



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
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-V080602-04.

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: HEBEI WEBIAN MEDICAL INSTRUMENT TRADING CO.,
LTD
Address: A1-2703 SHIDAI BUILDING, GUANG AN STREET,
CHANG AN DISTRICT, SHIJIAZHUANG CITY, HEBEI PROVINCE,
CHINA

SRN: CN-MF-000031958

Product Information

Name: Manual hospital bed

Model: A01、N01 (A)、N01 (B)、A02、A02-1、A02-2、A02-2A、
A02-3、A02-4、A02-5、A02-6、A02-7、A02-8、A02-10、
A03-2、A03-3、N03、R03、A03、A03-1、A04、A04-1、A04-2、
A06、A06-1、A06-2、A07、A08、A08-1、A09、A09-1、A09-2、
A11、B04、B04-1、B04-2、B04-3、B04-4、B04-5、B04-6、
B04W、B05、B05-1、N04B、N04A、A05、A05-1、A05-2、A10、
A12、B02、B02-1、B02-2、B02-3、B02-4、B02-5、B02-6、
B03、B03-1、N02A、N02B、R02、W02、Z02、N02、B01、
B01-1、B01-2、B01-3、B01-4、B01-5、R01

EMDN: V080602

GMDN: 34873

Basic UDI: 697593980MHB001R6

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: 2022.11.08

Position: GM Place: Hebei/China