



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
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

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.*

Manufacturer

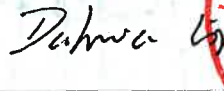
Name: Xiamen Dahton MediTech Co., Ltd.
Address: Area B, 6F, No. 588-1, TongFu Road,
361100 TongAn District, Xiamen City, Fujian
Province, P. R. CHINA
SRN: CN-MF-000003402

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

Position: PRRC/MR

Date: 2025.03.27

Place: Xiamen/China

