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

General description	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.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2007-07-01
Updated	2008-08-01

Permobil AB
Jan Åström
Director Quality & Environment

EC-declaration of conformity

As manufacture confirm
Permobil AB
Box 120
861 23 Timrå
Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: C300S All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2012-05-01
Updated	-

Permobil AB
Jan Åström
Director Quality & Environment

EC-declaration of conformity

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Permobil AB
Box 120
861 23 Timrå
Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: C300 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2005-01-01
Updated	2007-08-01

Permobil AB
Jan Åström
Director Quality & Environment

EC-declaration of conformity

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Permobil AB
Box 120
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Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: K450 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2008-01-01
Updated	-

Permobil AB
Jan Åström
Director Quality & Environment

EC-declaration of conformity

As manufacture confirm
Permobil AB
Box 120
861 23 Timrå
Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: K300 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2008-01-01
Updated	2010-06-01

Permobil AB
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Director Quality & Environment

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Directive 93/42/EEC
Medical Devices

General description	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: Chairman HD All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	1996-01-08
Updated	2007-07-01

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Director Quality & Environment

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Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: C500 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2004-06-01
Updated	2007-01-01

Permobil AB
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Director Quality & Environment

EC-declaration of conformity

As manufacture confirm
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Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: C400 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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 2004-06-01
Updated 2007-01-01

Permobil AB
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Director Quality & Environment

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Permobil AB
Box 120
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Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: X850 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2012-01-01

Permobil AB
Jan Åström
Director Quality & Environment

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Directive 93/42/EEC
Medical Devices

General description	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: STREET All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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 2003-09-01
Updated 2007-06-01

Permobil AB
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Director Quality & Environment

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Directive 93/42/EEC
Medical Devices

General description	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: M400S All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2011-03-01
Updated	-

Permobil AB
Jan Åström
Director Quality & Environment

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Directive 93/42/EEC
Medical Devices

General description	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: M400 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2011-03-01
Updated	-

Permobil AB
Jan Åström
Director Quality & Environment

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Sweden
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Directive 93/42/EEC
Medical Devices

General description	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: M300 All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	2011-03-01
Updated	-

Permobil AB
Jan Åström
Director Quality & Environment

EC-declaration of conformity

As manufacture confirm
Permobil AB
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Directive 93/42/EEC
Medical Devices

General description	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: KOALA All models are manufactured by Permobil.
Design drawings	Required design drawings, circuit diagrams and other manufacture documentation are 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 1441, from 2002 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 121 84.
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 are 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	1996-01-08
Updated	2007-08-01

Permobil AB
Jan Aström
Director Quality & Environment