



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
EN 12183:2014

Remark

*The declaration of conformity is valid in connection
with the release technical document CE/MDR-
Y122103-02.*

*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: 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 wheelchair

Model: WB809, WB4635, WB4635-5, WB4636-1, WB4637,
WB4612, WB4612-1, WB4612-2, WB4617, WB4617-1, WB4618,
WB4619, WB4620-2, WB4620-4, WB4620-5, WB4620-8, WBXR01,
WBRO1, WB809-1, WB809-2, WB863, WBRO2, WBS01, WBZ01,
WB3628A, WB3628C, WB3628D, WB3628E

GMDN: 37687

EMDN: Y122103

Basic UDI: 697593980MW001T4

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