

EC-declaration of conformity

As manufacturer confirms

Permobil AB

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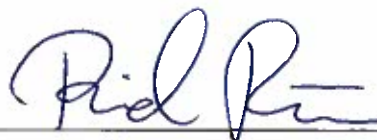
that below specified product is in conformity with the

Directive 93/42/EEC

Medical Devices

implemented in Swedish law 1993:584

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|-----------------------------------|---|
| General description | Electrically powered wheelchair ISO code 12 23 06 under ISO 9999 and its accessories. All the devices are classified as Class 1 devices. The trade name of the wheelchair is: X850 Corpus 3G All models are manufactured by Permobil. |
| Product class: | Class I (according to rule 12) |
| Conformity procedure used: | Annex VII |
| Design drawings | Required design drawings, circuit diagrams and other manufacture documentation is filed in the Master Device File for each device. |
| Descriptions | Descriptions, explanations and operation descriptions will be seen from the manufacture documents, where appropriate. |
| Risk analysis | 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 ISO 14971 |
| EMC | All devices confirm to the requirements specified in EN 12184. |
| Standards | All devices confirm to the appropriate parts of EN 12184. |
| User manual | 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 is delivered without such instructions. |
| Corrective action | All reported malfunctions and incidents/accidents are filed and reviewed and where appropriate reported to the competent authority. |
| Drawn up | 2007-01-01 |
| Updated | 2018-06-07 |



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