



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: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-T040102-03.*

*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: ANHUI XIAOSHAN HOPE MEDICAL
DEVICES CO.,LTD
Address: NO.518 HUISHAN ROAD,ECONOMIC
DEVELOPMENT ZONE,HUAYANG TOWN,JIXI
XUANCHENG,ANHUI PROVINCE.
SRN: CN-MF-000037849

Product Information

Name: Underpad
Model: XXS,XS,S,M,L,XL,XXL,XXXL,XXXXL
EMDN: T040102
Basic UDI-DI: 697676467UP003UK
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: 雷策斌 **Date:** 2023.9.4

Position: GM **Place:** Anhui/China

