



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH,
Harffstr. 47,40591 Düsseldorf, Germany
SRN:DE-AR-000010869

Manufacturer

Name: FOSHAN HUADUAN COSMETIC TECHNOLOGY
COMPANY LIMITED
Address:15 BLOCK, 58 INDUSTRIAL PARK, XIQIAO TOWN,
NANHAI DISTRICT,FOSHAN CITY,GUANGDONG CHINA
SRN:CN-MF-000018385

Conformity Assessment

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

Applicable Standards

EN ISO 14971: 2019
EN ISO 20417:2021
EN ISO 15223-1: 2016
ISO 10993-1: 2018
ISO 22196:2011
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN ISO13485:2016
EN 60601-2-52:2010+AC:2011+A1:2015
EN 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013+AC:2014+
A12:2014 +A2:2020

Product Information

Name: COSMETOLOGY MULTIFUNCTIONAL BED
Intend Use:To support the patient's body, the formation of
clinical need for posture.

Model: SWOP2 PRO,SWOP2L PRO,SWOP2W PRO,SWOP3
PRO,SWOP5 PRO,SWOP2 HYDRO,SWOP2L HYDRO,SWOP
SWOP3F HYDRO,SWOP4 HYDRO,SWOP2L UP,SWOP4
UP,SWOP5 UP,SWOP2LM ST,SWOP2LS ST,SWOP B4
PRO ,SWOPB4 UP,SWOPB4 GR, SWOPP3 PRO,SWOPP3
UP,SWOPS3 ST,SWOPS3 PRO,SWOPS4 UP,SWOPS4
GR,BLIGHT502,BLIGHT503

GMDN: 34870

BASIC UDI-DI: 697459027MEDICALBEDV2

Classification: Class I, according to Rule 1,Annex VIII,
Regulation (EU) 2017/745

Declaration



Remark

The declaration of conformity is valid in connection with the release technical document [CE/MDR-BEHB-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.

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Wong

Date:

2025.6.18

Position: GM

Place: Foshan/China

