

## EC DECLARATION of CONFORMITY

## Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices

We, MOBILEX A/S
Registered place of business
Grønlandsvej 5
8660 Skanderborg
Denmark



SRN: DK-MF-000021885

Hereby declare under our sole responsibility as a legal manufacturer that the product specified on the product list below, meet the essential health and safety requirements and is in conformance with the provisions of the Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices.

The product is classified as Class I, medical device. The classification is based on the requirements of Rule 1 of annex VIII, of the Regulation (EU) 2017/745.

The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745.

Intended purpose: To be used to assist patients in wheelchairs or scooters enable the passage of

elevated points (e.g. Stairs).

**PRODUCT LIST** 

Single-folded ramp:

REF / item no.	SC-045	SC-060	SC-090	SC-120	SC-150	SC-180
UDI-DI	57400014	57400014	57400014	57400014	57400014	57400014
	03121	03138	03145	03152	03169	03176
BASIC-UDI-DI	57400014SC-RAMPSDY					

## **ACCESSORIES LIST**

Item nr.	Accessories item nr.		
SC-060	SB-060		

Harmonized norms used during conformity estimation:

EN 12182:2012, PN-EN ISO 14971:2012, EN 1041:2009

Skanderborg, 2022-04-12, Thomas N. Christensen, Managing Director

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