

EC Declaration of Conformity

assigned to devices of medical and
rehabilitation equipment

CE 0123

manufacturer: h/p/cosmos sports & medical gmbh
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notified body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München / Germany, www.tuev-sued.de

product: Treadmill Ergometer

Classification MDD Directive 93 / 42 EEC	Class IIb
Classification according to DIN EN 957-1	S, I, A
UMDNS Code	14-141
GMDN Codes	33015 EXERCISER, TREADMILL, LINE-POWERED 36679 ERGOMETER, TREADMILL
NBOG Code	MD 1108 active rehabilitation devices

model family 170-190/65 (quasar/pulsar):

h/p/cosmos stellar lt med (cos30003va17)

h/p/cosmos stellar med (cos30003va18)

h/p/cosmos quasar lt med (cos30003va19)

h/p/cosmos quasar med (cos30003va20)

h/p/cosmos pulsar lt (cos30004va01)

h/p/cosmos pulsar 3p lt (cos30004va02)

h/p/cosmos pulsar (cos30004va03)

h/p/cosmos pulsar 3p (cos30004va04)

We herewith declare that the above mentioned models/types meet the following:

European Council Directive 93/42/EEC + 2007/47/EC (MDD medical device directive).

annex **I** + **II** of 93/42/EEC are applicable. Note: Exclusion of the segment/article 4 from the annex **II** 93/42/EEC.

The CE 0123 - mark gets affixed to the products. The following listed and fulfilled norms are elements of our production and service:

EN 60601-1, EN 60601-1-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-6, EN 62366, EN 62353 (VDE 0751-1), EN 957-1, EN 957-6, EN ISO 14971, ISO 9001, EN ISO 13485, EN 62304

Note: The issue date of the applied and above mentioned referenced norm is reported in the respective technical documentation of the named model family.

This declaration of conformity is valid for all above mentioned treadmill-versions which have been produced by h/p/cosmos on 30.11.2010 or after 30.11.2010. The validity of this declaration of conformity expires with the release of a new declaration of conformity if this is required due to technical amendments or due to legal amendments of the norms and standards – however, at the latest on the expiry date of the EC-certificate according to MDD medical device directive 93/42 (2007/47) EEC with the certificate number G1 08 12 45283 005.

DE 83365 Nussdorf-Traunstein, November 30 - 2010, signed for and on behalf of h/p/cosmos sports & medical gmbh



Franz Harrer
President & CEO / R & D Manager



Wolfgang Petry
Safety Representative (Medical Devices § 30)