

CE Declaration of Conformity

assigned to devices of medical and rehabilitation equipment

Legal manufacturer:

h/p/cosmos sports & medical gmbh

Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany, commercial register # HRB 7563 Traunstein
phone +49 86 69 86 42 0 fax +49 86 69 86 42 49 email@hpcosmos.com www.hpcosmos.com

EUDAMED SRN:

single registration number [DE-MF-000006147](https://eudamed.europa.eu/en/registration-number/DE-MF-000006147)

BfArM registration number: (=Federal Institute for Drugs and Medical Devices registration number) DE/0000012774 (since June 02, 1999)

notified body:

TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München / Germany, <https://www.tuvsud.com>





product:





Treadmill (running machine) including options, accessories and spare parts

Classification MDD directive 93/42/EEC	Risk class IIb based on classification rule 9 classification rules 9 and 10 of MDD ANNEX IX. chapter III. apply. Medical treadmills are <ul style="list-style-type: none"> • class IIb active medical devices, classified as • active therapeutic devices and also <ul style="list-style-type: none"> • active devices intended for diagnosis and monitoring
Conformity assessment: h/p/cosmos decided for MDD Legacy Devices:	MDD Annex I (Essential Requirements) + Annex II (Full Quality Management System Certificate) based on ISO 13485. Note: Exclusion of the processes and procedures <i>sterilization</i> from the Annex II of Directive 93/42/EEC.
manufacturer EC Certificate	EC certificate No. G1 045283 0022 Re. 00 based on MDD is valid until January 31, 2024
Classification according to ISO 20957-1	S, I
Classification according to ISO 20957-6	A
EUDAMED EMDN CODE:	Z129006 TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
UMDNS Code	14-141 Running Machine
GMDN Codes	33015 EXERCISER, TREADMILL, LINE-POWERED
NBOG Code	36679 ERGOMETER, TREADMILL MD 1108 active rehabilitation devices
Intended purpose	h/p/cosmos medical treadmills are intended for walking or running in place for <ul style="list-style-type: none"> • Recreational fitness training (incl. athletes) • Gait training (with or without body weight support) h/p/cosmos medical treadmills can be used in combination with external devices for walking or running in place as <ul style="list-style-type: none"> • Stressing devices for neuromuscular and biomechanical measurements (e.g. EEG, EMG, motion analysis) • Stressing devices for cardiovascular measurements (e.g. ECG) • Stressing devices for cardiopulmonary measurements (e.g. ergospirometry) Prescribed fall prevention device for any application where falling might cause an unacceptable risk (osteoporosis, high speed or special applications, applications with subjects not able to jump off the running belt such as children, physically impaired, etc.).
any Common Specifications ('CS') (other than a standard, see Article 9 MDR)	N/A not applicable
IFU instructions for use downloadable	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Updated safety information such as Field Safety Notices FSN, Field Safety Corrective Actions FSCA, etc. on website	https://www.hpcosmos.com/en/safety






A) product family: treadmill h/p/cosmos 150/50 (pluto, mercury)

EUDAMED-DI	UDI-DI	model name	article #
B-40505880023364	 40505880023364	pluto® med	cos30026-01va02
B-40505880025658	 40505880025658	pluto® ef med	cos30027-01va14
B-40505880029090	 40505880029090	stratos® med	cos30000-02va10
B-40505880032106	 40505880032106	pluto® It med OEM	cos30027-01va16


EUDAMED-DI	UDI-DI	model name	article #
B-40505880024354	 40505880024354	pluto® It med	cos30027-01va02
B-40505880026198	 40505880026198	mercury® med	cos30000-02va02
B-40505880031734	 40505880031734	pluto® med OEM	cos30026-01va14
B-40505880031970	 40505880031970	mercury® med OEM	cos30000-02va12

OEM Version: COSMED srl


EUDAMED-DI	UDI-DI	model name	article #
B-40505880023500	 40505880023500	pluto® COSMED T150 DE LC MED	cos30026-01va04
B-40505880024590	 40505880024590	pluto® COSMED T150 E LC MED	cos30027-01va04

EUDAMED-DI	UDI-DI	model name	article #
B-40505880028482	 40505880028482	mercury® COSMED T150 DE MED	cos30000-02va04


OEM Version: emotion fitness GmbH & Co. KG

EUDAMED-DI	UDI-DI	model name	article #
B-40505880025108	 40505880025108	pluto® motion sprint 600 PL med	cos30027-01va10



OEM Version: Noraxon U.S.A. Inc.


