

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: For individuals who require seating support when bathing or showering

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

PRODUCT LIST

Commode and shower chair:

REF / item no.	302015	302018	302019	302020
UDI-DI	5740001400021	5740001400014	5740001400038	5740001400045
BASIC-UDI-DI	57400014COM.SHOWERCHAIR74			

ACCESSORIES LIST

Item nr.	Accessories item nr.		
302015	302125, 302017, 302125		
302018	302017, 302128, 302129, 302127, 302125, 302109, 302110, 302122, 302164		
302019	302128, 302129, 302126, 302125, 302154, 302155, 302122, 302165		
302020	302017, 302128, 302129, 302149, 302125, 302156, 302157, 302122, 302166		
Harmonized	Harmonized norms used during conformity estimation:		

PN-EN 12182:2012; PN-EN 12183:2010, EN ISO 14971:2012, EN 1041:2009, ISO 7176-1:1999, ISO 7176-3:2003; PN-ISO 7176-8:2002; PN-EN 1021:2007;

Skanderborg, 2022-04-05, Thomas N. Christensen, Managing Director