



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: 2016
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
IEC 60601-1:2005+A1:2012
IEC 60601-1-11:2015
IEC 60601-1-2:2014

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-V080701-02.*

*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: XIAMEN SENYANG CO.,LTD
Address: No.189-1, Tongji South Road, Jimei
District, Xiamen, 361000, Fujian, P.R.China
SRN: CN-MF-000018392

Product Information

Name: ANTI-BEDSORE INFLATABLE MATTRESS
Model: Pump:P01 P01S P02 P03 P05 P06A P06B
P06C P06D P08A P08B P08C P08E P08M P09
TKS02 TKS2012 TKS03 TKS05
Mattress: B01 B02 S01 T01 T02 T03 T04 T05 T06
T07 T08 T09
EMDN: V080701
Basic UDI-DI: 695207570009GP
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: Ping Wang

Date: 2023-04-22

Position: GM

Place: Xiamen/China

