

## **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 F3 Corpus

The manufacturer's internal article number(s) is: 108993-99-0

**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.

20250410

On behalf of Permobil AB

Asa Möllby

Site Quality Manager, EMEA Permobil PWC