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: The SoftSleep orthopaedic pillow is a medical device, designed for the persons with cervical spine diseases, for positioning of the head and neck during sleep, to reduce discomfort of the cervical spine.

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

PRODUCT LIST

SoftSleep Contour and SoftSleep:

REF / item no.	279061	279062	279063	279064
UDI-DI	5740001403503	5740001403817	5740001403824	5740001403831
BASIC-UDI-DI	57400014SOFTSLEEPH3			

ACCESSORIES LIST

Item nr.	Accessories item nr.
279061-64	No

Harmonized norms used during conformity estimation:

PN-EN ISO14971:2012, PN-EN 1041:2009

Skanderborg, 2023-08-03, Thomas N. Christensen, Managing Director

Issued: 2023/08

CE