

EU Declaration of conformity



We herewith declare that the below-mentioned product meets the provisions of **EU Regulation 2017/745** on medical devices (MDR) and Radio Equipment **Directive 2014/53/EU** (RED)

Manufacturer

Permobil AB Klökanvägen 16 863 41 Sundsvall

Sweden

General description

Electrically powered wheelchair

Intended use: To provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

The trade name of the product is M3 Corpus

The manufacturer's internal article number(s) is: 109047-99-0

Basic UDI-DI

7330818COMDM

SRN

SE-MF-000014317

Product class

Class 1 (according to Annex VIII Chapter III, rule 1 and rule 13)

Standards (RED)

Conformity to the essential requirements of RED has been demonstrated

by using the following standards:

ISO 7176-9:2009 ISO 7176-14:2008

EN 55032:2015

EN 62311:2008 ISO 14971:2019

ISO 7176-21:2009 Draft ETSI EN 301 489-19 v2.2.0 2020-09 Draft ETSI EN 301 489-52 v1.1.2 2020-12 ETSI EN 301 489-17 v3.2.4 2020-09

20-09 20-12

ETSI EN 301 489-17 V3.2.4 2020-05
ETSI EN 300 328 v2.2.2 2019-07
ETSI EN 303 413 v1.1.1 2017-06
ETSI EN 301 511 v12.5.1 2017-03
ETSI EN 301 908 v13.1.1 2019-11

ETSITS 151010-1 v13.11.0 Test case 12.2.1 and 12.2.2 2020-02

2025 0410

First CE marked

2023-06-30

Place and date

Sundsvall, Sweden

This EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

On behalf of Permobil AB

Asa Möllby

Site Quality Manager, EMEA Permobil PWC