

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 Name: 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/230308

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: 3th April, 2024

Expiry Date: 3th April, 2027



Schedule 1 to Declaration of Conformity

Product name: Manual wheelchair:

Type:

HO-W101, HO-W102, HO-W103

(Special specifications according to customer requirements)

Product name: Stretcher Trolley:

Type:

HO-708, HO-708A, HO-709, HO-709A, HO-709B

(Special specifications according to customer requirements)

Product name: Medical cart:

Type:

HO-M01, HO-M02, HO-M03, HO-M05, HO-M05A

(Special specifications according to customer requirements)

Product name: MRI accessories:

Type: MRI mobile I.V Stand HO-09

Type: MRI cylinder set HO-M11

Type: MRI fire extinguisher HO-M08

Type: Hand Held Metal Detector MCD-5180

Type: MRI transfer board HO-T01, HO-T02, HO-T03, HO-T04

Type: MRI stethoscope HO-M09

Type: MRI stool HO-M04

Type: Metal Detector HO-SCANNER

(Special specifications according to customer requirements)

END OF THE ANNEX

