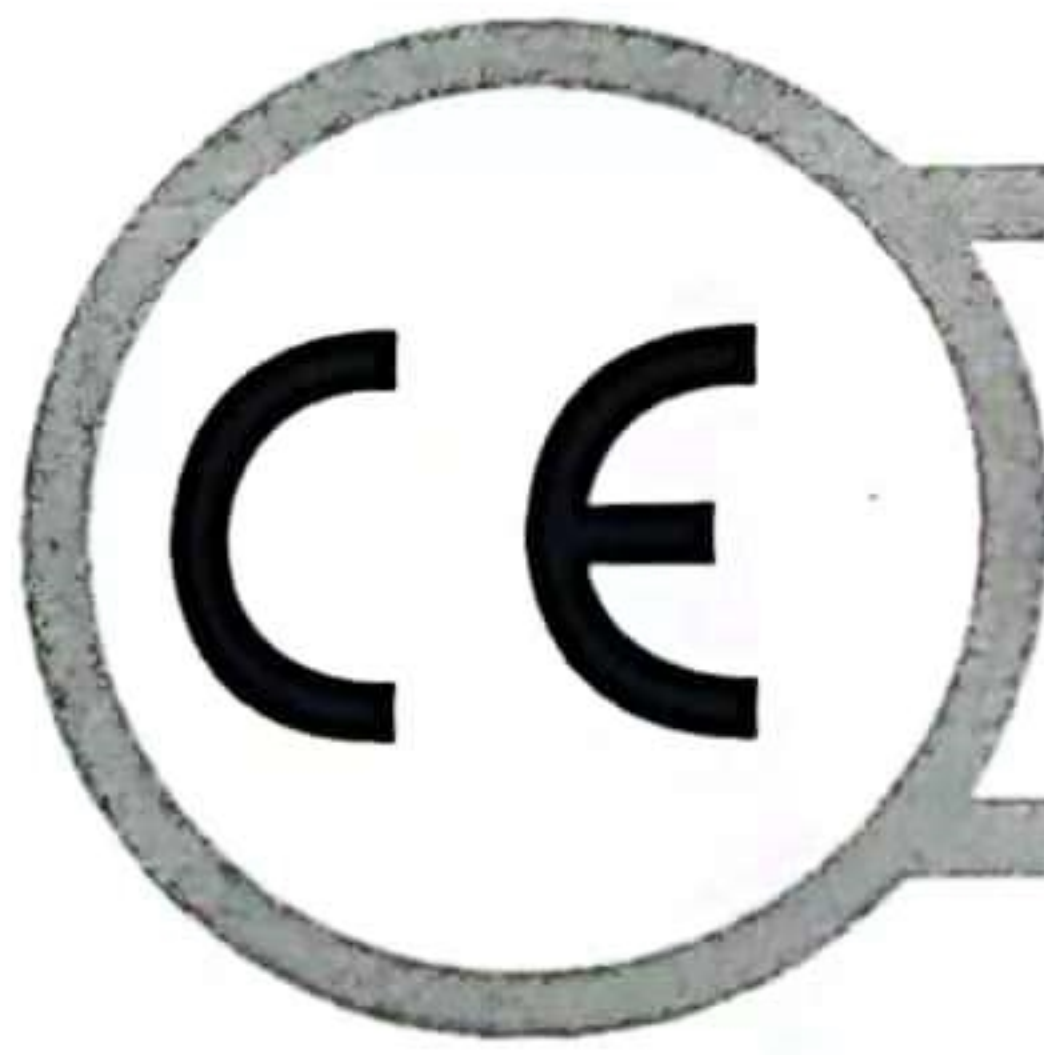




DECLARATION OF CONFORMITY

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, The 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: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Manufacturer

Name: ANHUI KONZERN PACKAGE MATERIAL
CO.,LTD
Address: NO.7 SONGHUAJIANG ROAD, JIANGNAN
INDUSTRIAL CONCENTRATION AREA, ANHUI, CHINA
SRN:

Product Information

Name: STERILIZATION POUCH / ROLL
Model: 57*130mm, 70*260mm, 90*165mm, 90*230 mm,
90*260mm, 135*260mm, 135*280mm, 135*300mm,
135*380mm, 190*360mm, 50mm*200m, 75mm*200m,
100mm*200m, 150mm*200m, 200mm*200m,
250mm*200m, 300mm*200m, 350mm*200m,
400mm*200m, 500mm*200m, 600mm*200m,
75mm*100m, 100mm*100m, 150mm*100m,
200mm*100m, 250mm*100m, 300mm*100m,
350mm*100m, 400mm*100m, 75mm*70m, 100mm*70m,
150mm*70m, 200mm*70m, 250mm*70m, 300mm*70m,
350mm*70m, 400mm*70m, 30*30cm, 35*35cm,
40*40cm, 45*45cm, 50*50cm, 60*60cm, 75*75cm,
90*90cm, 100*100cm, 120*120cm, Customized Size
EMDN: S0102
GMDN: 13735
Basic UDI: -
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: 2023.6.20

Position:

Place: Anhui/China

