



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-Y093303-01.*

*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: Wuyi Comon Medical Appliances Co., Ltd
Address: Juhua Road, Baihuashan Industry Zone, Wuyi
County, Jinhua City, Zhejiang Province
SRN: CN-MF-000034494

Product Information

Name: Shower Chair

Model:

2001,2002,2003,2004,2005,2006,2007,2008,2009,
2010,2011,2012,2013,2014,2015,2016,2017,2018,2019,
2020,2021,2022,2023,2024,2025,2026,2027,
2028,2029,2030,2031,2032

EMDN: Y093303

GMDN: 34936

Basic UDI-DI: 697628980ShowerChair01GF

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:2023-4-23

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Position: GM

Place: Zhejiang/China