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: Designed for individuals who require support standing to keep the balance.

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

PRODUCT LIST

Grab bar:

REF / item no.	311440	311460	311480
UDI-DI	5740001403657	5740001403664	5740001403671
BASIC-UDI-DI	57400014SUPPORTRAILGD		

REF / item no.	311540	311560	311580
UDI-DI	5740001403688	5740001403695	5740001403701
BASIC-UDI-DI	57400014SUPPORTRAILGD		

ACCESSORIES LIST

Item nr.	Accessories item nr.
311440+60+80; 311540+60+80	NO

Harmonized norms used during conformity estimation:
PN-EN ISO 14971:2012, PN-EN 12182:2012, PN-EN 1041:2009;

Skanderborg, 2022-04-25, Thomas N. Christensen, Managing Director

Issued: 2022/04