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: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 14683:2019+AC:2019 Type IIR

Remark

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

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.

Manufacturer

Unimax Medical Products Co., Ltd.
Special No.1 Liansai Road, Changshangkou Town, 433024 Xiantao City, Hubei Province, P. R. China
SRN:CN-MF-000017381

Product Information

Name: Non-woven Face Mask Type IIR
Model: With Ear-loop; With Ties; Anti-fog; Anti-fog and visor
Ref.: 400055,400066,400067,400068
EMDN: T020604
GMDN: 35177
Basic UDI-DI: 697349085UMMASKRDG
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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

For and on behalf of
UNIMAX MEDICAL PRODUCTS CO., LTD.
聯客醫用產品(湖北)有限公司
Authorized Signature(s)

Signature: Ning Haibo Date:2024/12/02

Position: GM Place: Hubei/China