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EC DECLARATION OF CONFORMITY

For the following equipment:
Electrically Powered Wheelchair
(Product Name)

JOY RIDER
NEW JOY RIDER
(Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning **Medical Device Directive (93/42/EEC) and amended (2007/47/EC)** with the compliance of the essential requirement – **Annex I** and the conformity assessment **Annex II** excluding section 4 (Module H) to be certified by DNVGL (Address: Det Norske Veritas AS, 1322 Høvik, Norway, notify body number – 2460).

For the evaluation regarding the **Class I** (per ***Rule 12*** *in Section III, Annex IX of the Directive 93/42/EEC*) product safety aspects, the following standards were applied:

- *EN 980: 2008 Symbols for use in the labelling of medical devices*
- *EN 1041: 2008 Information supplied by the manufacturer of medical devices*
- *ISO 7176-1: 2014 Wheelchairs – Part 1: Determination of static stability*
- *ISO 7176-2: 2001 Wheelchairs – Part 2: Determination of dynamic stability of electric wheelchairs*
- *ISO 7176-3: 2012 Wheelchairs – Part 3: Determination of effectiveness of brakes*
- *ISO 7176-4: 2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range*
- *ISO 7176-5: 2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space*

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- *ISO 7176-6: 2001 Wheelchairs – Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs*
- *ISO 7176-7: 1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions*
- *ISO 7176-8: 2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths*
- *ISO 7176-9: 2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs*
- *ISO 7176-10: 2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs*
- *ISO 7176-14: 2008 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods*
- *ISO 7176-15: 1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labelling*
- *ISO 7176-21: 2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers*
- *EN ISO 10993-1: 2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *EN ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *EN 12184: 2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods*
- *EN 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *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, labelling and information to be supplied – Part 1: General requirements*
- *IEC 62133: 2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

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- *UN 38.3 United Nations Recommendations on the Transport of Dangerous Goods (Rev. 6/Corr. 1) Section 38.3 Lithium Batteries*
- *IEC 62304: 2006 Medical device software - Software life cycle processes*
- *IEC 62366: 2015 Medical devices – Part 1: Application of usability engineering to medical devices*

The following representative in Europe is responsible for this declaration:

Y. Sung Handelsvertretung (Mr. Sung, Han-sheng)
(Representative Name)

Duesselthaler Str. 24, 40211 Duesseldorf Germany
(Representative Address)

Person responsible for making this declaration:

Tung Keng Enterprise Co., Ltd.
(Manufacturer Name)

No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist., Taichung City, Taiwan 42748
(Manufacturer Address)

General Manager / Frank Huang		09/16/2020
(Position / Title)	(Legal Signature)	(Date)

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