


DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

Device information	Description
Common device name	Wheelchair
Registered trade name or trade mark	 Excel Elise Travel Buggy Mobiquip Elise XL stroller
Authorized representative UK	UK APLAN CORPORATION LTD Wandle House Associates, 47, Wandle House, Wandle Road, CROYDON, Surrey, CR0 1DF, United Kingdom
Product series	<i>MK1000</i>
UK GMDN Code	41630 Wheelchair, attendant-driven, collapsible
Basic UDI-DI	Wheelchair MK1000:6973134780121
Risk class of the device	<i>Class I</i>
Common Specification (CS) references	Wheelchair, attendant-driven, collapsible, 4Wheels
Rule:	Rule I, Annex IX, Directive 93/42, Part II of the UK MDR 2002
Conformity Assessment Procedure:	Annex VII of the Directive 93/42, Part II of the UK MDR 2002

We hereby declare that the above-mentioned product meets the UK Medical Devices Regulations 2002 and the following standards:

- EN ISO 13485: 2016 Medical devices- Quality management systems-Requirements for regulatory purposes
- EN ISO 14971: 2019 Medical devices-Application of Risk Management
- EN ISO 15223-1: 2016 Medical device-Symbols to be used with medical device labels. Labelling and information to be supplied-Part 1: General requirements
- EN 62366-1: 2015 Medical devices Part 1--Application of usability engineering to medical devices
- EN 12182: 2012 Assistive products for persons with disability-General requirements and test methods
- EN ISO10993-1: 2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO10993-10: 2013 Biological evaluation of medical devices - Tests for irritation and skin sensitization

The following person is exclusively responsible for the compliance of declaration:

Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd.

No.26, Guangfu Road, Dongsheng Town, Zhongshan City, Guangdong Province, 528414, China.

(Manufacturer's name/ Registered address)



Hongmei Tian / General Manager

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