

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: Support belts with handles can be used in any situation where the helper

needs a firm grip in order to assist/support the client.

PRODUCT LIST

Product name	Support belt	
REF / item no.	278046	278047
UDI-DI	5740001434071	5740001434088
BASIC-UDI-DI	57400014SUPPORTBELTEA	

Harmonized norms used during conformity estimation:

PN-EN 12182:2012, PN-EN ISO14971:2012, PN-EN 1041:2009

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

CE

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