



EU 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**

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	<p>Risk class IIb based on classification rule 9</p> <p>classification rules 9 and sub-rule 10 of MDR Annex VIII chapter II and III apply. Medical treadmills are</p> <ul style="list-style-type: none"> • class IIb active medical devices, classified as • active therapeutic devices and also • active devices intended for diagnosis and monitoring
Conformity assessment based on MDR	<ul style="list-style-type: none"> • 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)	<p>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</p>
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	<p>MDA 0313: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</p> <p>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.</p> <p>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</p> <p>MDT 2001: Devices manufactured using metal processing</p> <p>MDT 2011: Devices which require packaging, including labelling</p>

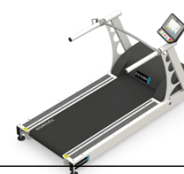
Intended purpose	<p>medical ergometers are intended for</p> <ul style="list-style-type: none"> Recreational fitness training (incl. athletes) Gait training (with or without body weight support) <p>medical ergometers can be used in combination with external devices for walking or running in place as</p> <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)
any Common Specifications ('CS') (other than a standard, see Article 9 MDR)	not applicable N/A
Intended duration of use	<p>can be following both, depending on the medical doctor's prescription:</p> <p>Transient: Normally intended for continuous use for less than 60 minutes</p> <p>Short term: Normally intended for continuous use for between 60 min. and 30 days</p>
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 (pluto, mercury)

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

article #	model name	UDI-DI
cos31002	pluto® lt med	40505880035862
cos31004	pluto® lt med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
cos31024	pluto® med OEM	40505880036852
cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) product family: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

article #	model name	UDI-DI
cos30003-01va02	quasar® med	40505880029540
cos30003-01va06	stellar® med	40505880030058
cos30004-01va02	pulsar® med	40505880030812
cos30004-01va06	stellar® 190/65 med	40505880031284
cos30003-01va04	quasar® lt med	40505880030294
cos30003-01va08	quasar® med OEM	40505880029786
cos30004-01va04	pulsar® lt med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) product family: treadmill h/p/cosmos 150/50 (locomotion) (in application of the transitional provisions MDR Art. 120 (3a))

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



D) product family: treadmill h/p/cosmos 150/50 (pluto, mercury) (in application of the transitional provisions MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® lt med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® lt med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



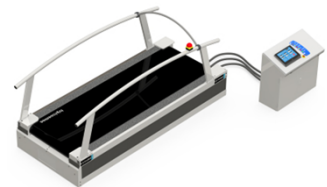
E) product family: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (in application of the transitional provisions MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va17	stellar® lt med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® lt med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® lt	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) product family: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (in application of the transitional provisions MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® lt 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) product family: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (in application of the transitional provisions MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30005-01va05	venus® 200/75	40505880015758
cos30005-01va06	venus® 200/75r	40505880016298
cos30006-01va05	venus® 200/100	40505880016748
cos30006-01va06	venus® 200/100r	40505880016816
cos30007-01va05	saturn® 250/75	40505880017356
cos30007-01va06	saturn® 250/75r	40505880017424
cos30008-01va05	saturn® 250/100	40505880017974
cos30008-01va06	saturn® 250/100r	40505880018032
cos30009-01va03	saturn® 250/125r	40505880018346
cos30010-01va05	saturn® 300/75	40505880018896
cos30010-01va06	saturn® 300/75r	40505880018964
cos30011-01va05	saturn® 300/100	40505880019404
cos30011-01va06	saturn® 300/100r	40505880019572
cos30012-01va03	saturn® 300/125r	40505880019886

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 following 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.

- A) product family: treadmill h/p/cosmos 150/50 G7**
- B) product family: treadmill h/p/cosmos 170-190/65 MCU6**

We herewith declare under our sole responsibility, that following devices, that are covered by the present declaration, are in conformity with this MDR Medical Device Regulation (EU) 2017/745 (in application of the transitional provisions MDR Art. 120 (3a)) and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

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.

- C) product family: treadmill h/p/cosmos 150/50 (locomotion)**
- D) product family: treadmill h/p/cosmos 150/50 G6**
- E) product family: treadmill h/p/cosmos 170-190/65**
- F) product family: treadmill h/p/cosmos 170-190/65 3p**
- G) product family: treadmill h/p/cosmos 200-300/75-125**

The  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 July 8, 2025.

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.

Based on Directive 2011/65/EU and (EU) 2015/863 (RoHS) and Regulation (EU) 2020/2096 (REACH)

This document also confirms that according to current knowledge all raw materials, components partially completed and completed products used within the manufacturing process of h/p/cosmos sports & medical gmbh products comply with the requirements of **Directive 2011/65/EU** and **(EU) 2015/863 (RoHS)** and **Regulation (EU) 2020/2096 (REACH)** for restriction of the use of certain hazardous substances.

h/p/cosmos sports & medical gmbh performs no testing of components and solely relies on information, confirmations and certificates provided by its suppliers for declaration of RoHS and REACH conformity.

Within the scope of our certification according to ISO 13485 we are in constant dialogue with our suppliers, also to ensure that all delivered products are RoHS and REACH compliant.

