

## **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**: Wheelchairs are for people with mobility limitations who have

problems with walking, standing or sitting without stable support.

**PRODUCT LIST** 

Barracuda wheelchair with adjustable back, Aluminium

REF / item no.	271840	271844	271848	271851
UDI-DI	57400014	57400014	57400014	57400014
	41031	41048	41055	41062
BASIC-UDI-DI	57400014BARRACUDATB			

## Barracuda wheelchair with drum brake, Aluminium

REF / item no.	272044	272048	
UDI-DI	5740001441031	5740001441048	
BASIC-UDI-DI	57400014BARRACUDATB		

## **ACCESSORIES LIST**

ACCESSORIES EIGT		
Item nr.	Accessories item nr.	
271840	271082, 271085, 271086, 271075, 271A81, 271A82, 27840H, 271645, 271649	
271844	271082, 271085, 271086, 271075, 271A83, 271A84, 27844H, 271646, 271649	
271848	271082, 271085, 271086, 271075, 271A85, 271A86, 27848H, 271647, 271650	
271851	271082, 271085, 271086, 271075, 271A87, 271A88, 27851H, 271648, 271650	
272044	271082, 271085, 271086, 271075, 271A83, 271A84, 27844H, 271646, 271649	
272048	271082, 271085, 271086, 271075, 271A85, 271A86, 27848H, 271647, 271650	

Issued: 2022/04

<u>Harmonized norms used during conformity estimation:</u>
PN-EN 12182, PN-EN 12183, ISO 7176-1, PN-ISO 7176-3, PN-ISO 7176-5, PN-ISO 7176-7, PN-ISO

7176-8, PN-ISO 7176-15, PN-ISO 7176-16

Skanderborg, 2022-04-12, Thomas N. Christensen, Managing Director

CE

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