

# EU Declaration of Conformity

**Manufacturers Name:** Ki Mobility

**Manufacturers Address:** 5201 Woodward Dr.  
Stevens Point, WI 54481

**SRN (Single Registration Number):** US-MF-000012633

**Authorized Representative Name (if applicable):** Etac Supply Center AB

**Authorized Representative Address (if applicable):** Langgatan 12  
33233 Anderstorp, Sweden

**Authorized Representative SRN:** SE-AR-000001601

**Basic UDI-DI:** 0850013379MANUALWN

**UDI-DI:** 00850013379309

**Name of the Device(s):** CR45

**GMDN product code:** 41498

**Device Classification:** Class I, Rule 1

**Intended Purpose:** A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

**Notified Body name:** Not Applicable

**Notified Body Address:** Not Applicable

**Notified Body Identification number:** Not Applicable

**Conformity assessment route:** Ki Mobility uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:



Class 1: EU conformity declaration according to annex VIII

This declaration of conformity is issued under the sole responsibility of Ki Mobility. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System certification to ISO 13485:2016 and on assessment of technical documentation.

All supporting documentation is retained at the premises of Ki Mobility.

**Name:** Mark Murphy

**Title:** Vice President of Operations, PRRC

**Signature:**

**Date (YYYY-MM-DD) of issue:** 2023-11-29