

## EC-declaration of conformity

As manufacture confirm

**Permobil AB**  
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that below specified product is in conformity with the  
**Directive 93/42/EEC**  
**Medical Devices**

### General description

A Co-pilot 2 is intended to be used by an attendant, making it ergonomic and comfortable for the attendant to maneuver and control the wheelchair. Since there can be a large number of different attendants using the chair it is important that the handle is intuitive to use and easy to operate. The Co-pilot can be used separately to control the wheelchair or together with a controller for the user.

Item number 331801.

The device is classified as Class 1.

The trade name of the product is "Co-pilot 2" and are manufactured by Permobil.

### Design drawings

Required design descriptions, circuit diagrams and other manufacturer documentation are filed in the technical file for the device.

### Descriptions

Descriptions, explanations and operation descriptions will be seen from the manufacturer documents, where appropriate.

### Risk analysis

The result of the risk analysis is declared in the technical file. The risk analysis are, where applicable, in compliance with ISO 14971

### EMC/Radio

The device confirm to appropriate parts of EN 12184.

### Standards

The device confirm to the appropriate parts of EN 12184, ISO7176, EN 1041 and EN 62304. Listed in the technical file.

### User manual

User manuals and labeling are defined in the technical file.

### Corrective action

All reported malfunctions and incidents/accidents are filed, reviewed and where appropriate reported to the competent authority.

### Drawn up Updated

2017-01-10

Permobil AB

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Utskrivet dokument visar gällande revision / Printed document shows valid revision 2017-01-10