

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):

57143390005PQ

Product(s):

See table on page 2

Risk Class:

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

ISO 9999 Class:

Stools Class 180906

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

DS/EN 1335-1 Office furniture – Office work chair – Part 1: Determinations of dimensions.

DS/EN 1335-2 Office furniture – Office work chair – Part 2: Safety requirements.

DS/EN 1335-3 Office furniture – Office work chair – Part 3: Test methods.

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.

And medical electrical equipment (see table on page 2) have been tested under

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 therefore, satisfies all essential requirements with reference to

EN12182 Assistive products for persons with disability – General requirements and test methods.

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 bariatric user in a sitting posture while performing indoor activities of daily living including work activities.

On behalf of Vermund Larsen A/S Aalborg, May 12th, 2023

Mathias Haslund Jungersen

Teamleader, Braduet Engineer

Teamleader, Product Engineering

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Basic UDI-DI 57143390005PQ includes the following products and their associated configurations:

Item no.	Product	GMDN Code	UDI-DI (GTIN)	Max. Load	Electrical
5025	VELA 'Bariatric' Patient Chair	58827	5714339063708	200 kg	No
5026	VELA Tango 300	58827	5714339087766	200 kg	No
5105	VELA Tango 300E	65508	5714339056748	200 kg	Yes
5106	VELA Tango 310E	65508	5714339058537	300 kg	Yes
5107	VELA 'Bariatric+' Patient Chair	65508	5714339062534	300 kg	Yes

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