

CE DECLARATION OF CONFORMITY CE

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:

Nanning Hhao Technology Co., Ltd

Address: No.1 Building, Keyuan West 10 Road, High-tech District, Nanning, Guangxi, China

SRN: CN-MF-000042933

EC Representative:

Company: ALPATRIS srl

Address: Viale regione siciliana n. 2396 90135 Palermo (PA) Italy

SRN: IT-AR-000034820

Product info and Basic UDI-DI: Refer to Schedule 1 attached to this declaration

Classification acc. to MDR Ax. VIII: Class 1, rule 1

Conformity Assessment Route: Annex II and Annex III, regulation (EU) 2017/745

Applicable standards:

EN ISO 14971:2019 ISO 15223-1: 2021 TS EN ISO 20417: 2021

TS EN ISO 10993-1: 2021 EN ISO 10993-5: 2009 TS EN ISO 10993-10: 2023 TS EN 12183: 2022

ISO 13485 certificate No.: ISA/HK/260301

Name of the Certification Body: International Standards Authority, Inc.

Remark:

The declaration of conformity is valid in connection with the release technical document CE-OMJ-01. All supporting documentations are retained under the premises of the manufacturer. The Declaration of Conformity is exclusively under the responsibility of manufacturer.

Declaration:

We herewith declare that the above-mentioned products meet the requirement of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: FAN LIMIN

Position: CEO

Place: Nanning / China

Issue Date: 2nd March, 2026

Expiry Date: 2nd March, 2029



Schedule 1 to Declaration of Conformity

Product name: Manual wheelchair:
Model: HO-W101
EMDN: Y122103
Basic UDI-DI: 697574057HO-W101Q3

Product name: Manual wheelchair:
Model: HO-W102
EMDN: Y122103
Basic UDI-DI: 697574057HO-W102Q5

Product name: Stretcher trolley
Model: HO-708
EMDN: V0805038001
Basic UDI-DI: 697574057HO-708H7

Product name: Stretcher trolley
Model: HO-708A
EMDN: V0805038001
Basic UDI-DI: 697574057HO-708AJT

Product name: Stretcher trolley
Model: HO-709
EMDN: V0805038001
Basic UDI-DI: 697574057HO-709H9

Product name: Stretcher trolley
Model: HO-709A
EMDN: V0805038001
Basic UDI-DI: 697574057HO-709AJW

Product name: Medical Cart
Model: HO-M05A
EMDN: Z12030580
Basic UDI-DI: 697574057HO-M05AP5

Product name: Medical Cart
Model: HO-M01
EMDN: Z12030580
Basic UDI-DI: 697574057HO-M01L2

Product name: MRI Transfer Board
Model: HO-T03
EMDN: V080504
Basic UDI-DI: 697574057HO-T03M9

Product name: MRI Transfer Board
Model: HO-T02
EMDN: V080504
Basic UDI-DI: 697574057HO-T02M7

Product name: MRI Mobile I.V Stand
Model: HO-09
EMDN: Z12030380
Basic UDI-DI: 697574057HO-09JG

END OF THE ANNEX

