



# EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

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## 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 10993-1 : 2020  
EN ISO 10993-5 : 2009  
EN ISO 10993-10 : 2013  
EN ISO 20417 : 2021  
EN 62366-1 :2015  
EN ISO 14683 :2019

## Manufacturer

**Name:** Xiantao Chenguang Protection Commodity Co., Ltd.  
**Address:** Huanglin Industry Garden, Longhuashan, Xiantao City, Hubei, China  
**SRN:** CN-MF-000025794  
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## Product Information

**Name:** MASQUES MEDICAUX A USAGE UNIQUE TYPE IIR (EN ISO 14683 :2019)  
**Model:** 161321  
**EMDN :** T020604  
**Basic UDI-DI:** 697478283FM001LD  
**UDI-DI:** INNER BOX 06974782830503  
OUTER CARTON 06974782830527  
**Intended use:** Medical mask (Type IIR) is used as barrier for user working in general medical environment to avoid unwanted inhalation or protecting from spray and spill to avoid any unexpected infection of flu or disease.  
**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-CG02-01](#).

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: Du Jiangwu Date: 2025.04.25

Du Jiangwu  
2025. 04. 25



Position: General Manager Place: Xiantao/China

