



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
ISO 11334-4:1999
ISO 11334-1:2007

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-Y1203-01.*

*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.*

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: Crutch

Model: WA1、WA2、WA3、WA4、WA5、WA6、WA7、WA8、WA9、
WA10、GZ01、GZ02、GZ03、GZ04、GZ05、WA5-R、WA5-E、
WA5-B、SGZ-1、SGZ-2、SGZ-3、SGZ-4、SGZ-5、SGZ-6、SGZ-7、
SGZ-8、SGZ-9、SGZ-10、SGZ-11、SGZ-12、SGZ-13、SGZ-14、
SGZ-15、SGZ-16、SGZ-17、ZXQ01、ZXQ02、ZXQ03、ZXQ04、
ZXQ05、ZXQ06、ZXQ07、ZXQ08、ZXQ09、ZXQ10、ZXQ11

EMDN: Y1203

GMDN: 31115/31113/31112/31116

Basic UDI: 697593980CRUTCH001CT

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