



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/A11:2021
ISO 15223-1: 2021/Amd1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001.
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.

File No.MDR-TCF-001-08

Manufacturer

Name: Guangzhou Athmedic Healthcare Co.,Ltd
Address: Room 415, Building 1, No. 9, Shinan second Road, Dashu Street, Panyu District, Guangzhou city, China 511400
SRN: CN-MF-000011674

Product Information

Name: CPR face shield
Model: See Annex
EMDN: R030180
Basic UDI-DI: 697620128dcprfaceshieldNX
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.

Signature:

 John Wong

Position: GM

Date: 2025.07.20

Place: Guangzhou/China

Annex

Model
AM14-001, AM14-002, AM14-003, AM14-007, AM14-004, AM14-005, AM14-008, AM14-009, AM14-006, AM14-010, AM14-016, Or customized size, PE/PVC/EVA material, 31.5*19.5cm, 20*20cm, 30*20cm, 17.5*17.5cm

