

EU DECLARATION OF CONFORMITY

1. Personal protective equipment **3D facial protective mask MY-002 class FFP-2.**
2. Name and address of the manufacturer:
Wenzhou MEIYI Medical Device Co., Ltd.
Hengjie Industrial, Xianjiang Street, Ruian Wenzhou, Zhejiang, China.
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: **Wenzhou MEIYI Medical Device Co., Ltd.**
Hengjie Industrial, Xianjiang Street, Ruian Wenzhou, Zhejiang, China.
4. Object of the declaration: **3D facial protective mask, model: MY-002, class FFP-2.** Respiratory protective equipment. **Filtering half mask to protect against COVID-19.**
5. The object of the declaration described in point 4 is in conformity with the relevant European Union harmonisation legislation: **Regulation (EU) 2016/425 of the European Parliament and of The Council of 9 March 2016 on Personal Protective Equipment and Repealing Council Directive 89/686/EEC.**
6. **Particle Filtering Half Mask MY-002, class FFP-2** meets the requirements of the harmonised standard **PN-EN 149+A1:2010 (EN 149:2001+A1:2009)**, in conformity with the provisions of **Regulation (EU) 2016/425** of the European Parliament and of The Council of 9 March 2016 on Personal Protective Equipment and Repealing Council Directive 89/686/EEC.
7. Notified body: **Polski Rejestr Statków S.A., al. Gen. Józefa Hallera 126, 80-416 Gdańsk, Polska**, notified body number – **1463**, performed the EU type-examination (**Module B**) and issued the EU type-examination certificate no. **CW/PPER/48/05/2020**, certificate date: **27.05.2020r.**
8. Where applicable, the PPE is subject to the conformity assessment procedure: conformity to type based on internal production control plus supervised product checks at random intervals (**Module C2**), under surveillance of the notified body: **Polski Rejestr Statków S.A., al. Gen. Józefa Hallera 126, 80-416 Gdańsk, Polska**, notified body number – **1463**, which had issued the certificate of conformity to type (**Module C2**) number **CW/PPER/52/06/2020**, certificate date: **16.06.2020r.**



We, the production company **Wenzhou MEIYI Medical Device Co., Ltd.**, declare on our sole responsibility that all units of the PPE **3D facial protective mask, model: MY-002, class FFP-2** are in conformity with the information provided in this document and with the provisions of EU regulation **R 2016/425, of 09.03.2016** on personal protective equipment as well as harmonised standard **PN-EN 149+A1:2010 (EN 149:2001+A1:2009)**, and are identical to the product certified by the notified body **Polski Rejestr Statków S.A., al. Gen. Józefa Hallera 126, 80-416 Gdańsk, Polska – notified body number 1463 (Modules B + C2).**

Signed for and on behalf of: **Wenzhou MEIYI Medical Device Co., Ltd.**

WENZHOU CHINA 17/11/2020

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(Place and date of issue)



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(Signed by) (Signature)

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