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 is 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: Indicated for people with mobility limitations who have problems with walking, standing or sitting without stable support.

PRODUCT LIST

Flipper wheelchair:

REF / item no.	**271940**	**271944**	**271948**	**271951**
UDI-DI	**5740001403770**	**5740001403787**	**5740001403794**	**5740001403800**
BASIC-UDI-DI	**57400014FLIPPERHF**			
REF / item no.	**271740**	**271744**	**271748**	**271751**
UDI-DI	**5740001403848**	**5740001403855**	**5740001403862**	**5740001403879**
BASIC-UDI-DI	**57400014FLIPPERHF**			

ACCESSORIES LIST

Item nr.	**Accessories item nr.**
271940, 271944, 271948, 271951	
271740, 271744, 271748, 271751	

Harmonized norms used during conformity estimation:

EN 12182:2005; EN 12183:2010; PN-ISO 7176 part 1,3,5,7,8,15,19; PN-EN 1021-1:2007; EN 14971:2012; EN 1041-2009.

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Skanderborg, 2022-04-20, Thomas N. Christensen, Managing Director

CE

Issued: 04/2022

CE 271940+44+48+51; 271740+44+48+51