

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: Designed for individuals who require seating support when bathing or

showering in bathtub.

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

PRODUCT LIST

Swivel bather:

REF / item no.	302022
UDI-DI	5740001403114
BASIC-UDI-DI	57400014BATHTUBSEATA4

ACCESSORIES LIST

Issued: 2022/04

Item nr.	Accessories item nr.
302022	302076

Harmonized norms used during conformity estimation:

PN-EN ISO 14971:2012, PN-EN 12182:1999, PN-EN 1041:2009;

Skanderborg, 2022-04-25, Thomas N. Christensen, Managing Director

