

# **ANQING TIANRUN PAPER PACKAGING CO., LTD.**

ADDRESS: NO.1 JINGSHI RD., DAQIAO DEVELOPMENT ZONE, ANQING, ANHUI  
PROVINCE, CHINA POST CODE: 246005  
TEL: (+86-556) 587 7076 FAX: (+86-556) 587 7079

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## **DECLARATION OF CONFORMITY**



**ACCORDING TO (EU) 2017/745 MEDICAL DEVICE**

## **REGULATION**

### **Manufacturer:**

Name: ANQING TIANRUN PAPER PACKAGING CO., LTD.

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PROVINCE, CHINA

### **EU REPRESENTATIVE:**

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Tel: +31 (0)20 21 11 106

### **Product Information:**

Name: Sterilization Packaging

Model: See Attachment of details

GMDN: 30015

Basic UDI-DI: /

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

### **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 ISO 1041:2008 +A 1 : 2013

ISO 10993-5 : 2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

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EN 868-5:2019

EN ISO 11607-1: 2020

EN ISO 11140-1:2015

## **Declaration**

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

## **Remark**

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

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 .

For ANQING TIANRUN PAPER PACKAGING CO., LTD.

Signature:



Name: Long Daoqin



October 15th,2021

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## ANNEX

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型号 CODE	产品 PRODUCTS	规格 SPECIFICATIONS
TRSP057100	自封袋 Self Sealing Sterilization pouch	57mm x 100mm
TRSP057130		57mm x 130mm
TRSP070260		70mm x 260mm
TRSP090135		90mm x 135mm
TRSP090165		90mm x 165mm
TRSP090230		90mm x 230mm
TRSP090260		90mm x 260mm
TRSP100230		100mm x 230mm
TRSP135250		135mm x 250mm
TRSP135280		135mm x 280mm
TRSP190330		190mm x 330mm
TRSP190360		190mm x 360mm
TRSP250400		250mm x 400mm
TRSP300460		300mm x 460mm
TRHFR050		热封平卷袋 Heat Sealing Flat Reel
TRHFR075	75mm x 100m	
TRHFR100	100mm x 100m	
TRHFR150	150mm x 100m	
TRHFR200	200mm x 100m	
TRHFR250	250mm x 100m	
TRHFR300	300mm x 100m	
TRHFR350	350mm x 100m	
TRHFR400	400mm x 100m	
TRHFR450	450mm x 100m	
TRHFR500	500mm x 100m	
TRHFP080250	热封平口袋 Heat Sealing Flat Pouch	80mm x 250mm
TRHFP120150		120mm x 150mm
TRHFP150350		150mm x 350mm
TRHFP200250		200mm x 250mm
TRHFP200400		200mm x 400mm
TRHFP250300		250mm x 300mm
TRHFP250350		250mm x 350mm
TRHFP300400		300mm x 400mm
TRHFP300500	300mm x 500mm	

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TRHGR075	热封立体卷袋 Heat Sealing Gusseted Reel	75mm x 100m
TRHGR100		100mm x 100m
TRHGR150		150mm x 100m
TRHGR200		200mm x 100m
TRHGR250		250mm x 100m
TRHGR300		300mm x 100m
TRHGR350		350mm x 100m
TRHGR400		400mm x 100m
TRHGR450		450mm x 100m
TRHGR500		500mm x 100m
TRTR075		特卫强卷袋 Tyvek Reel
TRTR100	100mm x 70m	
TRTR150	150mm x 70m	
TRTR200	200mm x 70m	
TRTR250	250mm x 70m	
TRTR300	300mm x 70m	
TRTR350	350mm x 70m	
TRTR400	400mm x 70m	
TRTR450	450mm x 70m	
TRTR500	500mm x 70m	