

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 F5 Corpus

The manufacturer's internal article number(s) is: 108992-99-0

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

EN 55032:2015

ISO 7176-14:2008

EN 62311:2008

ISO 7176-21:2009

ISO 14971:2019

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 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

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

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

Site Quality Manager, EMEA Permobil PWC