permobil

EU Declaration of Conformity

As manufacturer

Permobil AB
Klökanvägen 16
863 41 Sundsvall
Sweden

CE

declares under the sole responsibility that below specified product is in conformity with the following relevant Union harmonization legislation:

Regulation (EU) 2017/745 on medical devices (MDR)
Radio Equipment **Directive 2014/53/EU** (RED)

General description: Electrically powered wheelchair.
Intended use: The intended use of the **M3 Corpus** powered wheelchair is 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 wheelchair is **M3 Corpus** and is manufactured by Permobil AB. The manufacturer's internal article number is 109047-99-0.

Basic UDI-DI: **7330818COMDM**

SRN: SE-MF-000014317

Product class according to MDR: Class I (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

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On behalf of Permobil AB

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