



## EC-declaration of conformity

As manufacture confirm

**Permobil AB**

**Box 120**

**861 23 Timrå**

**Sweden**

that below specified product is in conformity with the

**Directive 93/42/EEC**

**Medical Devices**

<b>General description</b>	Electrically powered wheelchair ISO code 12 23 06 under ISO 9999 and its accessories. All of the devices are classified as Class 1 devices. The trade name of the wheelchair is: C350 All models are manufactured by Permobil.
<b>Design drawings</b>	Required design drawings, circuit diagrams and other manufacture documentation are filed in the Master Device File for each device.
<b>Descriptions</b>	Descriptions, explanations and operation descriptions will be seen from the manufacture documents, where appropriate.
<b>Risk analysis</b>	Where appropriate, the result of the risk analysis is declared in the Device Master File. The risk analyses are, where applicable, in compliance with EN 1441, from 2002 in compliance with EN ISO 14971
<b>EMC</b>	All devices confirm to the requirements specified in EN 12184.
<b>Standards</b>	All devices confirm to the appropriate parts of EN 121 84.
<b>User manual</b>	User manuals and labeling are defined in the Master Device File. User manuals are for some devices made as assembly instructions. Devices that can be used safely without user manual/assembly instruction are delivered without such instructions.
<b>Corrective action</b>	All reported malfunctions and incidents/accidents are filed and reviewed and where appropriate reported to the competent authority.
<b>Drawn up</b>	2007-07-01
<b>Updated</b>	2008-08-01
	Permobil AB
	Jan Åström Director Quality & Environment

Utskrivet dokument visar gällande revision / Printed document shows valid revision 2014-05-20