

Bayerisches Landesamt für  
Gesundheit und Lebensmittelsicherheit



Nr./No. AP-2697-22-V2892-D37816/2017

München, 29. November 2017 / Munich, November 29, 2017

**BESCHEINIGUNG DER VERKEHRS-  
FÄHIGKEIT (§34 (1) MPG)**

**CERTIFICATE OF MARKETABILITY  
(§34 (1) MPG)**

Das Bayerische Landesamt für Gesundheit und Lebensmittelsicherheit bescheinigt die Verkehrsfähigkeit folgender Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Union und in den anderen Vertragsstaaten des Abkommens über den Europäischen Wirtschaftsraum.

The Bavarian Health and Food Safety Authority certifies that the following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Union and in the other states having a contractual agreement with the European Economic Area.

**Produkte / Products:**

Siehe beigefügte Produktliste / see product list attached

Der für das erstmalige Inverkehrbringen im Europäischen Wirtschaftsraum Verantwortliche nach § 5 MPG:

h/p/cosmos sports & medical gmbh  
Am Sportplatz 8  
83365 Nussdorf-Traunstein  
Deutschland/Germany

Es wird auch bescheinigt, dass der Hersteller durch das CE-Kennzeichen zum Ausdruck bringt, dass die Medizinprodukte die Grundlegenden Anforderungen der

Richtlinie 93/42/EWG des Rates  
vom 14.06.1993

in der gegenwärtig gültigen Fassung erfüllen und das vorgeschriebene Konformitätsbewertungsverfahren durchgeführt wurde.

Responsible for the first placing the product on the European Economic Area market according to § 5 MPG:

It is also certified that the manufacturer with the CE-mark confirms that the medical devices fulfil the essential requirements of the

Council Directive 93/42/EEC  
of 14 June 1993

in the current valid version and that the required conformity assessment has been completed.

**Produktionsstätte(n) / Production facility(ies):**

h/p/cosmos sports & medical gmbh  
Am Sportplatz 8  
83365 Nussdorf-Traunstein  
Deutschland/Germany

Im Auftrag / By order

Dipl.-Ing. Ollig  
Technischer Amtsrat  
Tel.: +49 (9131) 6808-4001



## **Produktname / Product Name**

### **product / product family**

<b>h/p/cosmos treadmill Ergometer (running machine):</b>	product family: treadmill h/p/cosmos 150/50 LC product family: treadmill h/p/cosmos 150/50 product family: treadmill h/p/cosmos 170-190/65 product family: treadmill h/p/cosmos 170-190/65 3p product family: treadmill h/p/cosmos 200-300/75-125 product family: treadmill h/p/cosmos 450/300
<b>body weight support device:</b>	<b>body weight support device h/p/cosmos</b>
<b>expander pulling unit:</b>	<b>expander pulling unit h/p/cosmos</b>
<b>parallel bars:</b>	<b>parallel bars h/p/cosmos</b>

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**treadmill Ergometer (running machine)**

<b>Classification MDD Directive 93/42/EEC</b>	<b>Class IIb</b>
<b>Classification according to ISO 20957-1</b>	<b>S, I</b>
<b>Classification according to EN 957-6</b>	<b>A</b>
<b>UMDNS Code</b>	<b>14-141 Running Machine</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>

<b>article no.</b>	<b>vari-ant</b>	<b>product family</b>	<b>variant model name</b>	<b>CE</b>
cos30026	va02	treadmill h/p/cosmos 150/50 LC	pluto® med	CE 0123
cos30027	va02	treadmill h/p/cosmos 150/50 LC	pluto® lt med	CE 0123
cos30026	va04	treadmill h/p/cosmos 150/50 LC	pluto®   COSMED T150 DE LC med	CE 0123
cos30027	va04	treadmill h/p/cosmos 150/50 LC	pluto®   COSMED T150 E LC med	CE 0123
cos30027	va06	treadmill h/p/cosmos 150/50 LC	pluto®   SCHILLER MTM-1400 MED	CE 0123
cos30027	va08	treadmill h/p/cosmos 150/50 LC	pluto®   carefusion LE200 LC	CE 0123
cos30026	va06	treadmill h/p/cosmos 150/50 LC	pluto®   PHYSIORUN Trainer	CE 0123
cos30026	va08	treadmill h/p/cosmos 150/50 LC	pluto®   Kardiomed LC	CE 0123
cos30000	va05	treadmill h/p/cosmos 150/50	h/p/cosmos stratos lt med	CE 0123
cos30000	va06	treadmill h/p/cosmos 150/50	h/p/cosmos stratos med	CE 0123
cos30000	va07	treadmill h/p/cosmos 150/50	h/p/cosmos mercury lt med	CE 0123
cos30000	va08	treadmill h/p/cosmos 150/50	h/p/cosmos mercury med	CE 0123
cos30001	va01	treadmill h/p/cosmos 150/50	h/p/cosmos locomotion 150/50 E med	CE 0123
cos30001 -01	va02	treadmill h/p/cosmos 150/50	h/p/cosmos locomotion 150/50 DE med	CE 0123
cos30002	va01	treadmill h/p/cosmos 150/50	h/p/cosmos Gaitway II F	CE 0123

