

# 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

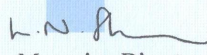
### ISO 13485:2016

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](http://www.cnca.gov.cn))

SNQA's website: [www.snqa.com.cn](http://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



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.





## 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 GUOMAO 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, 75mm\*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,<br>80x80cm,90x90cm,100x100cm,110x110cm,120x120cm;<br>Customized size are available |
| Medical Non-woven Wrap(SMS,SMMS)      | 30x30cm,40x40cm,45x45cm,50x50cm,60x60cm,70x70cm,75x75cm,<br>80x80cm,90x90cm,100x100cm,110x110cm,120x120cm;<br>Customized size are available |
| Medical Sterilization Indicator Tape  | 12mmx50m,19mmx50m,25mmx50m;Customized size are available                                                                                    |
| Medical Sterilization Indicator Strip | 15mmx100mm,20mmx110mm,16mmx200mm,40mmx80mm;<br>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;<br>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.



## Compliance Report

Applicant: Tianchang City Guomao Plastic Industry Co., Ltd.  
Address: No.139, Tiangkang 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).**

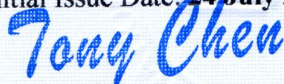
The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

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)