



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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
EN ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-23:2021
EN ISO 11199-2: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-Y120612-02.*

*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.*

Manufacturer

Name: A & I Industries Ltd Shunde Foshan
Address: Lian Du Industry Park, Le Liu Town, Shun
De District, Fo Shan City, Guangdong, China
SRN: CN-MF-000038647

Product Information

Name: Four-Wheel Vehicle
Model: 102 Carbon
EMDN: Y120612
Basic UDI-DI: / 697786880FourWVehicleEH
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:

Date: 2023.8.30



Position: GM

Place: Guangdong /China