

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: 00850013379118

Name of the Device(s): Focus CR

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