



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7, 2909V
A 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 15223-1:2022
EN 1041:2008+A1:2014
ISO 10993-1:2018
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-SC-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: FOSHAN SUNCARE MEDICAL PRODUCTS
CO., LTD

Address: No.168 Fusheng Rd, Fuwan Industry Area,
Gaoming District, Foshan City, Guangdong, P.R.
China

Product Information

Name: BATH BENCH

Model: See Annex

GMDN: 34936

Basic UDI-DI: 697457618BATHBENCHWD

SRN: CN-MF-000008985

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.

For and on behalf of
Foshan Suncare Medical Products Co., Ltd.
佛山市順康泰醫療設備有限公司

Signature: _____ Date: 2023-5-19

.....
Authorized Signature(s)

Position: GM

Place: Guangdong/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
BATH BENCH	SC6001/SC6001-KD/SC6001Q/SC6001Q-KD SC6001Q-KD-HD/SC6001-S/SC6005/SC6005Q SC6005Q-KD/SC6005Q-KD-HD/SC6010/SC6011 SC6011-KD/SC6015A/SC6015A-KD/SC6005Q-S SC6015C/SC6015C-KD/SC6020A/SC6020B SC6020C/SC6020D/SC6020E/SC6020F/SC6020G SC6020H/SC6025A/SC6025B/SC6025C SC6025D/SC6025C-W/SC6030A/SC6030A-KD SC6030B/SC6030B-KD/SC6030C/SC6030D SC6030D-KD/SC6040A/SC6040B/SC6040C SC6040D/SC6040E/SC6045A/SC6045B/SC6045B -B/SC6045C/SC6045C-N/SC6045D/SC6045E SC6045F/SC6050-1/SC6050-2/SC6050-3/SC6050 -4/SC6055A-N/SC6055A-KD/SC6055B-N/ SC6055B-KD/SC6055C/SC6055D/SC6055C-KD SC6055D-KD/SC6190A/SC6190B/SC6190C/ SC6190E	34936	697457618 BATHBENCH WD

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