



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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: 2013

Remark

*The declaration of conformity is valid in connection
with the release technical document HT-MDR-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: Changzhou Hongtai Paper Film Co.Ltd
Address: No.73 Donghu Rd, Henglin Town, Wujin
District, Changzhou, Jiangsu, China
SRN: CN-MF-000003240

Product Information

Name: Disposable Underpads
Model: DU1, DU2, DU3, DU4, DU5, DU6, DU7, DU8,
DU9, DU10
EMDN: V08068002
Basic UDI-DI: 697295200HT001EU
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:  Date: 26-07-2023

Position: GM Place: Jiangsu/China



扫描全能王 创建