

General conditions *

This document specifies changes which are permissible to make without affecting the CE marking of the wheelchair (the CE marking of the complete product).

Note: If the portion that is changed has its own CE marking it must necessarily be removed and replaced with a label "custom-made product" together with the responsible manufacturer, per current regulations. *(Most of the parts named in this document have their own CE marking, but there are some exceptions as specified in the text).* **Resetting to CE marking cannot be done.**

- All changes must be carried out with proper workmanship.
- The customer organization takes the responsibility that personnel carrying out these changes have sufficient competence for the task.
- When changes are made an assessment must be made that risks in use do not increase.
- Changes that lead to the wheelchair being used in a manner other than intended are not allowed.
- Requirements per EN12182 and EN12183 must be followed.
- **Materials used must meet the requirements of MDR (93/42/EEC).**
- When changes are made the overall condition of the wheelchair must be inspected for any defects.
- Changes must not increase the load on the wheelchairs original components. Modifications will void any warranty on the modified parts and attachments to those parts.

HD Rehab assumes no responsibility for material of independently manufactured components not provided by us, nor for finished components from other vendors.

In some cases there are agreements with vendors of complementary products. These vendors are responsible for providing correct information regarding assembly and use of their respective products.

HD Rehab can require that CE marking for the wheelchair is removed if changes are performed incorrectly.

For further information contact HD Rehab.

Note: Earlier versions of this document are nullified by this revision.

An asterisk * following the title indicates a field where changes have been made.

Changes in text are marked with a bold line to the left of the text section.

Armrests The general conditions must be met.
The arm rest pads can be supplemented with extra padding or cover. Effect on other functions (e.g. tray table) must be considered.
No changes may affect the armrest rails.
Raising and lowering is only allowed with parts / kits from HD Rehab.
Armrest variants from the HD Balance product line are marked per MDR and can be used. Consider the specific challenges for heavy users that can make use inappropriate.
Hemiplegia armrest from the HD Balance product line is marked per MDR and can be used. Consider the specific challenges for heavy users that can make use inappropriate.

Back cushion Can be modified if the general conditions are met.

Belt / Harness	No special restrictions regarding belt type. Belts generally do not affect CE marking of the wheelchair as long as the attachments do not affect the function or characteristics of the wheelchair. When possible the original belt mounts from HD Rehab should be used. A risk assessment of belt use must be done for individual cases. Note the general restrictions when using a belt.
Calf supports	The general conditions must be met. The calf support pads can be modified in regards to shape, padding, and upholstery.
Side pads	Side pads from the HD Rehab product line are marked per MDR and can be used.
Footrests	The general conditions must be met. Foot plates can be equipped with additions such as padding, foot straps, and similar. Holes can be drilled in the foot plates but no alterations can be made to attachments.
Headrest / Neck rest	The general conditions must be met. Headrests from the HD Balance product line are marked per MDR and can be used. Headrests from other manufacturers can be used if they are included in a Combination agreement.
IV pole	IV pole is available as an accessory from HD Rehab. Instructions in the user guide, assembly instructions, and info sheet must be followed.
Leg rests	Amputee leg rest from the HD Rehab product line is marked per MDR and can be used.
Leg rest tubes	The general conditions must be met. Changes can be made only per guidelines and with original parts from HD Rehab.
Oxygen tank holder	Oxygen tank holder is available as an accessory from HD Rehab. Instructions in the user guide, assembly instructions, and info sheet must be followed. Depending on the settings of the Flexi-back/ back cushion, use may not be possible.
Seat cushion	Alternate seat cushions from other manufactures that are CE marked and intended for use in wheelchairs are permitted if the general conditions are met. Note any weight limits and do not exceed the max user weight for the wheelchair.
Thoracic support	Thoracic supports from the HD Balance product line are marked per MDR and can be used. Consider the specific challenges for heavy users that can make use inappropriate.
Tray table	The general conditions must be met. The tray table surface can be modified and used with the wheelchair on the provided that the fittings and attachments are not changed. If the tray table surface is increased or if there is a change to the function or the use case for the tray table HD Rehab must be contacted for approval.