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

Manufacturer

Name: Xiamen Dahton MediTech Co., Ltd.
Address: Area B, 6F, No. 588-1, TongFu Road, 361100 TongAn District, Xiamen City, Fujian Province, P. R. CHINA
SRN: CN-MF-000003402

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2019/A11:2021
ISO 15223-1:2021/AMD1:2025
EN ISO 20417:2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-12:2021
EN ISO 10993-23:2021
EN 62366-1: 2015+A1:2020

Product Information

Name: CHOKE SUCTION DEVICE

Model: TW8648B / TW8648A

EMDN: R0599 [RESPIRATORY DEVICES, SUCTION AND DILATION SYSTEMS - OTHER]

Basic UDI-DI: 697426279CSDTY
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:

Name of the signatory: Dahwa Lin

Date: 2025.03.27

Position: PRRC/MR **Place**: Xiamen/China

Remark

The declaration of conformity is valid in connection with the release technical document.
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.