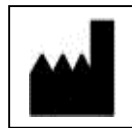




EC DECLARATION of CONFORMITY

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 ~~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.

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

PRODUCT LIST

Tube Slide Sheet Æ item no. 278011, 278012, 278013
Flat Slide Sheet Æ item no. 278015, 278016
Flat Slide Sheet with handles Æ item no. 278023
One-Way Slide Sheet Æ item no. 278031
Transfer Gloves Æ item no. 278041

Harmonized norms used during conformity estimation:

PN-EN ISO14971:2012, PN-EN 1041:2010, PN-EN 12182:2012; ISO 10993-10:2010

Skanderborg, 2020-03-18, Thomas N. Christensen, Managing Director

