



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008+A1 : 2013
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: 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.
Signature: 冯球球 (Feng Qiuli) Date: 2021-10-22

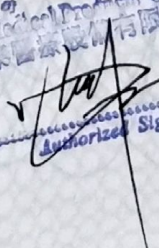
Authorized Signature(s)

Position: GM Place: Guangdong/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
BATH BENCH	SC6001/SC6001-KD/SC6001Q/SC6001Q-KD	34936	697457618 BATHBENCH WD
	SC6011Q-HD/SC6005/SC6005Q/SC6005Q-KD		
	SC6005Q-HD/SC6010/SC6011/SC6011-KD		
	SC6015A/SC6015A-KD/SC6015B/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			

For and on behalf of
 Shenzhen Sunaroo Medical Products Co., Ltd.
 Signature: 孙安国 孙安国有限公司



Date: 2021-10-22

Position: GM

Authorized Signature(s)

Place: Guangdong/China