

D Basic Requirements

CE 0123

Certificate of Compliance for devices for medical and rehabilitation purposes

Manufacturer

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Product

running machine (treadmill ergometer) Classification according to European Council
Directive 93/42 EEC: Class II b
UMDNS Code: 14-141 Classification according to DIN EN 957-1:2005-11: SA

Models

h/p/cosmos stratos lt med	h/p/cosmos stratos med
h/p/cosmos mercury lt med	h/p/cosmos mercury med
h/p/cosmos stellar lt med	h/p/cosmos stellar med
h/p/cosmos quasar lt med	h/p/cosmos quasar med
h/p/cosmos pulsar lt	h/p/cosmos pulsar
h/p/cosmos pulsar lt 3p	h/p/cosmos pulsar 3p
h/p/cosmos venus	h/p/cosmos saturn
h/p/cosmos gaitway II S	h/p/cosmos gaitway II F
h/p/cosmos 150/50 locomotion DE med	h/p/cosmos 150/50 locomotion E med

We herewith declare that the above mentioned types meet the 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 **CE 0123** - mark gets affixed to the products.

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

DIN VDE 0751-1:2001-10, DIN EN 60601-1:1990 + A1:1993 + A2:1995, DIN EN 60601-1-1:2001, DIN EN 60601-1-2:2001 + A1:2006, DIN EN 60601-1-4:1996 + A1:1999, DIN EN 60601-1-6:2004, DIN EN 957-1:2005-11, DIN EN 957-6:2001-11, DIN EN ISO 14971:2000, DIN EN ISO 9001:2000, DIN EN ISO 13485:2003

This certificate of compliance covers all running machine models which are listed above and which are produced by h/p/cosmos on and from November 24, 2006. 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, November 24, 2006



Franz Harrer
President



Wolfgang Petry
Safety Representative for Medical Devices