

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

Marlin wheelchair:

REF / item no.	271240	271244	271248	271251
UDI-DI	5740001403428	5740001403404	5740001403411	57400014033435
BASIC-UDI-DI	57400014MARLINC3			

ACCESSORIES LIST

Item nr.	Accessories item nr.	
271240, 271244, 271248, 271251	271077, 271078, 271083	

Harmonized norms used during conformity estimation:

EN 12182:2005, EN 12183:2011, ISO 7176 part 8,15, ISO 7176-part 1,3,5,7 PN-EN 1021-1:2007 EN 14971:2012; EN 1041-2009.

Skanderborg, 2022-04-22, Thomas N. Christensen, Managing Director

CE

Issued: 04/2022 CE 271240+44+48+51