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Changes permitted while maintaining CE-marking

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(Drehab

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.

Back cushion	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 angle the back.
	Checks and risk assessments must be done on a case-by-case basis when mounted. Beware particularly of forward-tipping risk.
	Refer to the specific Info Sheets and Assembly instructions for back spacers.

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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 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. Any Combination agreements are listed in document 95232.
Drive unit *	A drive unit can be mounted if there is a combination agreement. Refer to doc. nr. 95232.
	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 Motion 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 a maximum of 1 year for verifiable shelf time.
	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. It is the responsibility of the purchaser to inform and educate the users on how the wheelchair should be operated to minimize these strains. This especially concerns the fact that the drive unit enables pushing against barriers with great force. The risk for excessive strain increases with greater user weight.
	Some accessories and special adaptations cannot be used in combination with a drive unit.
	 For drive units manufactured by Decon, E-Drive, the following applies: Assembly instructions from Decon must be followed. The user manual from Decon must be followed as applicable. Some parts of the user manual from HD Rehab are no longer applicable. Brakes: The original caregiver brakes and user brakes no longer function and are replaced by the brake system of the drive unit. To avoid confusing caregivers and the user the original brakes should be completely removed. This means removing both the caregiver brakes and the user brakes, including their cables and control levers. See Technical Information, doc. nr. 96720-1. Use of a table tray if the drive unit user controls are mounted is limited. Some adjustments and functions may be limited, e.g. some amount of back recline, seat tilt, push bar adjustment, etc.
Foot box	The general conditions must be met. 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.
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. Footrest plates with slots are available as an option. Matching slots in the footrest covering can then be cut out. This applies to both single and separate footrest plates. Any Combination agreements are listed in document 95232.

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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.
Oxygen tank holder	An oxygen tank holder can be mounted on HD Motion with the following conditions: The first choice is to use the Oxygen tank holder accessory from HD Rehab. If a different make is used 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 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. Note that an oxygen tank holder can affect the function and hinder the use of other accessories. The user guide must be complemented with any necessary information. A warning label should be placed on the wheelchair. Any Combination agreements are listed in document 95232.
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.
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. 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. 37761). 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.
Other accessories, attachments to frames	It is generally permitted to attach other accessories such as computers, tablets, and the like by attaching a clamping 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.