

广州市富施达医疗器械有限公司
FIRSTAR HEALTHCARE Co., Ltd. (Guangzhou)

EU Declaration of Conformity

Manufacturer: FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)
Address: Rm. 901, Building No.2, Headquarters Center, Tian'an High-tech Ecological Park, Panyu,
511400 Guangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000009645
European: MedPath GmbH
Representative: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN: DE-AR-000000087
Trade name: CPR Face Shield
Product Name: CPR Face Shield
Product code: FS-100,FS-101,FS-102,FS-103,FS-105,FS-106
Applied Standard & Common Specification: EN ISO 14971:2019
Basic UDI: 69422726P5.01.01XW
Classification acc. to MDR Annex VIII: Class I, Rule 1
Conformity assessment procedure: Annex II + Annex III of MDR
CE certificate No: N.A
Name and ID of the Notified Body: N.A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature Janice-Li

Name: Janice-Li

Position: MR

Place: Guangzhou

Date: 2021.9.22