

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 specified on the product list below is "technical aid for the disabled", 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.

Intended purpose: To be used to assist patients in wheelchairs or scooters enable the passage of elevated points (e.g. Stairs).

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

PRODUCT LIST

Terrace ramp with hinged part:

REF / item no.	TSR130	TSR140
UDI-DI	5740001436006	5740001436013
BASIC-UDI-DI	57400014TSR-RAMPSAT	

ACCESSORIES LIST

Item nr.	Accessories item nr.
TSR130, TSR140	NO

Harmonized norms used during conformity estimation:

EN 12182:2012, PN-EN ISO 14971:2012, EN 1041:2001

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

