



To our dealers and installers

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Regulations for CE-marking of wheelchairs installed with Dahl Docking systems Mk II and VarioDock™

Since EU Regulation 2017/745 and the amendment of the EU Medicines Directive entered into force, we have been approached by dealers, OT's and others struggling with the interpretation of the applicable regulations and standards. This letter is meant to give a quick overview of the legislation relating to the installation of our docking stations for securing wheelchairs being used as seats in motor vehicles.

Consequences of modifying/installing non-approved equipment on CE-approved wheelchairs

According to the EU Medicines Directive, a wheelchair is classified as a Class 1 medical device and must be CE-marked and approved as such. Installing a non-approved docking station or adaptation brackets is considered a significant change to the CE-approved wheelchair which results in invalidating the CE-mark - because the installer is unable to demonstrate compliance with the applicable legislation and standards with regard to safety, durability and performance. As a result, the wheelchair user and other vehicle occupants can potentially be exposed to serious or life-threatening injuries in the event of an accident.

Anyone who installs or adapts non-approved equipment or installs equipment in a way that falls outside the wheelchair manufacturer's specifications will invalidate the CE- approval and will be considered as the manufacturer responsible for the equipment's quality, safety, performance, and not least technical documentation in accordance with the applicable regulations.

The modifier/installer must thus remove the wheelchairs CE-approval mark - and bring the modified/installed equipment in accordance with EU Regulation 2017/745 (annex 1), which translated means that compliance with the following standards must be demonstrated:

- ISO 7176-1
- ISO 7176-8
- ISO 7176-19
- ISO 14971,
- EN 12183 or
- EN 12184

- The modified wheelchair equipment must be registered, by the organization or company carrying out the modification, with the competent authorities in the country.
- The company or organization must appoint a person who is responsible for compliance with the regulations.

Recommendation – for non-approved wheelchairs

In the light of the arising safety issues and the large administrative workload and liability issues that fall on anyone who carries out the modification/installation, we do not recommend installing Dahl's docking stations model MK II and VarioDock™ on wheelchairs which have not been tested and CE-approved for it.

Documentation requirements for approved wheelchairs

Installing our docking stations which have been tested and approved according to ISO 10542-1 or i.e., 7176-19 with other wheelchairs is not sufficient documentation to avoid invalidating the CE-mark if installing the docking stations on wheelchairs which have not been approved for it. Manuals of chairs which have been tested, approved and CE-marked for the installation of a docking system, must contain detailed instructions for the installation and use with the docking system in question.

Installing a docking system not described in the manual or not respecting the instructions will also result in invalidating the wheelchairs CE-mark.

Only when installing our docking stations on wheelchairs that have been tested, approved and CE-marked by the wheelchair manufacturers in question will ensure that the CE approval remains intact. It is a condition that the instructions of the manual for the wheelchair in question will be respected.

At time of writing more than 150 wheelchair models have been tested and approved for the use with the Dahl docking stations. We are continuously working to expand the list with more wheelchairs, and we will be happy to work with any wheelchair manufacturer who is interested in certifying its wheelchair with our docking stations.

The list of approved wheelchairs

On the website www.dahlengineering.dk you can see the current list of wheelchairs, which have been tested and approved together with Dahl Docking models Mk. II and VarioDock. For documentation purposes, the manual with CE-conformity declaration and instructions for the installation and use with the Dahl docking stations, can be downloaded for each of the approved wheelchair models.

Click on: Products - Dahl Docking Systems - Approved wheelchairs and manuals - find the wheelchair in question and click on manual.

Yours sincerely

Dahl Engineering ApS



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CEO