



YESIANG ENTERPRISE CO., LTD.

Declaration of Conformity



17F., NO. 866-7, Zhongzheng Rd., Zhonghe Dist., New Taipei City 23586, Taiwan (R.O.C.)

declares under our sole responsibility that the product:

Model: Ear loop Type, 3 Ply, Flat-Pleated Style, Type II

(EBA-01 、EBA-02 、EBC-01 、EBC-02)

Ear loop Type, 3 Ply, Flat-Pleated Style, Type IIR

(EBAR-01 、EBAR-02 、EBCR-01 、EBCR-02)

Confirms with the provisions of the following EC Directive, including all amendments, and with national legislation implementing these directives:

Medical Device Directive 93/42/EEC Annex VII, Annex IX

The following harmonized standards were applied:

ISO 13485:2016 Medical devices - Quality management systems-System requirement for regulatory purposes

ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN 14683:2019 Surgical masks - requirements and test methods

EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

ISO 15223-1:2016 Symbols

ISO 22609:2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

This product carries the CE Mark, which was affixed in 2020.

Place
Taiwan

Signature

A handwritten signature in blue ink, appearing to read "James Chuang". The signature is written in a cursive, flowing style.

**James Chuang
General Manager**

Date

December/1st/2020

Authorized EU Representative:
Enceladus International AB,
Köpenhamnsvägen 42B, 217 71
Malmö, SWEDEN.
P.O.Box 30065, 20061 Limhamn,
SWEDEN