# Declaration of Conformity UDI: EU-41630a

# We,

 Product Manufacturer:
 Aidapt Bathrooms Limited
 Authorised Representative (EU):
 Aidapt B.V

 Address:
 Lancots Lane
 Address:
 Algolweg 22
 3821BH Amersfoot

 Sutton
 St Helens
 Netherlands
 +31-33 2779210

### declare under our sole responsibility that the device;

Device Name: Wheelchair (Attendant Propelled)

GMDN: 41630 Attendant-only-propelled wheelchair, non-bariatric

Basic UDI-DI: 5021196APWCVD

| Product\Catalogue Code | Description  | UDI-DI        |
|------------------------|--|---------------|
| VA169                  | Deluxe attendant propelled steel wheelchair (hammered) | 5021196673569 |
| VA169Black             | Deluxe attendant propelled steel wheelchair (black)    | 5021196847854 |
| VA169Blue              | Deluxe attendant propelled steel wheelchair (blue)     | 5021196725817 |
| VA169Red               | Deluxe attendant propelled steel wheelchair (red)      | 5021196758808 |
| VA170                  | Compact transport aluminium wheelchair (hammered)      | 5021196673576 |
| VA170Pink              | Compact transport aluminium wheelchair (pink)          | 5021196725824 |
| VA170Blue              | Compact transport aluminium wheelchair (blue)          | 5021196744887 |
| VA170Orange            | Compact transport aluminium wheelchair (orange)        | 5021196757146 |
| VA170Red               | Compact transport aluminium wheelchair (red)           | 5021196757153 |
| VA171                  | Compact transport steel wheelchair (black)             | 5021196674511 |
| VA171Red               | Compact transport steel wheelchair (red)               | 5021196764250 |
| VA171Blue              | Compact transport steel wheelchair (blue)              | 5021196764267 |
| VA171Pink              | Compact transport steel wheelchair (pink)              | 5021196764625 |
| VA171Ham               | Compact transport steel wheelchair (hammered)          | 5021196764694 |
| VA172                  | Compact aluminium wheelchair (black)                   | 5021196764823 |
| VA172Blue              | Compact aluminium wheelchair (blue)                    | 5021196764854 |
| VA172Red               | Compact aluminium wheelchair (red)                     | 5021196764878 |
| VA172Pink              | Compact aluminium wheelchair (pink)                    | 5021196764885 |
| VA172Ham               | Compact aluminium wheelchair (hammered)                | 5021196764861 |
| VA173                  | York attendant propelled steel wheelchair (red)        | 5021196800866 |

#### **Intended Purpose:**

A non-powered wheeled mobility device with a seat designed to enable a healthcare provider/carer to transport a non-bariatric person without the full capacity to walk, typically over short distances and over smooth ground. Often referred to as a transport wheelchair, it is typically designed with four small wheels and includes rear-fitted handles for attendant control of the chair; it does not provide the occupant a mechanism for self-propulsion (it is not a push-rim wheelchair).

**Object:** 



to which this declaration relates is classified as risk Class 1, according to the rules set out in Annex VIII, is in conformity with the following relevant EU harmonisation legislation;

• Regulation (EU) 2017/745 relating to medical devices

## and carry the required CE mark.

## We confirm that the listed devices are in conformity with the following standards;

- BS EN ISO 11199-1:2021 Walking aids. Assistive products for walking manipulated by both arms. Requirements and test methods Walking frames
- BS EN ISO 14971:2019 Medical devices. Application of risk management to medical devices

Place and date of issue: Lancots Lane, Sutton, St Helens, Merseyside WA9 3EX UK August 2023

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Signed by, for and on behalf of Aidapt Bathrooms Limited:

**Designation:** 

Managing Director

Mr Mark Benyon



Author

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