



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 Wheelchair
Name:	Model C2
Medical Device Class:	Class I, Annex VIII Chapter III Rule 13
MDA Code:	MDA0313
Intended purpose:	To provide mobility to individuals who are comfortable with operating a powered wheelchair.
Basic UDI-DI:	457007230PWDWheelchairXL
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 General Safety and Performance Requirements in accordance with the EU Regulation 2017/745.

-DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC

-DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

-DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

-REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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 10-00301-TD.STD-01 Applicable Standard List

Junpei Naito 5/14/2023

Tokyo, Japan

Signature / Date / Place of Issue

Name / Function: Junpei Naito, CDO