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Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: Tianjin Kepler Vehicle Industry Co.,Ltd

Address: Xinmin road, west area of economic and technological development zone.
Tianjin, China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Basic UDI-DI: 697400707KPL001EA 697400707KPL002EC

Name: Scooter

The below scooter models are technically the same, just with cosmetic differences

Model: 824032 BLUE 824032 GREY 824032 RED

824044 WHITE 824044 ORANGE

Intended Purpose: The scooter is designed for a single user to compensate for a loss of mobility as a result of a disability. It is suitable for indoor use and outdoor use on smooth surfaces.

Classification: I

Rule: According to Rule 13, Annex VIII, Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Medical Device Regulation (EU) 2017/745) and the following standards.

EN ISO 14971:2012	ISO7176-1:2014	ISO7176-8:2014	ISO7176-22:2003
EN ISO 15223-1:2016	ISO7176-2:2001	ISO7176-9:2009	ISO7176-25:2013
ISO 10993-1:2018	ISO7176-3:2012	ISO7176-10:2008	EN12182:2012
EN ISO 10993-5: 2009	ISO7176-4:2008	ISO7176-13:1989	EN12184:2014
EN ISO 10993-10: 2013	ISO7176-5:2008	ISO7176-14:2008	EN 60601-1-2:2015
EN 1041:2008	ISO7176-6:2001	ISO7176-15:1996	
EN 62366-1:2015	ISO7176-7:1998	ISO7176-16:2012	

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Signature: Position:

Date: 2020.12.23

Authorized Signature (S)