EU Declaration of Conformity

assigned to devices of medical and rehabilitation equipment

CE 0123

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**

notified body: **TÜV SÜD Product Service GmbH**, Ridlerstrasse 65, 80339 München / Germany. NB code: 0123
Tel: +49 89 5791-0 Fax: +49 89 5791-1551 info@tuvsud.com www.tuvsud.com

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

Classification MDR (EU) 2017/745	**Risk class IIb** based on **classification rule 9** classification rules 9 and sub-rule 10 of MDR Annex VIII chapter II and III apply. Medical treadmills are • **class IIb active medical devices**, classified as • **active therapeutic devices** and also • **active devices intended for diagnosis and monitoring**
Conformity assessment based on MDR	• **Annex I** (GENERAL SAFETY AND PERFORMANCE REQUIREMENTS). Note: Exclusion of the processes and procedures sterilization from the Annex I of MDR • **Annex IX** (CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION) **Chapter I** (Full QUALITY MANAGEMENT SYSTEM Certificate) based on ISO 13485. • **Annex IX** (CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION) **Chapter III** (ADMINISTRATIVE PROVISIONS) archiving period for documentation.
EU Quality Management System Certificate (MDR)	No. G10 045283 0027 Rev. 00 valid until November 17, 2027 https://www.hpcosmos.com/sites/default/files/uploads/documents/20221118_hpcosmos_tuev_sued_mdr_eu2017-745_certificate_g100452830027_rev.00_en.pdf
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
MDR Codes	**MDA 0313**: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport **MDS 1004**: Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council. **MDS 1009**: Devices incorporating software / utilizing software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices **MDS 1010**: Devices with a measuring function (within / combined to a system, e.g. ECG, CPET, VO2max. Heart Rate Monitor, etc.) **MDS 1011**: Devices in systems or procedure packs (treadmills can be stand alone devices or can be within / combined to / be part of a system, e.g. gait training system consisting of treadmill and unweighting device; stress test system consisting of treadmill with ECG, CPET, VO2max. Heart Rate Monitor, etc.) **MDT 2001**: Devices manufactured using metal processing

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	MDT 2011: Devices which require packaging, including labelling
Intended purpose	h/p/cosmos medical treadmills are intended for walking or running in place for • 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 • 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)	not applicable N/A
Intended duration of use	can be following both, depending on the medical doctor's prescription: Transient: Normally intended for continuous use for less than 60 minutes Short term: Normally intended for continuous use for between 60 min. and 30 days
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 G7

Basic UDI-DI code: **4050588cos31000R4** / GTIN-14 GS1

UDI-DI	model name	article #
40505880035862	**pluto® lt med**	**cos31002**
40505880036098	**pluto® lt med OEM**	**cos31004**
40505880036234	**pluto® ef med**	**cos31012**
40505880036470	**pluto® ef med OEM**	**cos31014**
40505880036616	**pluto® med**	**cos31022**
40505880036852	**pluto® med OEM**	**cos31024**

UDI-DI	model name	article #
40505880037088	**stratos® med**	**cos31032**
40505880037224	**stratos® med OEM**	**cos31034**
40505880037460	**mercury® med**	**cos31042**
40505880037606	**mercury® med OEM**	**cos31044**

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B) product family: treadmill h/p/cosmos 170-190/65 MCU6

Basic UDI-DI code: **4050588cos30003-015X** / GTIN-14 GS1 (EUDAMED registration date: 28/01/2022)

UDI-DI	model name	article #
40505880029540	**quasar® med**	**cos30003-01va02**
40505880030058	**stellar® med**	**cos30003-01va06**
40505880030812	**pulsar® med**	**cos30004-01va02**
40505880031284	**stellar® 190/65 med**	**cos30004-01va06**

UDI-DI	model name	article #
40505880030294	**quasar® lt med**	**cos30003-01va04**
40505880029786	**quasar® med OEM**	**cos30003-01va08**
40505880031420	**pulsar® lt med**	**cos30004-01va04**
40505880031048	**pulsar® med OEM**	**cos30004-01va08**

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regulations and standards:

Reference Number	Date of Issue	Title
Regulation (EU) 2017/745	5 April 2017	Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. (MDR)
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 (ISO 20957-6)	2010+A1:2014 (2021-02)	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 MDR Medical Device Regulation (EU) 2017/745 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.

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 listed devices which have been produced by h/p/cosmos on or after June 18, 2024.

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 EU Quality Management System Certificate according to medical device regulation (EU) 2017/745 with the certificate number G10 045283 0027 Rev. 00 on 17.11.2027.

DE 83365 Nussdorf-Traunstein, June 18, 2024

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

Alexander Böck
Managing Director

ppa. Nadine Schott
Nadine Schott
Quality Manager and PRRC

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

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