



EU DECLARATION OF CONFORMITY

CE Marking

RoHS

1. Product name: Medical Electric Scooter & Medical Powered Wheelchair
Model number: TE-778NR, TE-778S, TE-778XLSBN, TE-779XLS, TE-7A, TE-888iX, TE-888NR, TE-888NRS, TE-888NRSB, TE-888SL, TE-888SLB, TE-889AE, TE-889ASN, TE-889DXD, TE-889NR, TE-889NRS, TE-889SL, TE-889SLBF, TE-889XLSBF, TE-889XLSBN, TE-9D, AT889, TE-C600, TE-889XLSBN w/ CABIN, TE-E900, TE-FS4, TE-GK10, TE-GK-4, TE-GK7-3, TE-GK-8, TE-GK9, TE-S1500, TE-S7-4, SC777, TE-SL7-4, 858WM, 888WA, 888WNLE, 888WNLLHD, P424MT, UL8W12

2. Manufacturer information:

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|-------------------------------|---|
| Name of manufacturer: | Pihsiang Machinery Manufacturing Co., Ltd. |
| Manufacturer SRN | TW-MF-000002499 |
| Address | No. 108, Hsin-He Road, Hsin-Feng Hsiang 304 Hsinchu County, Taiwan |
| Authorized Representative | Wellkang Ltd. |
| Authorized Representative SRN | XI-AR-000001836 |
| Address: | Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland |

SRN: Single Registration Number

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Pihsiang Machinery Manufacturing Co., Ltd.
4. The Basic UDI-DI as referred to in Part C of Annex VI of Regulation (EU) 2017/745.
5. The risk class of products in Pihsiang Machinery Manufacturing Co., Ltd are classified as Class I in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/745.

6. The object of the declaration described above is in conformity with the relevant Community harmonization legislations and carries CE Mark accordingly:
 - (1) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
 - (2) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

7. The products are covered by the present declaration is in conformity with this Regulation(EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

8. Following standards are performed in relation to which conformity is declared:
 - EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers- Requirement and test methods
 - EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
 - EN ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
 - EN 50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Signed for and on behalf of:
Place and date of issue:
Name, Title:

Pihsiang Machinery Manufacturing Co., Ltd.
Hsinchu County, Taiwan, at Apr. 12, 2021
Maurice Tseng, Technical Department Manager


