

EU-declaration of conformity

As manufacturer

Permobil AB Box 120 Per Uddéns väg 20 861 23 Timrå Sweden

declares under the sole responsibility that below specified product is in conformity with the

Regulation (EU) 2017/745 on medical devices (MDR)

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 wheelchair is **M1** and is manufactured by Permobil

AB. The manufacturer's internal article number is

108006-99-0

BASIC UDI-DI 7330818BASCJ

SRN SRN will be assigned when Eudamed is up and running.

Product class: Class I (according to Annex VIII Chapter III, rule 1 and rule 13)

Conformity procedure

used:

Annex IX

Standards Conformity to the general safety and performance requirements have

been demonstrated by using the following standards:

EN ISO 13485 EN 12184 IEC 62304 EN ISO 14971 EN 1041

EN ISO 10993-1

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On behalf of Permobil AB

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