# 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**<br>**Am Sportplatz 8**<br>**83365 Nussdorf-Traunstein**<br>**Germany** |
| **Manufacturer's SRN:** | **DE-MF-000006147** |
| **Products:** | **Please see Annex A for complete product list** |
| **CH-REP:** CH REP | **QUNIQUE GmbH**<br>**Bahnhofweg 17**<br>**5610 Wohlen**<br>**Switzerland** |
| **QUNIQUE's CHRN:** | **CHRN-AR-20000058** |

Wohlen, 26.Feb.2024

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
*hpcosmos_eu_declaration_of_conformity_for_airwalk_body_weight_support_device_1.pdf*
*hpcosmos_ce_declaration_of_conformity_med_legacy_devices_1.pdf*
*hpcosmos_eu_declaration_of_conformity_treadmill_devices_of_medical_and_rehabilitation_equipment_3.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 |
| 03 | Updated DoCs | February 26, 2024 |

# EU Declaration of Conformity

assigned to devices of medical and rehabilitation equipment

CE

**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:** **n.a. for class I devices**

**product:** **body weight support device including options, accessories and spare parts**

| | |
|---|---|
| **Classification MDR (EU) 2017/745** | **Risk class I**<br>based on **classification rule 13** (All other active devices)<br>**Active Therapeutic Device** |
| **EU Quality Management System Certificate (MDR)** | **n.a. for class I devices** |
| **Classification according to ISO 20957-1** | **S, I** |
| **Classification according to ISO 20957-6** | not applicable |
| **EUDAMED EMDN Code** | **Z120602** PHYSIOTHERAPY EQUIPMENT<br>**Y050201** STANDING SUPPORT GAIT TRAINERS |
| **UMDNS Code** | **11-623** exercisers |
| **GMDN Codes** | **58876** Gait rehabilitation system harness |
| **MDR Codes** | **MDA 0313**: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport<br>**MDS 1011**: Devices in systems or procedure packs<br>(unweighting devices can be stand alone devices or can be within / combined to / be part of a system, e.g. gait training system consisting of unweighting device and treadmill, stress test system consisting of unweighting device, treadmill with ECG, CPET, VO2max. Heart Rate Monitor, etc.)<br>**MDT 2001**: Devices manufactured using metal processing<br>**MDT 2011**: Devices which require packaging, including labelling |
| **Intended purpose** | • Body weight support of a subject (during treadmill therapy / training)<br>• Fall protection of a subject (during treadmill therapy / training)<br>• Emergency stop in case of falling during treadmill therapy / training<br>• Balance training under unweighted and/or secured conditions<br>• Functional movement and gait training under unweighted and/or secured conditions<br>• Overspeed / hyperspeed and excess frequency training in athletics (only for sports applications)<br>Prescribed fall prevention device for any application where falling might cause an unacceptable risk (e.g. high speed or special applications, applications with subjects not able to support their weight properly, physically impaired, newly operated hip patients, invasive probes, osteoporosis, 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: body weight support device h/p/cosmos (airwalk)**

**Basic UDI-DI code**: **4050588cos30028RK** / GTIN-14 GS1 (EUDAMED registration date: 15/12/2022)

| UDI-DI | model name | article # |
|---|---|---|
| 40505880023050 | **airwalk® ap** | **cos30028** |

| UDI-DI | model name | article # |
|---|---|---|
| 40505880025276 | **airwalk® ap LT** | **cos30028-lt** |

**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**) Medical Device Regulation |
| 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). "**Machinery Directive**" |
| Directive 2011/65/EU and (EU) 2015/863 | 8 June 2011 and 31 March 2015 | DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. **RoHS**. COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. |
| Regulation (EU) 2020/2096 | 15 December 2020 | COMMISSION REGULATION (EU) 2020/2096 of 15 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants. |
| DIN EN ISO 14971 | 2020 | Medical devices - Application of risk management to medical devices |
| IEC 62366-1 | 2015 + COR1:2016 | Medical devices - Part 1: Application of usability engineering to medical devices |
| IEC TR 62366-2 | 2021 | 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 |

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 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 January 25, 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, January 25, 2024**
signed for and on behalf of h/p/cosmos sports & medical gmbh

