

EU-declaration of Conformity

Manufacturer: Meyland-Smith A/S
Gøteborgvej 8-12
9200 Aalborg
Denmark
Phone: +45 98961985
CVR: 26921465
SRN: DK-MF-000002369

Hereby declare that

Basic UDI-DI (GMN):	57143390011PK
Product(s):	See table on page 2
Risk Class:	Class I (according to rules set out in Annex VIII)

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 10353 Hoists for the transfer of disabled persons – Requirements and test methods
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

Is intended for lifting a seated patient without capacity to walk in and out of a vehicle or wheelchair.

On behalf of Meyland-smith A/S
Aalborg, January 25th, 2022



Mathias Haslund Jungersen
Teamleader, Product Engineering

Basic UDI-DI 57143390011PK includes the following products and their associated configurations:

Item no.	Product	GMDN Code	UDI-DI (GTIN)	Max. Load
M123100	VELA Person Lift u/liftsejl	41602	5714339909273	125 kg
M123110	VELA Person Lift m/liftsejl Medium	41602	5714339909280	125 kg
M123120	VELA Person Lift m/liftsejl Large	41602	5714339909297	125 kg