

Changes Permitted While Maintaining CE Marking - HD Balance

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 home-made 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 widened max 5 cm and lengthened max 10 cm. No changes may affect the armrest rails. Raising and lowering is only allowed with parts / kits from HD Rehab.
Back cushions	Can be modified if the general conditions are met.
Back spacers	Adjusting the back system forward can only be done with original parts and guidelines from HD Rehab. There is a special back spacer accessory. It is permitted to mount back spacers on one side only in order to tilt the back. Checks and risk assessments must be done on a case-by-case basis when mounted. Beware particularly of forward-tipping risk.
Belt / Chest 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 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. Combination agreements exist, see document 95232.

Brakes	<p>If the wheelchair is equipped with caregiver brakes the user brakes on the 24" model can be removed under the following circumstances: The wheelchair is operated by caregivers and the user does not drive it. Under special circumstances where use risk is considered to be safe.</p>
Calf supports	<p>The general conditions must be met. The calf support pads can be modified in regards to shape, padding, and upholstery. It is permitted and possible to move the calf support plates further back. Components for this can be ordered from HD Rehab.</p>
Drive unit	<p>A drive unit can be mounted if there is a combination agreement. Refer to doc 95232.</p> <p>General information: Drive units should be mounted to new wheelchairs. If a drive unit is to be mounted to a used wheelchair it should first be reconditioned per instructions from HD Rehab, with particular care to ensure that the wheelchair is free from defects. The specified lifetime for HD Balance is 10 years, but use of a drive unit reduces this to 5 years counting from the delivery of the wheelchair. Lifetime of the wheelchair can be increased by max 1 year for verifiable shelf time.</p> <p>Limitations on warranty: As wheelchairs equipped with drive units can experience greater strain than intended, particularly with misuse, there are certain limitations to the wheelchair warranty. This applies particularly to the castors. The wheel frame can also experience greater strain in some cases. Some accessories and special adaptations cannot be used in combination with a drive unit. It is the responsibility of the purchaser to inform and educate the user on how the wheelchair should be used to minimize these strains. This especially concerns the fact that the drive unit enables pushing against barriers with great force. The risk for undesirable strain increases with greater user weight.</p>
Fill cushions	<p>Extra cushions are permitted if the general conditions are met. No CE marking needs to be removed when existing parts are not modified.</p>
Foot box *	<p>The general conditions must be met. Extensions can only be done with original parts and guidelines from HD Rehab. Foot plates can be fitted with additions such as padding, foot straps, and the like. Holes can be drilled in foot plates but no alterations can be made to other parts.</p>
Footrests*	<p>The general conditions must be met. Extensions can only be done with original parts and guidelines from HD Rehab. Foot plates can be fitted with additions such as padding, foot straps, and the like. Holes can be drilled in foot plates but no alterations can be made to foot plate forks.</p>
Headrest / Neck support	<p>The general conditions must be met. Headrest and neck support padding and upholstery can be modified under the condition that original fittings and fasteners are maintained.</p>
IV pole *	<p>IV pole is available as an accessory from HD Rehab. Instructions in the user guide, assembly instructions, and info sheet must be followed.</p>
Leg rest tubes	<p>The general conditions must be met. Shortening of leg rest tubes is allowed. A new hole (dia 8.5) for the snap-in lock must be drilled 70 mm from the bottom of the tube. Lengthening is only permissible with original parts and guidelines from HD Rehab.</p>

Oxygen tank holder *

An oxygen tank holder can be mounted on HD Balance under the following conditions:

- The preferred option is to use the accessory Oxygen tank holder from HD Rehab.
- For other holders the following applies:

The general conditions must be met.

There must be no alterations to the frames of the wheelchair.

The attachment should be as low as possible, primarily on the wheel frame or seat frame. For practical reasons though, it is often only possible to mount to the back frame. This can lead to increased risks. Check that no problems or risks arise when the wheelchair position controls are used. In particular tipping and pinching risks must be checked. The wheelchair tilt angle may need to be limited.

The maximum weight for equipment mounted on the back frame is 6 kg, on the seat or wheel frame 10 kg. Ensure that the total weight (user + equipment) does not exceed the maximum allowable load of the wheelchair.

Anti-tip devices should be used in extended position.

Note that an oxygen tank holder can affect the function and hinder the use of other accessories.

Oxygen tank holders should not be used together with bag hook accessories.

The user guide must be complemented with any necessary information.

A warning label should be placed on the wheelchair.

No CE marking needs to be removed when existing parts are not modified.

- Any combination agreements are specified in document 95232.

Seat cushions

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.

Seat plate

The general conditions must be met.

Cut-outs in the front edge of the plate to compensate for leg length, as well as attachment of fittings for other cushion systems with glue, screws, or other fasteners are permitted. Also permitted to lengthen one side of seat plate.

The seat plate is not a CE marked accessory so no CE marking needs to be removed.

Seat shell

Mounting a seat shell is permitted per the following:

The general conditions must be met.

The seat shell is to be mounted to the original seat plate with glue, screws, or the like. If necessary the seat plate can be locked in place with screws that pass into the seat rails. The seat shell should be secured to the back frame. No alteration to the back frame is permitted. If the back angle is to be fixed the gas spring should be replaced with a fixed back bar (art. nr. 67707). Installation is to be done such that the seating position deviates as little as possible from the intended position with cushions.

Note and take into account conflicts that can arise with armrests, leg rests, and accessories, and that changes to these can mean that CE marking of components is no longer valid.

Increased risks relating to stability and handling must be investigated.

The seat plate is not a CE marked accessory so no CE marking needs to be removed.

Table tray

The general conditions must be met.

The table surface can be modified and used with the wheelchair with the condition that fittings and fasteners are maintained.

If the table surface is to be increased, or changed in function or usage conditions, HD Rehab must be contacted for approval.

Thoracic support	The general conditions must be met. The thoracic support padding, size, shape, and upholstery can be modified under the condition that the original fittings and fasteners are maintained.
Other accessories, attachments to frames	It is generally permitted to attach other accessories such as computers, tablets, and the like by attaching a bracket to the wheelchair frame. That said it is never permitted to make alterations to the frame by drilling, welding, or other methods. The general conditions must be met, with the exception that some increased load on the frame members may be made in this case. It is important to always perform a case-by-case risk assessment for the individual user so that, for example, tip risks or pinching risks do not arise with mounting of accessories. Ensure that the total weight (user + equipment) does not exceed the maximum allowable load of the wheelchair.