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cos30002	va02	treadmill h/p/cosmos 150/50	h/p/cosmos Gaitway II S	CE 0123
cos30000	va09	treadmill h/p/cosmos 150/50	CareFusion LE 100CE 150/50	CE 0123
cos30000	va10	treadmill h/p/cosmos 150/50	CareFusion LE 200CE 150/50	CE 0123
cos30000	va18	treadmill h/p/cosmos 150/50	COSMED T150 DE MED	CE 0123
cos30000	va19	treadmill h/p/cosmos 150/50	proxomed Kardiomed Mill F	CE 0123
cos30000	va20	treadmill h/p/cosmos 150/50	proxomed Kardiomed Mill S	CE 0123
cos30000	va23	treadmill h/p/cosmos 150/50	SCHILLER MTM 1500 med	CE 0123
cos30003	va17	treadmill h/p/cosmos 170-190/65	h/p/cosmos stellar lt med	CE 0123
cos30003	va18	treadmill h/p/cosmos 170-190/65	h/p/cosmos stellar med	CE 0123
cos30003	va19	treadmill h/p/cosmos 170-190/65	h/p/cosmos quasar lt med	CE 0123
cos30003	va20	treadmill h/p/cosmos 170-190/65	h/p/cosmos quasar med	CE 0123
cos30003	va01	treadmill h/p/cosmos 170-190/65	CareFusion LE 250CE 170/65	CE 0123
cos30003	va02	treadmill h/p/cosmos 170-190/65	CareFusion LE 300CE 170/65	CE 0123
cos30003	va03	treadmill h/p/cosmos 170-190/65	CareFusion LE 500CE 170/65	CE 0123
cos30003	va11	treadmill h/p/cosmos 170-190/65	COSMED T170 DE MED	CE 0123
cos30003	va12	treadmill h/p/cosmos 170-190/65	COSMED T170 DE sportmed	CE 0123
cos30004	va01	treadmill h/p/cosmos 170-190/65	h/p/cosmos pulsar lt	CE 0123
cos30004	va03	treadmill h/p/cosmos 170-190/65	h/p/cosmos pulsar	CE 0123
cos30024	va01	treadmill h/p/cosmos 170-190/65	h/p/cosmos locomotion 190/65 E med	CE 0123
cos30024	va03	treadmill h/p/cosmos 170-190/65	h/p/cosmos locomotion 190/65 DE med	CE 0123
cos30004	va02	treadmill h/p/cosmos 170-190/65 3p	h/p/cosmos pulsar lt 3p	CE 0123

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<b>article no.</b>	<b>vari-ant</b>	<b>product family</b>	<b>variant model name</b>	<b>CE</b>
cos30004	va04	treadmill h/p/cosmos 170-190/65 3p	h/p/cosmos pulsar 3p	CE 0123
cos30024	va02	treadmill h/p/cosmos 170-190/65 3p	h/p/cosmos locomotion 190/65-3p E med	CE 0123
cos30024	va04	treadmill h/p/cosmos 170-190/65 3p	h/p/cosmos locomotion 190/65-3p DE med	CE 0123
cos30003	va25	treadmill h/p/cosmos 170-190/65 3p	COSMED T170 DE 3p sportmed	CE 0123
cos30003	va26	treadmill h/p/cosmos 170-190/65 3p	h/p/cosmos quasar med 3p	CE 0123
cos30005 -01	va01	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 580CE 200/75	CE 0123
cos30005 -01	va02	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 580CE 200/75 R	CE 0123
cos30005 -01	va03	treadmill h/p/cosmos 200-300/75-125	COSMED T200 S	CE 0123
cos30005 -01	va05	treadmill h/p/cosmos 200-300/75-125	h/p/cosmos venus 200/75	CE 0123
cos30005 -01	va06	treadmill h/p/cosmos 200-300/75-125	h/p/cosmos venus 200/75 r	CE 0123
cos30006 -01	va01	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 590CE 200/100	CE 0123
cos30006 -01	va02	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 590CE 200/100 R	CE 0123
cos30006 -01	va04	treadmill h/p/cosmos 200-300/75-125	COSMED T200 MR	CE 0123
cos30006 -01	va05	treadmill h/p/cosmos 200-300/75-125	h/p/cosmos venus 200/100	CE 0123
cos30006 -01	va06	treadmill h/p/cosmos 200-300/75-125	h/p/cosmos venus 200/100 r	CE 0123
cos30007 -01	va01	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 600CE 250/75	CE 0123
cos30007 -01	va02	treadmill h/p/cosmos 200-300/75-125	CareFusion LE 600CE 250/75 R	CE 0123
cos30007 -01	va05	treadmill h/p/cosmos 200-300/75-125	h/p/cosmos saturn 250/75	CE 0123

