



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 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

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*200mm, 75mm*200mm, 100mm*200mm,
150mm*200mm, 200mm*200mm, 250mm*200mm, 300mm*200mm, 350mm*200mm, 400mm*200mm,
500mm*200mm, 600mm*200mm, 60mm*100mm, 75mm*100mm, 100mm*100mm, 150mm*100mm,
200mm*100mm, 250mm*100mm, 300mm*100mm, 350mm*100mm, 400mm*100mm, 500mm*100mm,
75mm*100mm*25mm, 100mm*100mm*50mm, 150mm*100mm*55mm, 200mm*100mm*65mm,
250mm*100mm*70mm, 300mm*100mm*80mm, 350mm*100mm*80mm,
400mm*100mm*100mm, 415mm*1000mm, 830mm*1000mm, 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: 697424517

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:  Date: 2021.12.24

Position: Director

Place: Anhui/China



Annex to Cert. No.: EU 074518

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
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,20mmx108mmCustomized 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

END OF THE ANNEX



Verification of Conformity

Applicant: Tianchang City Guomao Plastic Industry Co., Ltd.
Address: No.139, Tiangkang Road, Economic Development District, Tianchang, Anhui, China.
Product(s): See Annex for details
Type(s): 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 Directive 2007/47/EC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2012
EN ISO 1041:2008; EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009; EN ISO 10993-10:2013
EN ISO11607-1:2009; EN ISO11607-2:2006

The review result of the technical files and test report support the self declaration for the devices listed above. 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.

SUNGO Certification Company Limited



Executive Director
Issued: Nov. 24 2017
Cert. No.: EU 074518
Expiration Date: Nov. 23 2022