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):	Box 203, 33424 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

CE

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:	Mark Murphy Digitally signed by Mark Murphy Date: 2022.01.21 13:01:29 -06'00'
Date (YYYY-MM-DD) of issue:	2022-01-21