



## Declaration of Conformity

We WHILL, Inc. hereby declare that the Declaration of Conformity is issued under our sole responsibility and belongs to the following product:

Product Name:	Powered Scooter
Name:	WHILL Model R 4-wheel/ WHILL Model R 3-wheel
Medical Device Class:	Class I, Annex VIII Chapter III Rule 13
MDA Code:	MDA0313
Intended purpose:	To provide outdoor and indoor mobility to individuals who are comfortable with operating a powered scooter.
Basic UDI-DI:	457007230PWDScooterH7
SRN:	JP-MF-000016481
Manufacturer:	WHILL, Inc.
Address:	2-1-11 Higashishinagawa, Shinagawa-ku, Tokyo, 140-0002, Japan
Authorized Representative:	CMC Medical Devices
SRN:	ES-AR-000000293
Address:	C/ Horacio Lengo n18 C.P 29006 Málaga-Spain



The product described above is in conformity with the relevant directive and regulations:

- REGULATION (EU)2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.  
The product meets with the Annex I of essential requirements in accordance with the EU Regulation 2017/745.
- REGULATION (EU)2023/1230 OF THE EUROPEAN PARLIAMEN AND OF THE COUNCIL of 14 June 2023 on machinery, and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
- REGULATION (EU) 2023/1542 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC
- REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- 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
- DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment

Harmonised Standards Applied: See 10-00701-TD.STD-01 Applicable Standard List

*Junpei Naito*      8/14/2024  
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Tokyo, Japan

Signature / Date / Place of Issue

Name / Function: Junpei Naito, CDO

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