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.

Intended purpose: To help people with movement difficulties to get in or out of the car, bed or chair.

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

PRODUCT LIST

Product name	Swivel Seat Cushion	Swivel Seat Cushion	Swivel Seat Cushion	Swivel Seat Cushion
REF / item no.	278051	278052	278055	278056
UDI-DI	5740001441093	5740001441109	5740001434095	5740001434101
BASIC-UDI-DI	57400014SWIVELSEATCD			

ACCESSORIES LIST

Item nr.	Accessories item nr.
278051-52 + 278055-56	NO

Harmonized norms used during conformity estimation:

PN-EN ISO14971:2012, PN-EN 1041:2009, PN-EN 12182:2012; ISO 10993-10:2010, ISO 3759:2007 /5077:2007/6330:2000+Amd.1:2008, ISO 10535

Skanderborg, 2022-04-26, Thomas N. Christensen, Managing Director

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CE