



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
1041:2008+A1:2013, EN ISO 15223-1:
2016, ISO 10993-1:2018, EN ISO
10993-5:2009, EN ISO 10993-10:2013,
ISO 17966:2016

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE-MDR-TCF004.*

*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: FOSHAN SHUNKANGDA MEDICAL TECH
CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai
District , 528251 Foshan City,Guangdong P.R. China
SRN: CN-MF-000008483

Product Information

Name: Shower Chair
Model: See Annex
GMDN: See Annex
Basic UDI-DI: 697222325040001K5
Classification: Class I, according to Rule 1, Annex
VIII, Regulation (EU) 2017/745
Intended use: The shower chair is used as bathing
tools for people with disabilities, patients and the
elderly who are difficult to maintain balance while
showering

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: *Xu Ruizhuo* Date: *Feb 13th 2023*

Name: Yu Jinwei Place: Foshan / China
Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Shower Chair	CA311, CA314, CA330, CA333L, CA336L, CA3361L, CA3362L, CA3362U, CA337L, CA3372L, CA3373L, CA3374L, CA338L, CA339L, CA340L, CA3402L, CA341, CA342L, CA342L-KD, CA342LW-KD, CA343L, CA343LW, CA3432L, CA344L, CA3442L, CA345L, CA3451, CA346L, CA347L, CA3472L, CA3473L, CA348L, CA3481L, CA350L, CA3501L, CA351L, CA351LS, CA351LW-KD, CA3511L-KD, CA3512L, CA3521L-KD, CA3522L, CA354L, CA3542L, CA355L, CA3552L, CA3553L, CA3555L, CA3561L, CA3562L, CA3563L, CA3563LQ, CA357U, CA3571, CA3573U, CA3581L, CA359L, CA360L, CA3601L, CA3602L, CA362L, CA363L, CA3631L, CA364L, CA3525L, CA371LW, CA374, CA3741, CA3742, CA3742L, CA358L, CA333L2, CA343L2, CA3522L2	34936	697222325040001K5

Signature:

Xu Ruizhuo

Date:

Feb 13th 2023

Position: GM

Place:

Foshan/China