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 is 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.

Intended purpose: Indicated for multiple applications involving people with mobility limitations, who require assistance during: positioning and/or transferring of patients with severely restricted mobility, positioning and/or transferring of patients who are highly sensitive to pain.

PRODUCT LIST

Product name	**Tube Slide Sheet**	**Tube Slide Sheet**	**Tube Slide Sheet**	**Flat Slide Sheet**
REF / item no.	**278011**	**278012**	**278013**	**278015**
UDI-DI	**5740001434002**	**5740001434019**	**5740001434026**	**5740001434033**
BASIC-UDI-DI	**57400014SOFTSLEEPH3**			
Product name	**Flat Slide Sheet**	**Flat Slide Sheet with handles**	**One-Way Slide Sheet**	**Transfer Gloves**
REF / item no.	**278016**	**278023**	**278031**	**278041**
UDI-DI	**5740001434040**	**5740001434057**	**5740001434064**	**5740001434125**
BASIC-UDI-DI	**57400014SOFTSLEEPH3**			

Harmonized norms used during conformity estimation:

PN-EN ISO14971:2012, PN-EN 1041:2009, PN-EN 12182:2012; ISO 10993-10:2010

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

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CE