



Declaration of conformity with the purpose for medical and rehabilitation devices

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: Treadmill Ergometer (running machines)

Classification MDD Directive 93/42 (2007/47) EEC	Class IIb
Classification according to DIN EN 957-1:2005-11	S, I, A
UMDNS Code	14-141
GMDN Code	33015 EXERCISER, TREADMILL, LINE-POWERED
NBOG Code	MD 1108 active rehabilitation devices

Models:

COSMED T 150 Med	COSMED T 170 DE Med	COSMED T 250 SR
COSMED T 150 D Med	COSMED T 170 DE Sportmed	COSMED T 250 M
COSMED T 150 E Med	COSMED T 200 S	COSMED T 250 MR
COSMED T 150 DE Med	COSMED T 200 M	COSMED T 250 LR
COSMED T 170 Med	COSMED T 200 MR	COSMED T 300 S
COSMED T 170 D Med	COSMED T 250 S	COSMED T 300 SR
COSMED T 170 E Med		COSMED T 300 M

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

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

The appendix **I + II** of the Directive 93/42 (2007/47) 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 EN 62353:2008-8 (VDE 0751-1:2008-8), DIN EN 60601-1:2007 (VDE 0750-1:2008-8)

DIN EN 957-1:2005-11, DIN EN 957-6:2001-11, DIN EN ISO 14971:2007,

DIN EN ISO 9001:2000, DIN EN ISO 13485:2007

This Declaration of conformity covers all running machine models which are listed above and which are produced by h/p/cosmos on and from March 21, 2010. The validity of this Declaration of conformity expires on the release date of a Declaration of conformity with a later issue date, which may be necessary due to technical modifications or due to changes of standards, guidelines and directives.

DE 83365 Nussdorf-Traunstein, March 21, 2010

Franz Harrer
President & CEO

Wolfgang Petry
Safety Representative for Medical Devices § 30 MPG