

Certificate of Registration



This is to certify that the Quality Management System of

Tianchang City Guomao Plastic Industry Co., Ltd.

Unified Social Credit Code: 91341181666222240C

Operation Address: No.139, Tiankang Road, Economic Development District, Tianchang City, Chuzhou City, Anhui Province, China

Registered Address: No.139, Tiankang Road, Economic Development District, Tianchang City, Anhui Province, China

applicable to

Production and sales of medical sterilization packaging bags/rolls(within the scope of qualification)

has been assessed and registered by NQA against the provisions of

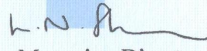
ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn


Managing Director

Certificate Number: **45020**

Issue Date: 11 July 2018

Reissue Date: 11 July 2024

Valid Until: 11 July 2027



0015





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7
2909VA Capelle aan den IJssel -
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards

EN ISO14971:2019
EN ISO15223-1:2021
EN ISO10993-1:2020
EN ISO10993-5:2009
EN ISO10993-10:2010
EN ISO 20417: 2021

Manufacturer

Name: TIANCHANG CITY GUOMA O PLASTIC
INDUSTRY CO.,LTD.
Address: NO.139,TIANKANG ROAD,ECONOMIC
DEVELOPMENT DISTRICT,TIANCHANG,ANHUI,CHINA
SRN: CN-MF-000019462

Product Information

Name: STERILIZATION POUCH / ROLL

Model

57*100mm, 57*125mm, 57*130mm, 50*220mm, 70*165mm, 70*230mm, 70*260mm, 90*135mm, 90*165mm, 90*170mm, 90*260mm, 135*230mm, 135*255mm, 135*260mm, 135*280mm, 135*285mm, 130*300mm, 190*330mm, 190*360mm, 230*408mm, 250*340mm, 250*370mm, 250*400mm, 260*380mm, 260*410mm, 300*380mm, 300*410mm, 300*430mm, 300*460mm, 50mm*200m, 75m*200m, 100mm*200m, 150mm*200m, 200mm*200m, 250mm*200m, 300mm*200m, 350mm*200m, 400mm*200m, 500mm*200m, 600mm*200m, 60mm*100m, 75mm*100m, 100mm*100m, 150mm*100m, 200mm*100m, 250mm*100m, 300mm*100m, 350mm*100m, 400mm*100m, 500mm*100m, 75mm*100m*25mm, 100mm*100m*50mm, 150mm*100m*55mm, 200mm*100m*65mm, 250mm*100m*70mm, 300mm*100m*80mm, 350mm*100m*80mm, 400mm*100m*100mm, 415mm*1000m, 830mm*1000m, 30*30cm, 40*40cm, 45*45cm, 50*50cm, 60*60cm, 70*70cm, 75*75cm, 80*80cm, 90*90cm, 100*100cm, 110*110cm, 120*120cm. Customized size are available.

EMDN: S0102

Basic UDI-DI: 697424517SPR001PK

Classification: Class I, According to Rule 1, Annex VIII,
Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-S0102-01.

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.

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

Signature: 高健 (Gao Jian) Date: 2025/4/8

Position: General Manager

Place: Anhui/China





Annex to Report (No. 02748)

Tianchang City Guomao Plastic Industry Co., Ltd.

Product Name	Type
Medical Dialysis Paper	415mmx1000m,830mmx1000m; Customized size are available
Medical Adhesive Coated Paper	415mmx1000m,830mmx1000m; Customized size are available
Medical Tyvek Paper	Customized size are available
Medical Crepe Paper	30x30cm,40x40cm,45x45cm,50x50cm,60x60cm,70x70cm,75x75cm,80x80cm,90x90cm,100x100cm,110x110cm,120x120cm; Customized size are available
Medical Non-woven Wrap(SMS,SMMS)	30x30cm,40x40cm,45x45cm,50x50cm,60x60cm,70x70cm,75x75cm,80x80cm,90x90cm,100x100cm,110x110cm,120x120cm; Customized size are available
Medical Sterilization Indicator Tape	12mmx50m,19mmx50m,25mmx50m;Customized size are available
Medical Sterilization Indicator Strip	15mmx100mm,20mmx110mm,16mmx200mm,40mmx80mm; 20mmx140mm,20mmx108mm Customized size are available
Medical Sterilization Label	1.5cmx1.5cm,2cmx2cm,3cmx3cm; Customized size are available
Dental Bibs	33cmx45cm,33cmx48cm; Customized size are available
B-D Test Pack	130mmx115mmx20mm; Customized size are available
Medical Paper Tray	205x110x10mm,225x140x15mm,255x135x15mm; Customized size are available

This annex is only valid if attached to the report mentioned above.



Annex to Report (No. 02748)

Tianchang City Guomao Plastic Industry Co., Ltd.

Product Name	Type
Self Sealing Sterilization Pouch	57*100mm, 57*125mm, 57*130mm, 50*220mm, 70*165mm, 70*260mm, 90*165mm, 90*260mm, 135*255mm, 135*285mm, 130*300mm, 190*330mm, 190*360mm, 230*408mm, 250*400mm, 300*410mm, Customized size are available
Medical Sterilization Pouches and Reels	57x130mm,70x260mm,90x135mm,90x170mm,90x260mm,135x260mm,135x280mm,190x360mm,250x370mm,260x410mm,300x410mm,300x460mm,50mmx200m,75mmx200m,100mmx200m,150mmx200m,200mmx200m,250mmx200m,300mmx200m,350mmx200m,400mmx200m,500mmx200m,600mmx200m,75mmx100m,100mmx100m,150mmx100m,200mmx100m,250mmx100m,300mmx100m,350mmx100m,400mmx100m,500mmx100m,60mmx100m; Customized size are available
Medical Sterilization Paper Bag	90x50x170mm,90x45x180mm,90x45x260mm,110x30x190mm,140x75x290mm,140x50x340mm,160x80x340mm,180x95x380mm,250x100x385mm; Customized size are available
Medical Paper-Plastic Pouch	57x100mm,70x230mm,90x105mm,90x140mm,90x230mm,135x230mm,135x250mm,190x330mm,250x340mm,260x380mm,300x380mm,300x430mm; Customized size are available
Medical Tyvek Pouch	57x130mm,70x260mm,90x135mm,90x170mm,90x260mm,135x260mm,135x280mm,190x360mm,250x370mm,260x410mm,300x410mm,300x460mm; Customized size are available

This annex is only valid if attached to the report mentioned above.



nqa

Compliance Report

Applicant: Tianchang City Guomao Plastic Industry Co., Ltd.
Address: No.139, Tiakang Road, Economic Development District,
Tianchang, Anhui, China.
Product: Self Sealing Sterilization Pouch, Medical Sterilization Pouches
and Reels, Medical Sterilization Paper Bag, Medical
Paper-Plastic Pouch, Medical Tyvek Pouch, Medical Dialysis
Paper, Medical Adhesive Coated Paper, Medical Tyvek Paper,
Medical Crepe Paper, Medical Non-woven Wrap(SMS,SMMS),
Medical Sterilization Indicator Tape, Medical Sterilization
Indicator Strip, Medical Sterilization Label, Dental Bibs, B-D
Test Pack, Medical Paper Tray
Type: See annex for details
Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

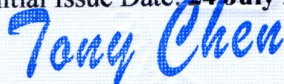
The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02748

Initial Issue Date: 24 July 2017



General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.