



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 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-SM-03.

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: SUNSMED PROTECTIVE PRODUCTS LTD.
Address: No 18, Industrial Park, Maozui
Town, Xiantao City, 433000, Hubei
Province, China
SRN: C N - M F - 0 0 0 0 0 8 6 9 6

Product Information

Name: Bed Sheet
Model: S-601, S-602, P20/210130, P20/210150, P20/210160, P20/21080
GMDN: 47456
Basic UDI-DI: 6973296770077EZ
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
SUNSMED PROTECTIVE PRODUCTS LIMITED
仙桃盛美工贸有限公司

Signature:  **Date:** 2021/04/27
Authorized Signature(s)

Position: GM

Place: Hubei/China