

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 walking and 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

Wall mounted folding	support rail:
DEE / itom no	

REF / item no.	315021
UDI-DI	5740001438024
BASIC-UDI-DI	57400014FOREARMCRUTCHFQ

ACCESSORIES LIST

Item nr.	Accessories item nr.
315021	NO

Harmonized norms used during conformity estimation:

PN-EN 11334-1:2007, EN ISO 14971:2012, EN 1041:2009

pores N. Cr

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