

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

Telescopic ramp:

REF / item no.	TM-055	TM-150	TM-210	TM-300
UDI-DI	57400014	57400014	57400014	57400014
	15193	15209	15216	15223
BASIC-UDI-DI	57400014TM-RAMPSKV			

ACCESSORIES LIST

Issued: 2022/04

Item nr.	Accessories item nr.
TM-055+150+210+300	NO

Harmonized norms used during conformity estimation:

EN 12182:1999, PN-EN ISO 14971:2004, EN 1041:2001

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

