

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

Dolphin wheelchair, Aluminium

Dolphin Wildordan, Adaminan						
REF / item no.	271340	271344	271348	271351	271354	271357
UDI-DI	574000141	574000141	574000141	574000141	57400014	57400014
	5032	5049	5056	5063	15070	15087
BASIC-UDI-DI	57400014DOLPHINET					

Dolphin wheelchair with drum brake. Aluminium

REF / item no.	271440	271444	271448	271451	271454	271457
UDI-DI	574000141 5094	574000141 5100	574000141 5117	574000141 5124	57400014 15131	57400014 15148
BASIC-UDI-DI	57400014DOLPHINET					

ACCESSORIES LIST

Issued: 2022/04

Item nr.	Accessories item nr.
271340	271082, 271085, 271086, 271075, 271A81, 271A82, 27840H, 271645, 271649
271344	271082, 271085, 271086, 271075, 271A83, 271A84, 27844H, 271646, 271649
271348	271082, 271085, 271086, 271075, 271A85, 271A86, 27848H, 271647, 271650
271351	271082, 271085, 271086, 271075, 271A87, 271A88, 27851H, 271648, 271650
271354	271082, 271085, 271086, 271075, 27854H
271357	271082, 271085, 271086, 271075, 27857H
271440	271082, 271085, 271086, 271075, 271A81, 271A82, 27840H, 271645, 271649
271444	271082, 271085, 271086, 271075, 271A83, 271A84, 27844H, 271646, 271649
271448	271082, 271085, 271086, 271075, 271A85, 271A86, 27848H, 271647, 271650
271451	271082, 271085, 271086, 271075, 271A87, 271A88, 27851H, 271648, 271650
271454	271082, 271085, 271086, 271075, 27854H
271457	271082, 271085, 271086, 271075, 27857H

Harmonized norms used during conformity estimation:

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, 2022-04-26, Thomas N. Christensen, Managing Director

