EU Declaration of Conformity

Manufacturers Name:	Ki Mobility
Manufacturers Address:	5201 Woodward Dr. Stevens Point, WI 54481
Authorized Representative Name (if applicable):	Ki Mobility Portugal, Unipessoal Lda
Authorized Representative Address (if applicable):	Rua Santos Pousada, 157 4º andar sala 17 4000-485 Porto
Basic UDI-DI:	0850013379SEATINGAG
UDI-DI:	00850013379200
Name of the Device(s):	Axiom Cushion SPF
GMDN product code:	11100
Device Classification:	Class I, Rule 1
Intended Purpose:	A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair but may also be sold separately as a replacement part.
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 in conformance 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: 2021.05.03 09:00:22 -05'00'
Date (YYYY-MM-DD) of issue:	2021-05-03

Attachment to declaration of conformity Axiom Cushion SPF

Harmonized Standards

Reference number	Description and Rev
ISO 13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019	Application of Risk Management to Medical Devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2005	Biological evaluation of medical devices- Part 5- tests for in vitro cytotoxicity
ISO 10993-12:2012	Biological evaluation of medical devices- Part 12- Sample preparation and sample materials
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
EN12182:2012	Assistive products for persons with Disability- General requirements and test methods
EN12183:2014	Manual Wheelchairs-Requirements and test methods
EN614-1:2006 +A1	Ergonomic Design Principles
ISO 7176-16: 2012	Wheelchairs- Resistance of ignition of postural support devices

Common Specifications

Reference number	Description and Rev
N/A	N/A