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cos30007 -01	va06	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 250/75 r	CE 0123
cos30008 -01	va01	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 650CE 250/100	CE 0123
cos30008 -01	va02	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 650CE 250/100 R	CE 0123
cos30008 -01	va04	treadmill h/p/cosmos 200- 300/75-125	COSMED T250 MR	CE 0123
cos30008 -01	va05	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 250/100	CE 0123
cos30008 -01	va06	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 250/100 r	CE 0123
cos30009 -01	va01	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 680CE 250/125 R	CE 0123
cos30009 -01	va03	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 250/125 r	CE 0123
cos30010 -01	va01	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 690CE 300/75	CE 0123
cos30010 -01	va02	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 690CE 300/75 R	CE 0123
cos30010 -01	va05	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 300/75	CE 0123
cos30010 -01	va06	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 300/75 R	CE 0123
cos30011 -01	va01	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 700CE 300/100	CE 0123
cos30011 -01	va02	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 700CE 300/100 R	CE 0123
cos30011 -01	va05	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 300/100	CE 0123
cos30011 -01	va06	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 300/100 r	CE 0123
cos30012 -01	va01	treadmill h/p/cosmos 200- 300/75-125	CareFusion LE 720CE 300/125 R	CE 0123
cos30012 -01	va03	treadmill h/p/cosmos 200- 300/75-125	h/p/cosmos saturn 300/125 r	CE 0123
cos30013 -01	va01	treadmill h/p/cosmos 450/300	h/p/cosmos saturn 450/300 rs	CE 0123

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**body weight support device**

Classification MDD Directive 93/42/EEC	Class IIa
Classification according to ISO 20957-1	S, I
UMDNS Code	11-623 exercisers
GMDN Codes	30928 training aid, physical, arm / trunk / leg
NBOG Code	MD 1108 active rehabilitation devices

article no.	vari-ant	product family	variant model name	CE
cos30017 -01		body weight support device h/p/cosmos	h/p/cosmos airwalk se	CE 0123
cos30028		body weight support device h/p/cosmos	h/p/cosmos airwalk ap	CE 0123

**expander pulling unit**

Classification MDD Directive 93/42/EEC	Class I
Classification according to ISO 20957-1	S, I
Classification according to EN 957-6	C
UMDNS Code	11-623 exerciser 11-625 exerciser arm
GMDN Codes	35060 EXERCISER, leg 11625 EXERCISER, arm
NBOG Code	MD 103 Non-active orthopaedic and rehabilitation devices

article no.	vari-ant	product family	variant model name	CE
cos30022	va01	expander pulling unit h/p/cosmos	h/p/cosmos robowalk expander F 150/50	CE
cos30022	va02	expander pulling unit h/p/cosmos	h/p/cosmos robowalk expander F 170-190/65	CE
cos30022	va03	expander pulling unit h/p/cosmos	h/p/cosmos robowalk expander F aw se 135	CE
cos30023-03		expander pulling unit h/p/cosmos	h/p/cosmos robowalk expander B	CE
cos101659	va01	expander pulling unit h/p/cosmos	h/p/cosmos robomove expander vh 1.2 m	CE
cos101659	va02	expander pulling unit h/p/cosmos	h/p/cosmos robomove expander vh 2 m	CE

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**parallel bars**

<b>Classification MDD Directive 93/42/EEC</b>	<b>Class I</b>
<b>Classification according to ISO 20957-1</b>	<b>S, I</b>
<b>UMDNS Code</b>	<b>12-957 Parallel Bars</b>
<b>GMDN Codes</b>	<b>30926 Parallel Bars, non-powered</b>
<b>NBOG Code</b>	<b>MD 103 Non-active orthopaedic and rehabilitation devices</b>

<b>article no.</b>	<b>vari-ant</b>	<b>product family</b>	<b>variant model name</b>	<b>CE</b>
cos30018	va01	parallel bars h/p/cosmos	h/p/cosmos parawalk 3m with wooden plate	CE
cos30018	va02	parallel bars h/p/cosmos	h/p/cosmos parawalk 3m	CE
cos30019	va01	parallel bars h/p/cosmos	h/p/cosmos parawalk 4m with wooden plate	CE
cos30019	va02	parallel bars h/p/cosmos	h/p/cosmos parawalk 4m	CE
cos30020	va01	parallel bars h/p/cosmos	h/p/cosmos parawalk 5m with wooden plate	CE
cos30020	va02	parallel bars h/p/cosmos	h/p/cosmos parawalk 5m	CE

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