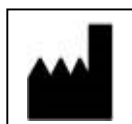


EC DECLARATION of CONFORMITY

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 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: For making comfort when a person is sitting in a wheel chair and to reduce discomfort when sitting for a long time. The cushion is intended for use at home and in nursing or care institutions.

PRODUCT LIST:

Wheelchair cushion from PU foam with polyester cover : BASIC-UDI-DI : 57400014BARRACUDATB

REF / item no.	272044	272048	272071	27840L	278401
UDI-DI	5740001415322	5740001415339	5740001415346	5740001415353	5740001415360
REF / item no.	27840M	27842L	278421	27842M	27845L
UDI-DI	5740001415377	5740001415384	5740001415391	5740001415407	5740001415414
REF / item no.	278451	27845M	27847L	27847M	27850L
UDI-DI	5740001415421	5740001415438	5740001415445	5740001415452	5740001415469
REF / item no.	27850S	27850M			
UDI-DI	5740001415476	5740001415483			

Wheelchair cushion from PU foam with incontinence cover : BASIC-UDI-DI : 57400014INCON.PUKN

REF / item no.	278372	278373	27840N	278402	27840P
UDI-DI	5740001415490	5740001415506	5740001415513	5740001415520	5740001415537
REF / item no.	27842N	278422	27842P	27845N	278452
UDI-DI	5740001415544	5740001415551	5740001415568	5740001415575	5740001415582
REF / item no.	27845P	27847N	27847P	27850N	27850P
UDI-DI	5740001415599	5740001415605	5740001415612	5740001415629	5740001415636
REF / item no.	27840H	27842H	27844H	27848H	27851H
UDI-DI	5740001415643	5740001415650	5740001415667	5740001415674	5740001415681
REF / item no.	27854H	27857H			
UDI-DI	5740001415698	5740001415704			

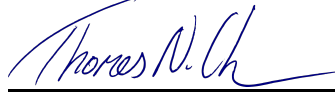
**Two-layer standard wheelchair cushion (viscoelastic+PU) with incontinence cover:
BASIC-UDI-DI : 57400014INCON.VISCO.PU42**

REF / item no.	27840Q	278407	27840R	27842Q	278427
UDI-DI	5740001415711	5740001415728	5740001415735	5740001415742	5740001415759
REF / item no.	27842R	27842S	27845Q	278457	27845R

UDI-DI	5740001415766	5740001415773	5740001415780	5740001415797	5740001415803
REF / item no.	27845S	27845F	27847Q	27847R	27850Q
UDI-DI	5740001415810	5740001415827	5740001415834	5740001415841	5740001415858
REF / item no.	27850R	27855R			
UDI-DI	5740001415865	5740001415872			

Harmonized norms used during conformity estimation:

PN-EN 12183:2014; PN-EN 12182:2012; ISO 7176-part 8, 16; PN-EN 14971:2012, PN-EN 1041:2009



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

