DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-XXW-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: Danyang New Hope Medical Equipment Co., Ltd.
Address: No.889 Central West Road, Danbei Town, Danyang City, Jiangsu Province, China

Product Information

Name: Examination Couch
Model: See annex
GMDN: 38458
Basic UDI-DI: /
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: 2021.5.31

Position: GM Place: Jiangsu/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
Examination Couch	HS5240, HS5240A, HS5240B, HS5240D, HS5240G, HS5238B, HS5241, HS5243, HS5246, HS5247, HS5235, HS5236, HS5237, HS5238, HS5239, HS5240C, HS5240E, HS5240H, HS5240M, HS5241C, HS5242, HS5244, HS5245	38458	/

Signature:

Date: 2021.5.31

Position: GM

Place: Jiangsu/China