DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert Gmbh

Harffstr. 47,40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971:2019

ISO 15223-1:2021/Amd 1:2025

EN ISO 20417: 2021

EN ISO 10993-1:2020

EN ISO 10993-5:2009

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

EN 12184:2022

EN 60601-1:2006/A2:2021

EN 60601-1-2:2015/A1:2021

EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001.

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-001-08

Ver: A/0

Manufacturer

Name: ZHEJIANG FEILECHI MEDICAL EQUIPMENT CO., LTD.

Address: Building 3&4, No. 4 Xinyuan Road, Xinbi Street, Jinyun County, Lishui City, Zhejiang Province

SRN:CN-MF-000048168

Product Information

Name: ELECTRIC WHEELCHAIR

Model: See Annex

EMDN: Y122127

Basic UDI-DI: 697830568EW001KG

Classification: Class I, According to Rule 13, 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: Z. Xian Date:2025/5/16

Position: General Manager Place:Zhejiang/China

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Annex

Name	Model
ELECTRIC WHEELCHAIR	FLCW01(FortiGO),FLCW01-01,FLCW01-02(ifold),FLCW01-03, FLCW01-04,FLCW01-05,FLCW01-06,FLCW01-07, FLCW01-08,FLCW01-09,FLCW01-10,FLCW01-11, FLCW01-12,FLCW01-13,FLCW01-14,FLCW01-15, FLCW02,FLCW02-01,FLCW02-02, FLCW02-03,FLCW02-04,FLCW02-05,FLCW02-06, FLCW02-07,FLCW02-08,FLCW02-09,FLCW02-10, FLCW02-11,FLCW02-12,FLCW02-13,FLCW02-14, FLCW02-15,FLCN03(GO-TIM),FLCN03-01,FLCN03-02,FLCN03-03(FLY), FLCN03-04,FLCN03-05,FLCN03-06,FLCN03-07,FLCN03-08, FLCN03-09,FLCN03-10,FLCN03-11,FLCN03-12,FLCL04, FLCL04-01,FLCL04-02,FLCL04-03,FLCL04-04,FLCL04-05, FLCL04-06,FLCL04-07,FLCL04-08,FLCL04-09, FLCL04-10,FLCL04-11,FLCL04-12

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