EUDAMED-DI	UDI-DI	model name	article #
B-40505880028000	 40505880028000	pluto® PhysTread med	cos30026-01va10

OEM Version: PHYSIOMED ELEKTROMEDIZIN AG


EUDAMED-DI	UDI-DI	model name	article #
B-40505880023746	 40505880023746	pluto® PHYSIORUN Trainer	cos30026-01va06


OEM Version: Proxomed Medizintechnik GmbH

EUDAMED-DI	UDI-DI	model name	article #
B-40505880023982	 40505880023982	pluto® Kardiomed LC	cos30026-01va08
B-40505880028864	 40505880028864	mercury® proxomed Kardiomed Mill S	cos30000-02va04


EUDAMED-DI	UDI-DI	model name	article #
B-40505880025412	 40505880025412	pluto® kardiomed 521	cos30027-01va12


OEM Version: SCHILLER AG

EUDAMED-DI	UDI-DI	model name	article #
B-40505880024736	 40505880024736	pluto® SCHILLER MTM-1400 MED	cos30027-01va06


EUDAMED-DI	UDI-DI	model name	article #
B-40505880028628	 40505880028628	mercury® SCHILLER MTM-1500 med	cos30000-02va06

OEM Version: Vyaire Medical GmbH

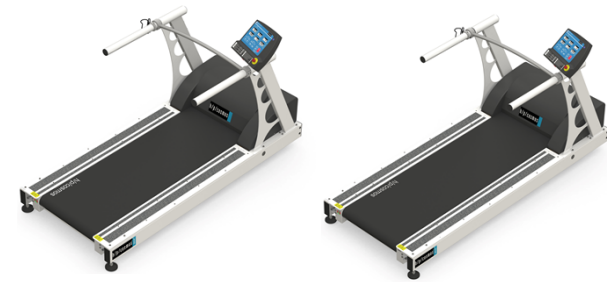
EUDAMED-DI	UDI-DI	model name	article #
B-40505880028178	 40505880028178	pluto® LE100CE (med)	cos30026-01va11

EUDAMED-DI	UDI-DI	model name	article #
B-40505880028246	 40505880028246	pluto® LE200CE	cos30027-01va08





B) product family: treadmill h/p/cosmos 150/50 (locomotion)




EUDAMED-DI	UDI-DI	model name	article #
B-40505880023050	 40505880023050	locomotion® 150/50 DE med	cos30001-01va02







C) product family: treadmill h/p/cosmos 170-190/65 (quasar, pulsar)

EUDAMED-DI	UDI-DI	model name	article #
B-40505880004936	 40505880004936	stellar® lt med	cos30003va17
B-40505880005162	 40505880005162	quasar® lt med	cos30003va19
B-40505880005544	 40505880005544	pulsar® lt med	cos30004va01
B-40505880026198	 40505880026198	locomotion® 190/65 DE med	cos30024va03


EUDAMED-DI	UDI-DI	model name	article #
B-40505880005094	 40505880005094	stellar® med	cos30003va18
B-40505880005230	 40505880005230	quasar® med	cos30003va20
B-40505880005780	 40505880005780	pulsar®	cos30004va03

OEM Version: COSMED srl

EUDAMED-DI	UDI-DI	model name	article #
B-40505880004318	 40505880004318	COSMED T170 DE MED	cos30003va11


EUDAMED-DI	UDI-DI	model name	article #
B-40505880004486	 40505880004486	COSMED T170 DE sportmed	cos30003va12

OEM Version: Noraxon U.S.A. Inc.




EUDAMED-DI	UDI-DI	model name	article #
B-40505880027560	 40505880027560	KinTread med	cos30003va28


OEM Version: Vyaire Medical GmbH

EUDAMED-DI	UDI-DI	model name	article #
B-40505880003328	 40505880003328	LE 250CE 170/65	cos30003va01
B-40505880003564	 40505880003564	LE 500CE 170/65	cos30003va03


EUDAMED-DI	UDI-DI	model name	article #
B-40505880003496	 40505880003496	LE 300CE 170/65	cos30003va02

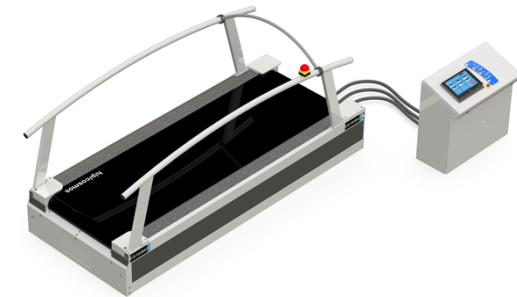
D) product family: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p)

EUDAMED-DI	UDI-DI	model name	article #
B-40505880015444	 40505880015444	quasar® med 3p	cos30003va26
B-40505880005612	 40505880005612	pulsar® It 3p	cos30004va02
B-40505880005858	 40505880005858	pulsar® 3p	cos30004va04




EUDAMED-DI	UDI-DI	model name	article #
B-40505880021148	 40505880021148	locomotion® 190/65 3p DE med	cos30024va04




OEM Version: COSMED srl


EUDAMED-DI	UDI-DI	model name	article #
B-40505880015376	 40505880015376	COSMED T170 DE 3p sportmed	cos30003va25










E) product family: treadmill h/p/cosmos 200-300/75-125 (venus, saturn)

