Declaration of Conformity

for the

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Loopwheel 2
Legal Manufacturer: (Name on Label)	**Loopwheels Ltd** Unit 202 Boughton Industrial Estate Newark, Nottinghamshire, NG22 9LD United Kingdom
Manufacturers SRN:	Not yet available
Basic UDI-DI:	506093580LW2H7
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	To improve comfort and mobility for people who use a manual wheelchair.
MDR Classification:	Accessory, Class I [Annex VII, Rule 1]
Notified Body:	Not applicable
EC Certificate:	Not applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Gemma Pearce **Position** Managing Director

Signed Gemma Pearce **Date** 04/10/23 **Place** Boughton, Newark UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 7176-8:2014	Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN/EMDN Code
24URE	Loopwheels Urban 24” - with regular springs	Y122499 (Wheelchairs Accessories – Other)
24UST	Loopwheels Urban 24” - with stiff springs	Y122499
24USO	Loopwheels Urban 24” - with soft springs	Y122499
25URE	Loopwheels Urban 25” – with regular springs	Y122499
25UST	Loopwheels Urban 25” - with stiff springs	Y122499
25USO	Loopwheels Urban 25” - with soft springs	Y122499
24XRE	Loopwheels Extreme - with regular springs	Y122499
24XST	Loopwheels Extreme - with stiff springs	Y122499
24LT	Loopwheels LT	Y122499

Version History

Version	Compiled by	Date	Description
1.0	Gemma Pearce	2.11.21	EU Declaration of Conformity created
1.1	Gemma Pearce	13.10.22	Corrected Basic UDI-DI
1.2	Gemma Pearce	4.10.23	Added Loopwheels LT catalogue number
2	Gemma Pearce	13.11.24	Updated company name to Loopwheels Ltd from Jelly Products Ltd.