

Basic requirements

CE 0123

Certificate of Compliance for devices for medical and rehabilitation purposes

Manufacturer

h/p/cosmos sports & medical gmbh
Am Sportplatz 8 - DE 83365 Nussdorf-Traunstein / Germany
phone +49 / 86 69 / 86 42 0 - fax+49 / 86 69 / 86 42 49
email@h-p-cosmos.com www.h-p-cosmos.com

Product unweighting system **UMDNS Code:** n.a.
Classification according to 93/42 EEC: **Class II a**
Classification according to DIN EN 957-1:2005-11: **S A**

Model h/p/cosmos airwalk se 135

We herewith declare that the above mentioned type meets following standards:

European Council Directive 93/42 EEC (MDD medical device directive),
the appendix **I + II** of the directive 93/42 EEC is being applicable.

The CE₀₁₂₃ – mark gets affixed to the product.

The following listed and fulfilled norms are elements of our production:

DIN EN 60601-1:2006,
DIN EN 957-1:2005-11
DIN EN 12100-1:2003
DIN EN 10535:2006
DIN EN 61000-6-1:2001, DIN EN 61000-6-3:2001 A11:2004, DIN EN 61000-3-2:2000,
DIN EN 61000-3-3:1995 A1:2001,
DIN EN ISO 14971:2007, DIN EN ISO 9001:2000, DIN EN ISO 13485:2003

This certificate of compliance covers the unweighting system airwalk se 135 which is produced by h/p/cosmos. The validity of this certificate of compliance expires on the release date of a certificate of compliance with a later issue date, which may be necessary due to technical modifications or due to changes of standards, guidelines and directives.

83365 Nussdorf-Traunstein, 05.02.2009



Franz Harrer
President
h/p/cosmos sports & medical gmbh



Richard Schmidt
Technical Director, authorized signatory
h/p/cosmos sports & medical gmbh