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

Applicable Standards
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2021
EN ISO 15883-1:2025

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-008

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.

File No.: MDR-TCF-008-08

Manufacturer

Name: MEDIWISH CO., LTD
Address: No. 336, Tianhe Road, Luyang Industrial Park, Hefei City, Anhui Province, China
SRN: CN-MF-000008849

Product Information

Name:
WASHER CLEANING EFFECTIVENESS TEST INDICATOR
Model: 2345678, CVC-10, CVC-50, CVWC-20, 647913
EMDN: S0199
Basic UDI-DI: 697440969WCETIUX
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:2026/2/10

张莹莹

Position: GM Place: Anhui/China

安徽美志斯工贸有限公司
MEDIWISH CO.,LTD
张莹莹