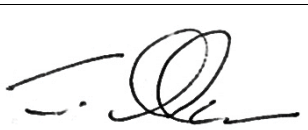
EU Declaration of Conformity for the Snappi Interface

Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

This EU declaration of conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in the Medical Device Regulation (EU) 2017/745, and other applicable Union legislation as listed in Annex I to this declaration, have been fulfilled in relation to the devices listed in Annex III of this declaration.

Name of Manufacturer or Trade Name:	Tendercare Ltd
Single Registration Number (SRN):	DE-AR-000041484
Manufacturers Address	Unit 10 Minster Court, Courtwick Lane, Littlehampton, BN17 7RN, UK
Basic UDI-DI:	506083770TPSZ
Product Name:	Snappi Interface
Product Codes or Catalogue Numbers:	See ANNEX III – Device Listing
Intended Purpose:	Interface to mount special seating for the disabled to Tendercare Wheelbases.
Risk Class:	Class I
Classification Rule:	Rule 1
EU Authorised Representative:	Thomas Hilfen für Körperbehinderte GmbH& Co. Medico KG. SRN: DE-MF-000006303
Additional Information:	None

Declaration Signature:	
Name:	Mr J Adams
Position:	Managing Director
Location:	Littlehampton, United Kingdom
Date:	26 / 04 / 2024

ANNEX I – Union legislation

The devices listed in Annex III are in conformity with the following Union legislation:

- Medical Device Regulation (EU) 2017/745

ANNEX II – Applicable Standards

Reference	Description
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

ANNEX III – Device Listing

Product Code	UDI-DI (GTIN)	Device Description	EMDN Code
SN8215	05060837700097	Snappi Interface Size 1	Y1299 Personal mobility devices – other
SN8220	05060837700103	Snappi Interface Size 2	

Revision History:

Version	Compiled By	Date	Description
1.0	Robert Footitt	22-FEB-2024	First Issue
1.1	Robert Footitt	26-APR-2024	Added SRN