provincija, Kinija

Atstovai:

Pavadinimas: SUNGO Europe B.V.

Adresas: Olympisch Stadion 24, 1076DE Amsterdamas

Atitikties įvertinimas :

Atitikties įvertinimo procedūra

Annex II+III reguliacijos EU 2017/745

Aplikuojami standartai :

EN ISO 14971 : 2019

EN ISO 15223-1 : 2016

ISO 10993-1 : 2018

EN ISO 10993-5: 2009

EN ISO 10993-10 : 2013

EN 868-5 :2019

EN ISO 11140-1:2015

Pastaba :

Atitikties deklaracija yra galiojančiai susijusi su techniniu dokumentu CE/MDR-BJ01

Visi patvirtinantys dokumentai yra saugojami gamintojo.

Atitikties įvertinimas yra gamintojo įsipareigojimas.

Produktai:

Pavadinimas : Juosta sterilizavimui

Modelis : ZFD SERIJA ,RFD SERIJA , PMJD SERIJA , LTJD SERIJA

GMDN : 13735

Pagrindinis : UDI-DI : /

Klasifikacija: 1 klasė

Pagal 1 taisyklę, annex VIII, reguliacija EU 2017/745

Deklaracija

Pareiškama, kad pirmiau nurodytas medicinos prietaisas atitinka esminius reikalavimus EU 2017/745, išvardytus Europos medicinos prietaisų direktyvos .

/Antapaudas/ parašas/

**Data :2021.05.21**