EU DECLARATION OF CONFORMITY

Manufacturer:	Name: United Care Products B.V. Address: Bremenweg 5, 9723 TC Groningen info.unitedcare@directhealthcaregroup.com SRN: NL-MF-000035901
Product name:	Wendy Drive 2
Product code:	11000810 WendyDrive 2, 230kg, 2-point spreader bar 11000820 WendyDrive 2, 230kg, electric 4-point spreader bar
Basic UDI-DI:	872061814312DF
Range of products:	SN 2409025 and upwards

Intended use:
The WendyDrive 2 is a mobile hoisting device which, together with approved accessories, assists caregivers in hoisting and/or transferring patients that have little to no muscular function in a seated or supine position over short to medium length distances indoors, such as from one room to another.

Risk class of the device: Class I (self-certified), rule I and XIII

Applicable standards:
ISO 10535:2021
EN ISO 13485:2016
ISO 14971:2019
ISO 15223-1:2016
ISO 62366-1:2015
IEC 60601-1:2005/AMD1:2012/AMD2:2020
IEC 60601-1-2:2014/ IEC 60601-1-2:2014/AMD1:2021
EN ISO 21856:2022
EN ISO 20417:2021

This EU Declaration of conformity is issued under the sole responsibility of United Care Products B.V.

The Conformity assessment has been conducted according to ANNEX II and ANNEX III of the Medical Device Regulation (EU) 2017/745.

We, hereby, declare that the device(s) specified above are in compliance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC , Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC.

Place and date of issue: Groningen, 17 December, 2024
Signature:

Elisabet Lindberg,
EU Head of Quality and Environmental,
PRRC – §15; MDR 2017/745