EUDAMED-DI	UDI-DI	model name	article #
B-40505880016120	 40505880016120	venus® 200/75	cos30005-01va05
B-40505880016748	 40505880016748	venus® 200/100	cos30006-01va05
B-40505880017356	 40505880017356	saturn® 250/75	cos30007-01va05



EUDAMED-DI	UDI-DI	model name	article #
B-40505880016298	 40505880016298	venus® 200/75r	cos30005-01va06
B-40505880016816	 40505880016816	venus® 200/100r	cos30006-01va06
B-40505880017424	 40505880017424	saturn® 250/75r	cos30007-01va06


B-40505880017974	 40505880017974	saturn® 250/100	cos30008-01va05
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B-40505880018896	 40505880018896	saturn® 300/75	cos30010-01va05
B-40505880019404	 40505880019404	saturn® 300/100	cos30011-01va05





B-40505880018032	 40505880018032	saturn® 250/100r	cos30008-01va06
B-40505880018346	 40505880018346	saturn® 250/125r	cos30009-01va03
B-40505880018964	 40505880018964	saturn® 300/75r	cos30010-01va06
B-40505880019572	 40505880019572	saturn® 300/100r	cos30011-01va06
B-40505880019886	 40505880019886	saturn® 300/125r	cos30012-01va03



OEM Version: COSMED srl

EUDAMED-DI	UDI-DI	model name	article #
B-40505880015994	 40505880015994	COSMED T200 S	cos30005-01va03
B-40505880017806	 40505880017806	COSMED T250 MR	cos30008-01va04

EUDAMED-DI	UDI-DI	model name	article #
B-40505880016502	 40505880016502	COSMED T200 M	cos30006-01va03

OEM Version: Vyaire Medical GmbH

EUDAMED-DI	UDI-DI	model name	article #
B-40505880015758	 40505880015758	LE 580CE 200/75	cos30005-01va01
B-40505880016366	 40505880016366	LE 590CE 200/100	cos30006-01va01
B-40505880016984	 40505880016984	LE 600CE 250/75	cos30007-01va01
B-40505880017592	 40505880017592	LE 650CE 250/100	cos30008-01va10

B-40505880018414	 40505880018414	LE 690CE 300/75	cos30010-01va01
B-40505880019022	 40505880019022	LE 700CE 300/100	cos30011-01va01

EUDAMED-DI	UDI-DI	model name	article #
B-40505880015826	 40505880015826	LE 580CE 200/75 R	cos30005-01va02
B-40505880016434	 40505880016434	LE 590CE 200/100 R	cos30006-01va02
B-40505880017042	 40505880017042	LE 600CE 250/75 R	cos30007-01va02
B-40505880017660	 40505880017660	LE 650CE 250/100 R	cos30008-01va02
B-40505880018100	 40505880018100	LE 680CE 250/125 R	cos30009-01va01
B-40505880018582	 40505880018582	LE 690CE 300/75 R	cos30010-01va02
B-40505880019190	 40505880019190	LE 700CE 300/100 R	cos30011-01va02
B-40505880019640	 40505880019640	LE 720CE 300/125 R	cos30012-01va01

regulations and standards:

Reference Number	Date of Issue	Title
Directive 93/42/EEC	14 June 1993	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)
Directive 2006/42/EC	17 May 2006	DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)
Directive 2014/30/EU	26 Feb 2014	DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility (recast)
Directive 2014/35/EU	26 Feb 2014	DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
Directive 2014/53/EU	16 Apr 2014	The radio equipment directive 2014/53/EU (RED)
DIN EN 60601-1	Edition 3.1; 2013-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
DIN EN ISO 14971	2020-07	Medical devices - Application of risk management to medical devices
DIN EN 62304	2016-10	Medical device software - Software life cycle processes
IEC 62366-1	2015 + COR1:2016	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 62366-2	2016-04	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
ISO 10993-1	2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10);
ISO 20957-1	2013	Stationary training equipment - Part 1: General safety requirements and test methods
EN 957-6	2010+A1:2014	Stationary training equipment – Part 6: Treadmills, additional specific safety requirements and test methods

We herewith declare under our sole responsibility, that above listed devices, that are covered by the present declaration, are in conformity with this Medical Device Directive 93/42/EEC (MDD) and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

The **CE** 0123- mark gets affixed to the products.

We herewith declare under our sole responsibility that h/p/cosmos sports & medical gmbh also meets the applicable requirements of MDR (EU) 2017/745 within the transition period for legacy devices.

This declaration of conformity is an important part of our certified Quality Management System according to the ISO 13485 standard and it is valid for all above mentioned devices which have been produced by h/p/cosmos on or after 12.07.2022.

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 medical device directive 93/42/EEC with the certificate number G1 045283 0022 Rev. 00 on 31.01.2024.

DE 83365 Nussdorf-Traunstein, July 12, 2022

signed for and on behalf of h/p/cosmos sports & medical gmbh



Franz Harrer
Managing Director



Nadine Schott
Quality Manager and PRRC



Joschka Zimmer
Product Manager and person authorized to compile the technical file