CH-REP CERTIFICATE

QUNIQUE herewith attests that the Manufacturer named below is allowed to use QUNIQUE as their Swiss Authorized Representative for the products listed below.

QUNIQUE has verified that the EU declaration of conformity and technical documentation have been drawn up and that an appropriate conformity assessment procedure has been carried out by the manufacturer.

Written mandate contract Nr.:	**2022-CHAR-229**
Effective Date:	**25.05.2023**
Manufacturer:	**h/p/cosmos sports & medical GmbH** **Am Sportplatz 8** **83365 Nussdorf-Traunstein** **Germany**
Manufacturer's SRN:	**DE-MF-000006147**
Products:	**Please see Annex A for complete product list**
CH-REP:	**QUNIQUE GmbH** **Bahnhofweg 17** **5610 Wohlen** **Switzerland**
QUNIQUE's CHRN:	**CHRN-AR-20000058**

Wohlen, July 27, 2023

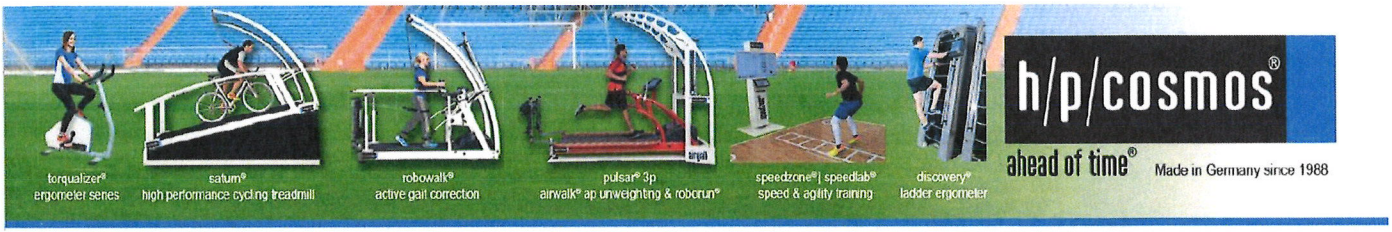
Angelina Hakim
CEO QUNIQUE GmbH
Bahnhofweg 17
5610 Wohlen / Switzerland

Annex A Complete Product Listing

airwalk® ap	**EMDN: Z120602**
170/190/65 MCU6 treadmill family (quasar/pulsar)	**EMDN: Z129006**
150/50 G6 treadmill family (pluto/mercury)	**EMDN: Z129006**
170/190/65 3p treadmill family (quasar 3p/pulsar 3p)	**EMDN: Z129006**
200-300/75-125 treadmill family (venus/saturn))	**EMDN: Z129006**

Note: for products' variants, please refer to the current DoCs below
20210520_hpcosmos_body_weight_support_CE_EU_Declaration_of_Conformity_med_scan.pdf
h-p-cosmos_ce_declaration_of_conformity_med_legacy_devices.pdf
hpcosmos_eu_declaration_of_conformity_devices_of_medical_and_rehabilitation_equipment_1.pdf

Version	Change Description	Date
01	First release	May 25, 2023
02	New CH-REP certificate template, addition of product variants/details according to the attached DoCs	July 27, 2023



EU Declaration of Conformity

assigned to devices of medical and

rehabilitation equipment

CE

manufacturer: **h/p/cosmos sports & medical gmbh**

(=EU representative) 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

BfArM / DIMDI: Federal Institute for Drugs and Medical Devices registration number: DE/0000012774 (since 02.06.1999)

product: **body weight support device**

Risk Classification MDD 93/42/EEC	**Risk class I | classification rule 12 of Annex IX apply**
Risk Classification MDR (EU) 2017/745	**Risk class I | classification rule 13 of Annex VIII apply**
Classification according to ISO 20957-1	**S, I**
Classification according to EN 957-6	not applicable
UMDNS Code	**11-623** exercisers
GMDN Codes	58876 Gait rehabilitation system harness
NBOG Code	**MD 1108** active rehabilitation devices

product family: body weight support device h/p/cosmos (airwalk)

UDI-DI: 4050588004064

BfArM: DE/CA59/BS 5123/2020-R/Kn initial registration date: November 12, 2013

UDI-DI	model name	article #		UDI-DI	model name	article #
4050588002305	**airwalk® ap**	**cos30028**		4050588002312	**airwalk® ap lt**	**cos30028-lt**

We herewith declare under our sole responsibility that the above models / types meet the essential requirements of:

Annex I (essential requirements) **+ Annex VII** (EC DECLARATION OF CONFORMITY) of the European Council Directive 93/42/EEC.

Note: Exclusion of the processes and procedures *sterilization* from the Annex II of Directive 93/42/EEC.

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

The CE - 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 mentioned devices which have been produced by h/p/cosmos on or after 20.05.2021. 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.

