



INFORMATION

Implementation of the Medical Device Stair climber by Sunwa / Marketing Authorisation Holder Karl H. Bartels Ltd

Equipment without CE sign is forbidden to use on the market:

- 1.) Medical Devices Act, second subparagraph "Requirements for medical devices and their operation" §6 "Requirements for placing on the market and putting into service"

Abridged Text:

...medical devices may only be placed on the market or put into service if they bear the CE marking...

- 2.) Medical Devices Act second subparagraph "Requirements for medical devices and their operation" §14 "Installation, operation, use and maintenance of medical devices"

Abridged Text:

Medical devices may only be installed, operated ...in accordance with the ordinance issued under §37, paragraph 5.
They may not be operated ...if they exhibit defects which could place patients ... at risk.

- 3.) Medical Devices Act second paragraph "Requirements for medical devices and their operation" §4 "Prohibitions to ensure the protection of patients, users and other persons"

Abridged Text:

It is prohibited for medical devices to be placed on the market, installed, put into service, operated or used if there are grounds to suspect that the safety and health of patients, users or third persons could be compromised ... when properly used.

The marketing authorisation holder, Karl H. Bartels Ltd, refers to the above-mentioned paragraphs as a result of the following safety defects and factual information:

- 1.) The lock release mechanism between the adapter and the driving unit can be unintentionally opened!
- 2.) Stair climber with CE does have 2 pins which are additionally inserted for protection between the adapter and the driving unit!
- 3.) Drive and emergency-stop switch operate via bowden cable. Emergency switch does not click into place as a result.



Emergency-stop switch "AR22m4R" Order No.TKA-89/a (non-latching) applied until Nov. 1995! Emergency-stop switch "AR22Vrr" Order No.TKA-89/b (latching) applied from Dec. 1995 onwards.

- 4.) The marketing authorisation holder, Karl H. Bartels Ltd, of the stair climber manufacturer company Sunwa, has been issuing the CE marking since 1995! All devices without a CE marking may no longer be used.

Annual inspection and inspection before further use of the stair climber with a CE marking by Sunwa /marketing authorization holder Karl H.Bartels Ltd. Should be done only by authorised specialist companies (medical devices consultants)

- 1.) Medical Devices Act second subparagraph "Requirements for medical devices and their operation" §31 "Medical devices consultant"

Abridged Text:

Any person who provides technical information to experts or instructs them in the proper handling of medical devices on a professional basis (medical devices consultant), may only carry out such an activity if he/she possess ... the requisite expert knowledge as well as the experience needed ...

Authorised specialist companies will confirm their identity by means of a certificate, issued by the marketing authorisation holder Karl H.Bartels Ltd.

These specialist companies will obtain the necessary expert knowledge by means of training on the medical device.

In case of non-compliance with the above-mentioned instructions, the warranty as well the insurance coverage is not applicable!

Yours faithfully
KARL H. BARTELS LTD.



Matthias Bartels
Safety Inspector Rehabilitation