



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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 15223-1:2016
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 20417: 2021

Manufacturer

Name: Hengshui Huinuo Medical Equipment Co., Ltd.

Address: No. 2, Wangkou Village, Weitun Town,
Binhu New District, Hengshui, Hebei

Product Information

Name: MANUAL HOSPITAL BED

Model : HN-A01-01, HN-A01-02, HN-A01-03,
HN-A01-04, HN-A01-05, HN-A01-06, HN-A01-07,
HN-A01-08, HN-A01-09, HN-A01-10, HN-A01-11,
HN-A01-12, HN-A01-13, HN-A01-14, HN-A01-15,
HN-A01-16, HN-A01-17, HN-A01-17, HN-A01-18,
HN-A01-19, HN-A01-20, HN-A01-21, HN-A01-22,
HN-A01-23, HN-A01-24, HN-A01-25, HN-A01-26,
HN-A01-27, HN-A01-28, HN-A01-29, HN-A01-30,
HN-A01-31, HN-A01-32, HN-A01-33, HN-A01-34,
HN-A01-35, HN-A01-36, HN-A01-37, HN-A01-38,
HN-A01-39, HN-A01-40, HN-A01-41, HN-A01-42,
HN-A01-43, HN-A01-44, HN-A01-45, HN-A01-46,
HN-A01-47, HN-A01-48, HN-A01-49, HN-A01-50,
HN-A01-51

EMDN: V080602

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080502-01.

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.

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

Signature:

[Handwritten signature]

Position:GM