DE 83365 Nussdorf-Traunstein, May 20, 2021

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

Franz Harrer
President & CEO (Geschäftsführer)

h/p/cosmos
sports & medical gmbh
Am Sportplatz 8 DE 83365 Nussdorf-Traunstein
phone +49 (0) 86 69 /86 42-0 email@h-p-cosmos.com
fax +49 (0) 86 69 /86 42-49 www.h-p-cosmos.com

CE 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

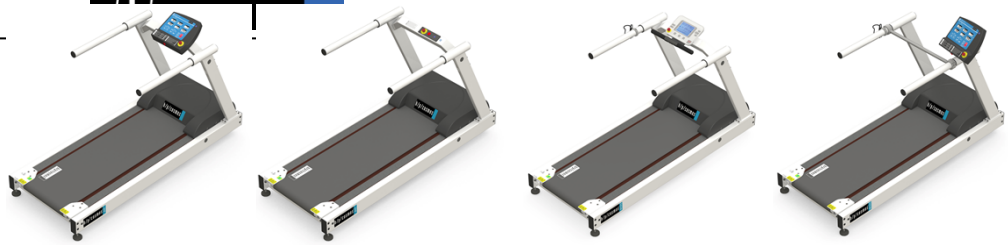
BfArM registration number: (=Federal Institute for Drugs and Medical Devices registration number) DE/0000012774 (since June 02, 1999)

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 ANNEXX IX. chapter 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: 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 *sterilization* 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 • 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)	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

h/p/cosmos CE Declaration of Conformity (med legacy devices)



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-40505880028932	40505880028932	**stratos® med**	**cos30000-02va10**
B-40505880032106	40505880032106	**pluto® lt med OEM**	**cos30027-01va16**

EUDAMED-DI	UDI-DI	model name	article #
B-40505880024354	40505880024354	**pluto® lt med**	**cos30027-01va02**
B-40505880026020	40505880026020	**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**	**cos30000-02va08**

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**

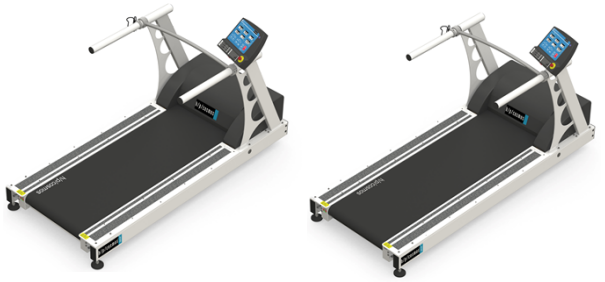
OEM Version: Vyaire Medical GmbH

EUDAMED-DI	UDI-DI	model name	article #
B-40505880028178	40505880028178	**pluto® | LE100CE**	**cos30026-01va11**

EUDAMED-DI	UDI-DI	model name	article #
B-40505880028246	40505880028246	**pluto® | LE200CE**	**cos30026-01va12**

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**	**cos30004va01**
B-40505880020844	40505880020844	**locomotion® 190/65 E med**	**cos30024va01**

EUDAMED-DI	UDI-DI	model name	article #
B-40505880005094	40505880005094	**stellar® med**	**cos30003va18**
B-40505880005230	40505880005230	**quasar® med**	**cos30003va20**
B-40505880005780	40505880005780	**pulsar®**	**cos30004va03**
B-40505880021070	40505880021070	**locomotion® 190/65 DE med**	**cos30024va03**

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: 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**

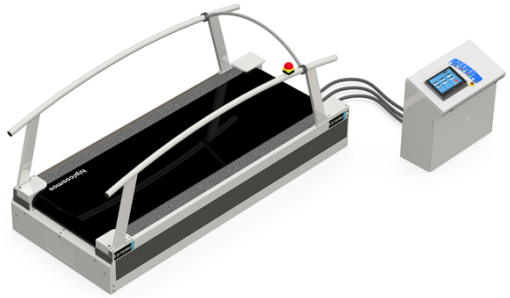
D) product family: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p)

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

EUDAMED-DI	UDI-DI	model name	article #
B-40505880020912	40505880020912	**locomotion® 190/65 3p E med**	**cos30024va02**
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-40505880015758	40505880015758	**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**
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**	**cos30008-01va01**
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 26.08.2022.

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, August 26, 2022

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

Franz Harrer	Nadine Schott	Joschka Zimmer
Managing Director	Quality Manager and PRRC	Product Manager and person authorized to compile the technical file

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, 10 and 11 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
NBOG Code	**36679** ERGOMETER, TREADMILL **MD 1108** active rehabilitation devices
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 **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
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 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**

regulations and standards:

Reference Number	Date of Issue	Title
Regulation (EU) 2017/745	4 May 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 March 07, 2023.

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 10.01.2023.

DE 83365 Nussdorf-Traunstein, March 07, 2023

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

Franz Harrer	Nadine Schott	Joschka Zimmer
Managing Director	Quality Manager and PRRC	Product Manager and person authorized to compile the technical file