

EU Declaration of Conformity

EU-TD/0101-1B EC Declaration of Conformity

Effective Date: 6/23/2022 Rev: D

App'd: D. Milincic

According to Regulation No. 2017/745

Manufacturer Information: Pride Mobility Products Corporation

401 York Avenue Duryea, PA 18642 USA

MF SRN (Single Registration Number):

AR SRN (Single Registration Number):

NL-AR-000001684

<u>Authorized Representative Information:</u> Pride Mobility Products Europe BV

De Zwaan 3

1601 MS Enkhuizen

Netherlands

Basic UDI-DI: 6065090060650930010*1FM

Name of the Device(s):

Electric Powered Scooter
Class A per EN 12184

Class A per EN 12184

Model Name: Go-Go Elite Traveller, 4 wheel

Model Number: SC44E

Product code: N/A

Classification: Class I

According to Annex VIII of the MDR

Intended Use: Scooter: 890.3800 - A motorized three-wheeled vehicle is a

gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled

persons.

Applied Standards: EN 12184: 2014 - Electrically powered wheelchairs, scooters and

their chargers. Requirements and test methods

ISO 14971: 2007 - Medical devices - Application of risk

management to medical devices

Signature: Date of issue: Area of responsibility:

Annex I: General safety and performance

9/8/2022 requirements

Mark Maguire

General Manager, R&D Product Verification

Pennsylvania, USA

<u>Conformity assessment route:</u> Pride Mobility Products uses the following requirements for the

CE-labeling of their products According to Regulation No.

2017/745:

Class I: EC conformity declaration according to Annex VIII

This declaration of conformity is issued under the sole responsibility of Pride Mobility Products. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signature

Date of issue: Area of responsibility:

9/8/2022 Annex II through Annex XVII

Dragana Milincic

Sr. Officer of Compliance & Regulatory

Netherlands