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

Hereby declare under our sole responsibility as a legal manufacture 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 ñtechnical aid for the disabledò, 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.

PRODUCT LIST

DynaWalk

Verticalizer/Walking Frame 313001, 313002

Harmonized norms used during conformity estimation:

PN-EN ISO 11199:2005, EN ISO 14971:2011, EN 1041:2009, EN 21182:2005, PN-EN 1985:2002

Skanderborg, 2020-03-11, Thomas N. Christensen, Managing Director

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