

# EC Declaration of Conformity

assigned to devices of medical and  
rehabilitation equipment

# CE 0123

**manufacturer:** h/p/cosmos sports & medical gmbh  
Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany / commercial register # HRB 7563 Traunstein  
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**notified body:** TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München / Germany, www.tuev-sued.de

**product:** Treadmill Ergometer

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

**model family 200-450 x 75-300 (venus/saturn):**

h/p/cosmos venus (cos30005va05) = 200x75	h/p/cosmos saturn (cos30009va03) = 250x125r
h/p/cosmos venus (cos30005va06) = 200x75r	h/p/cosmos saturn (cos30010va05) = 300x75
h/p/cosmos venus (cos30006va05) = 200x100	h/p/cosmos saturn (cos30010va06) = 300x75r
h/p/cosmos venus (cos30006va06) = 200x100r	h/p/cosmos saturn (cos30011va05) = 300x100
h/p/cosmos saturn (cos30007va05) = 250x75	h/p/cosmos saturn (cos30011va06) = 300x100r
h/p/cosmos saturn (cos30007va06) = 250x75r	h/p/cosmos saturn (cos30012va05) = 300x125
h/p/cosmos saturn (cos30008va05) = 250x100	h/p/cosmos saturn (cos30012va06) = 300x125r
h/p/cosmos saturn (cos30008va06) = 250x100r	

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 QM-certificate according to EN ISO 13485:2003 / AC: 2009 with the certificate number Q1N 10 12 45283 007.

**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)