Alexander Böck
Managing Director
Sales Director

ppa. Nadine Schott
Nadine Schott
Quality Manager and PRRC

Joschka Zimmer
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**<br>classification rules 9 and sub-rule 10 of MDR Annex VIII chapter II and III apply.<br>Medical treadmills are<br>• **class IIb active medical devices**, classified as<br>• **active therapeutic devices**<br>and also<br>• **active devices intended for diagnosis and monitoring** |
| **Conformity assessment based on MDR** | • **Annex I** (GENERAL SAFETY AND PERFORMANCE REQUIREMENTS).<br>Note: Exclusion of the processes and procedures sterilization from the Annex I of MDR<br>• **Annex IX** (CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION)<br>**Chapter I** (Full QUALITY MANAGEMENT SYSTEM Certificate) based on ISO 13485.<br>• **Annex IX** (CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION)<br>**Chapter III** (ADMINISTRATIVE PROVISIONS) archiving period for documentation. |
| **EU Quality Management System Certificate (MDR)** | No. G10 045283 0027 Rev. 00<br>valid until November 17, 2027<br>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<br>**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.<br>**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<br>**MDS 1010**: Devices with a measuring function (within / combined to a system, e.g. ECG, CPET, VO2max. Heart Rate Monitor, etc.)<br>**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<br>**MDT 2011**: Devices which require packaging, including labelling |
| **Intended purpose** | h/p/cosmos medical treadmills are intended for walking or running in place for<br>• Recreational fitness training (incl. athletes)<br>• Gait training (with or without body weight support)<br>h/p/cosmos medical treadmills can be used in combination with external devices for walking or running in place as<br>• Stressing devices for neuromuscular and biomechanical measurements (e.g. EEG, EMG, motion analysis)<br>• Stressing devices for cardiovascular measurements (e.g. ECG)<br>• Stressing devices for cardiopulmonary measurements (e.g. ergospirometry)<br>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:<br>Transient: Normally intended for continuous use for less than 60 minutes<br>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 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 | 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 January 25, 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, January 25, 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

# 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**<br>classification rules 9 and 10 of MDD ANNEXX IX. chapter III. apply.<br>Medical treadmills are<br>• class IIb active medical devices, classified as<br>• active therapeutic devices<br>and also<br>• active devices intended for diagnosis and monitoring |
| **Conformity assessment:**<br>h/p/cosmos decided for<br>MDD Legacy Devices: | MDD Annex I (Essential Requirements) +<br>Annex II (Full Quality Management System Certificate) based on ISO 13485.<br>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 and Confirmation Letter CL 045283 0028 Rev. 00 |
| **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<br>**MD 1108** active rehabilitation devices |
| **Intended purpose** | h/p/cosmos medical treadmills are intended for walking or running in place for<br>• Recreational fitness training (incl. athletes)<br>• Gait training (with or without body weight support)<br>h/p/cosmos medical treadmills can be used in combination with external devices for walking or running in place as<br>• Stressing devices for neuromuscular and biomechanical measurements (e.g. EEG, EMG, motion analysis)<br>• Stressing devices for cardiovascular measurements (e.g. ECG)<br>• Stressing devices for cardiopulmonary measurements (e.g. ergospirometry)<br>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)

**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** |

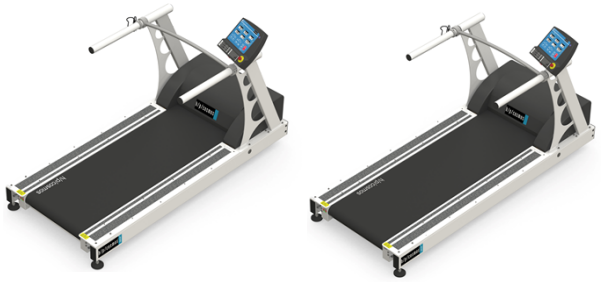
**OEM Version: Vyaire Medical GmbH**

| 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** |

**A) 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** |



**B) 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** |

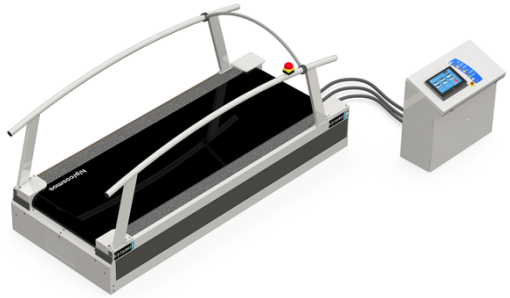
**C) product family: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p)**

| 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** |



**D) 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 25.01.2024.

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 EC-certificate according to medical device directive 93/42/EEC with the certificate number G1 045283 0022 Rev. 00 on 31.01.2024.
Following EU 2023/607 the Notified Body (TÜV SÜD Product Service GmbH) issued Confirmation letter CL 045283 0028 Rev. 00, extending the transition period until 31.12.2028.

**DE 83365 Nussdorf-Traunstein, January 25, 2024**
signed for and on behalf of h/p/cosmos sports & medical gmbh

Alexander Böck
Managing Director

Nadine Schott
Quality Manager and PRRC

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