Declaration of Conformity

As manufacturer of the Tendercare Cloud Pushchair, the company:

Tendercare Limited
Unit 10, Minster Court,
Courtwick lane,
Littlehampton
West Sussex, BN17 7RN

Tel: (01903) 726161
Fax: (01903) 734083

Declares that the product known as the Cloud Pushchair is a CLASS 1 device in compliance with:

The United Kingdom Regulations,
The Medical Devices Regulations 2002
Statutory Instrument 2002 No. 618, and The Medical Devices
(Post-market Surveillance Requirements) (Amendment)
(Great Britain) Regulations 2024

Product Description:
Mobility pushchair to provide postural seating in a mobile platform for the disabled.

Product Order Codes and Serial Numbers:

Product Code	GTIN	Device Description
CL5400	05060837700332	Cloud Pushchair Complete Size 1
CL5301	05060837700349	Cloud Pushchair Chassis Size 1
CL5021	05060837700325	Cloud Seat Size 1

Issue Date: 11 July 2025

Applicable Standards:

Reference	Description
Directive 93/42/EEC	Medical Device Directive (EU MDD)
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems – System requirements for regulatory purposes.
EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
MEDDEV 2.7.1: rev 4 June 2016	Clinical evaluation: A guide for manufacturers and notified bodies
EN ISO 21856:2022	Assistive products General requirements and test methods
ISO 7176-19:2008	Wheelchairs - Wheeled mobility devices for use as seats in motor vehicles
BS 5852:2006	Methods of test for assessment of the ignitability of upholstered seating by smouldering and flaming ignition sources

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Authorised By: Mr J Adams, Managing Director