

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 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 %echnical 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

1. Commode and shower chair 302015, 302018, 302019 & 302020

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 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, 2020-03-11, Thomas N. Christensen, Managing Director

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