

# **EU-declaration of Conformity**

Manufacturer: Vermund Larsen A/S, Gøteborgvej 8-12, 9200 Aalborg, Denmark

Phone: +45 96347600, CVR: 52796628

SRN: DK-MF-000002203

Hereby declare that

Basic UDI-DI (GMN):

57143390007PU

Product(s):

See table on page 2

Risk Class:

Class I (according to rules set out in Annex VIII)

ISO 9999 Class:

Stools Class 180915

#### Are in conformity with

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

## And have been tested under

EN 12182 Assistive products for persons with disability – General requirements and test methods.

EN 16139 Furniture – Strength, durability and safety – Requirements for non-domestic seating.

EN1021-1 Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette.

EN 1021-2 Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent.

EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

## And a risk analysis has been made according to

EN ISO 14971 Medical devices - Application of risk management to medical devices.

#### Intended use

To support a user in a sitting/resting posture in hospital environments.

On behalf of Vermund Larsen A/S Aalborg, August 27<sup>th</sup>, 2024

Mathias Hasland Jungersen

Teamleader, Product Engineering



# Basic UDI-DI 57143390007PU includes the following products and their associated configurations:

| Item no. | Product                     | GMDN Code | UDI-DI (GTIN) | Max. Load |
|----------|-----------------------------|-----------|---------------|-----------|
| 87211    | VELA Rumba                  | 47117     | 5714339026017 | 140 kg    |
| 87212    | VELA Neonatal/Pædiatri stol | 47117     | 5714339057257 | 140 kg    |
| 87213    | VELA Treatment Chair        | 47117     | 5714339060769 | 140 kg    |
| 87214    | VELA Neonatal/Pædiatri stol | 47117     | 5714339121033 | 140 kg    |
| 87215    | VELA Treatment Chair        | 47117     | 5714339123358 | 140 kg    |