

## TGA registered.

ARTG Identifier 107933

#### **International Standards**

Alber is CE-compliant according to the European Medical Devices Directive (MDR) 2017/745 and is tested and certified on a voluntary basis by the TÜV Süd, in line with the currently valid edition of the product standard EN 12184 and Complies with the EU Medical Device Directive 93/42/EEC. Alber comply with all applicable requirements of ISO 7176.

## M25

The e-motion and corresponding off-board charger comply with the applicable sections of standard EN 12184 and ISO 7176-8. for electric wheelchairs and with the currently applicable EC directive for medical devices, 93/42/EEC. The e-motion is a Class I medical device.

## E35 / E36

The e-fix conforms to the requirements laid down in the European Medical Device Directive 93/42/EEC as well as the applicable sections of standard DIN EN 12184. The battery charger conforms to European guidelines. The e-fix is a Class I medical device.

#### T24

The twion conforms to the requirements laid down in the European Medical Device Directive 93/42/EEC as well as the applicable sections of standard DIN EN 12184 and ISO 7176-8. The battery charger conforms to European guidelines. The twion is a Class I medical device.

## P15

The e-pilot and corresponding off-board charger comply with the applicable sections of standard EN 12184 for electric wheelchairs and meet the currently applicable EC directive for medical devices, 93/42/EEC. The e-pilot is a Class I medical device.

# 010

The smoov and the corresponding off-board charger comply with the applicable sections of standard EN 12184 for electric wheelchairs and standard ISO 7176-14 for wheelchairs and comply with the EU Medical Devices Directive (MDR). The smoov is a Class I medical device.

# V25

The viamobil conforms to the requirements laid down in the European Medical Device Directive 93/42/EEC as well as the applicable sections of standard DIN EN 12184.

#### S35/S36

The scalamobil conforms to the requirements laid down in the European Medical Device Directive 93/42/EEC. The scalamobil complies with all applicable requirements of ISO 7176-23.



# Passenger Transportation Using a wheelchair equipped with Alber power add on, as a seat in vehicles

Alber M25, E35, E36 and T24 are add-on drive units which can be mounted on different kinds of wheelchairs. To assure the security of the wheelchair user also in matters of using the wheelchair as a seat in vehicles (e.g. cars or vans), Alber carried out crash-tests according to ISO 7176-19 to verify the influence of the add-on drive to the manual wheelchair. For this reason, the same crash-test was performed with and without add-on drive unit. Based on this result, transportation in the wheelchair combined with Alber e-motion M25 can be allowed if following points are fulfilled.

- Local law allows the usage of the wheelchairs as seats in vehicles
- Combination of wheelchair and add-on unit allowed and documented by Alber
- The manufacturer of the affected wheelchair has given clearance for the transportation of persons in vehicles
- Wheelchair is equipped for usage as a seat in vehicles
- Fixation of combination over a tie-down system according to ISO 10542
- Additional three-point safety belt for the person in the wheelchair

As the crash-test is a simulation of one crash situation, but cannot simulate all possible situations, Alber recommends reseating the person from the wheelchair in a fixed car seat.

Certified in accordance with the latest medical products quality standard ISO 13485:2016 and environmental qualification according to ISO 14001.

For any further information please contact

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