

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)
Manufacturer address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological Park, Panyu, Guangzhou, 511400, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000009645

EU – Declaration of conformity

This declaration is issued under the sole responsibility of the manufacturer, its authorised representative and product importer. Thus is to declare and certify that the products specified below, in configuration marketed by us are in due compliance with the requirements of the relevant EU directives. The validity of this declaration will cease in case of any modification to the product without our prior consent and all supporting documentation is retained at the premises of the manufacturer, European appointed authorised representative and product importer within EEA.

Quality System approval issued by: TÜV SÜD Product Service GmbH. Ridlerstraße 65, 80339 München, Germany [notified body no.: 0123]

Certificate registration no: G2 047330 0058 Rev. 0

Report number: SH1918119

Brand: Dinilu

Product description: CPR Face Shields

Model: FS-102

Code references (indicating variance in cosmetic criteria such as colour and packaging quantity):

8720211210655, 8720211210624, 8720211210648, 8720211210686, 8720211210600,
8720211210662, 8720211210631, 8720211210617, 8720211210679, 8720211210693,
8720211210709

Lot and production date: refer to notation on product

Authorised EC representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8

80807 Munich

Germany

SRN: DE-AR-000000087



Basic UDI-DI: 69422726P5.01.01XW

Classification: Class I

Conformity assessment route: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU) uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

Class I, Rule 1: EC conformity declaration according to Annex II and Annex III

Conformant to the following regulation:

MDR 2017/745 | Medical directives

Conformant to the following standard:

EN ISO 14971: 2019 | Medical devices — Application of risk management to medical devices

Mark J. Tonino

Importer within EEA, Director

Dinilu Retail B.V. *SRN:* NL-IM-000004374

Hamseweg 68 A, 3828 AG Hoogland, The Netherlands

29th June 2022

