

# **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.

PROD	UCT	LIST
DI		1

Plastic grab bar:			
REF / item no.	311230	311245	311260
UDI-DI	5740001400168	5740001400175	5740001400182
BASIC-UDI-DI	57400014PLASTICGRABBARMN		

#### ACCESSORIES LIST

Item nr.	Accessories item nr.
311230+45+60	NO

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

Thoras N. (

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

