



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+A11:2021
EN ISO 15223-1: 2021+A1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2025
EN ISO 10993-5: 2009+A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021+A1:2025

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-004.

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.

Document No.:MDR-TCF-004-08

Manufacturer

Name: Danyang New Hope Medical Equipment Co., Ltd.

Address: Building A-10, No. 55 Ziyuan Road, Life Science Industrial Park,Danyang Development Zone,China

SRN: CN-MF-000027193

Product Information

Name: Examination couch

Model: See Annex

EMDN: V080603

Basic UDI-DI: 697867091HS5240PT

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: 2026.02.10



Position: GM

Place: Jiangsu/China

Annex

Model

HS5240, HS5240A, HS5240B, HS5240D, HS5240G, HS5238B, HS5241, HS5243, HS5246, HS5247, HS5235, HS5236, HS5237, HS5238, HS5239, HS5240C, HS5240E, HS5240H, HS5240M, HS5241C, HS5242, HS5244, HS5245, HS547E, HS5240M-D, HS5240M-B, HS5238C, HS5238W, HS5204, HS5206, HS5242B, Customized

