

EU-declaration of Conformity

Manufacturer: Vermund Larsen A/S
Gøteborgvej 8-12
9200 Aalborg
Denmark
Phone: +45 96347600
CVR: 52796628
SRN: Awaiting the Danish Medical Agency

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.

On behalf of Vermund Larsen A/S
Aalborg, May 1st, 2020



Bo Olesen
Business Process & Development Manager

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

Item no.	Product	UDI-DI (GTIN)	Max. Load	Electrical
5024	VELA Tango 300	5714339056731	200kg	No
5105	VELA Tango 300E	5714339056748	200kg	Yes
8024	VELA 'XL-Bariatrisk'	5714339057202	200kg	No
8025	VELA 'XL-Bariatrisk'	5714339057219	200kg	Yes