



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
SRN: DE-AR-000000001

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

ISO 14971: 2019, ISO 15223-1: 2021+A1:2025
ISO 20417: 2021, ISO 10993-1: 2020
ISO 10993-5: 2009, ISO 10993-10: 2021, EN 14683:2019, EN ISO 13485:2016, ISO 20417:2021

Remark

The declaration of conformity is valid in connection with the release ISO 13485 Certificate by TUV SUD with Notified Body identification no.0123:

ISO 13485:2016 Certificate: Q5 002037
0008 Rev. 06
Expire date of the Certificate:
2028-08-31
Place, Date of Issue: Hubei province,
P.R.C,2025-08-11

Manufacturer

Name: Allmed Medical Products Co., Ltd
ADDRESS: No.18 Qi xing Road, Majiadian Town, 443200Zhijiang City, Hubei province, PEOPLE' S REPUBLIC OF CHINA
SRN: CN-MF-000007970

Product Information

Name: Foliodress® Mask Loop Type IIR
Model: REF 992491, REF 992493, REF 992490
EMDN: T0206
Basic UDI: 69415580medfacemaskNSML
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Intended Use
It's used for physical separation of pollutants from the inhaled and exhaled air. The products are used in hospitals and the care area for nurses and patients, medical face mask can protect personnel from transfer of microorganisms, body fluids, and particles.

Declaration

We herewith declare in our own responsibility that the above mentioned products meet the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Position: General Manager of Quality

Name: Vince Tian

Place: Zhijiang City

Signature: *Vince Tian* Date: *Sep. 01. 2025*