BioComp statement:

h/p/cosmos sports & medical gmbh confirms the biocompatibility of all products to be used acc. to the intended use. Based on the evidence of long time experience h/p/cosmos abstained from individual testing of all components acc. to ISO 10993 "Biological evaluation of medical devices" and declares, there is no unacceptable risk resulting from skin contact to any part of the device.

DE 83365 Nussdorf-Traunstein, July 8, 2025

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



EU Konformitätserklärung

für medizinische Geräte und Rehabilitationsgeräte bestimmt



Gesetzlicher Hersteller: h/p/cosmos sports & medical gmbh

Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany, Handelsregister # HRB 7563 Traunstein
 Telefon +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

Produkt: Laufband einschließlich Optionen, Zubehör und Ersatzteilen

Klassifizierung MDR (EU) 2017/745	<p>Risikoklasse IIb gemäß Klassifizierungsregel 9</p> <p>Es gelten die Klassifizierungsregeln 9 und Unterregel 10 des MDR Anhang VIII Kapitel II und III. Medizinische Laufbänder sind</p> <ul style="list-style-type: none"> • aktive Medizinprodukte der Klasse IIb, klassifiziert als • aktive therapeutische Produkte <p>und außerdem</p> <ul style="list-style-type: none"> • aktive Produkte zur Diagnose und Überwachung
Konformitätsbewertung auf der Grundlage der MDR	<ul style="list-style-type: none"> • Anhang I (ALLGEMEINE SICHERHEITS- UND LEISTUNGSANFORDERUNGEN). Hinweis: Ausschluss der Sterilisationsprozesse und -verfahren aus Anhang I der MDR • Anhang IX (KONFORMITÄTSBEWERTUNG AUF DER GRUNDLAGE EINES QUALITÄTSMANAGEMENTSYSTEMS UND DER BEWERTUNG DER TECHNISCHEN DOKUMENTATION) • Kapitel I (Vollständiges Zertifikat für das QUALITÄTSMANAGEMENTSYSTEM) auf der Grundlage von ISO 13485. • Anhang IX (KONFORMITÄTSBEWERTUNG AUF DER GRUNDLAGE EINES QUALITÄTSMANAGEMENTSYSTEMS UND DER BEWERTUNG DER TECHNISCHEN DOKUMENTATION) • Kapitel III (VERWALTUNGSVORSCHRIFTEN) Aufbewahrungsfrist für Unterlagen.
EU-Zertifikat für Qualitätsmanagementsysteme (MDR)	<p>No. G10 045283 0027 Rev. 00 Gültig bis 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</p>
Klassifizierung gemäß ISO 20957-1	S, I
Klassifizierung gemäß 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	<p>MDA 0313: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</p> <p>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.</p> <p>MDS 1009: Devices incorporating software / utilizing software / controlled by software, including devices intended for controlling, monitoring or directly</p>

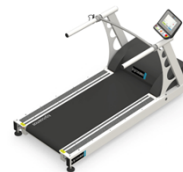
	<p>influencing the performance of active or active implantable devices MDT 2001: Devices manufactured using metal processing MDT 2011: Devices which require packaging, including labelling</p>
Verwendungszweck	<p>Medizinische Ergometer sind bestimmt für</p> <ul style="list-style-type: none"> • Freizeit-Fitnesstraining (einschließlich Sportler) • Gangtraining (mit oder ohne Körpergewichtsunterstützung) <p>Medizinische Ergometer können in Kombination mit externen Geräten zum Gehen oder Laufen an Ort und Stelle verwendet werden als</p> <ul style="list-style-type: none"> • Belastungsgeräte für neuromuskuläre und biomechanische Messungen (z. B. EEG, EMG, Bewegungsanalyse) • Belastungsgeräte für kardiovaskuläre Messungen (z. B. EKG) • Belastungsgeräte für kardiopulmonale Messungen (z. B. Ergospirometrie)
alle gemeinsamen Spezifikationen („CS“) (mit Ausnahme einer Norm, siehe Artikel 9 MDR)	nicht zutreffend N/A
Vorgesehene Nutzungsdauer	<p>Je nach ärztlicher Verschreibung kann es sich um Folgendes handeln: Vorübergehend: Normalerweise für eine kontinuierliche Anwendung von weniger als 60 Minuten vorgesehen. Kurzfristig: Normalerweise für eine kontinuierliche Anwendung zwischen 60 Minuten und 30 Tagen vorgesehen.</p>
IFU instructions for use downloadable	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Aktualisierte Sicherheitsinformationen wie Feldsicherheitsmitteilungen (FSN), Feldsicherheitskorrekturmaßnahmen (FSCA) usw. auf der Website	https://www.hpcosmos.com/en/safety



A) Produktfamilie: treadmill h/p/cosmos 150/50 G7 (pluto, mercury)

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

article #	model name	UDI-DI
cos31002	pluto® It med	40505880035862
cos31004	pluto® It med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
cos31024	pluto® med OEM	40505880036852
cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) Produktfamilie: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

article #	model name	UDI-DI
cos30003-01va02	quasar® med	40505880029540
cos30003-01va06	stellar® med	40505880030058
cos30004-01va02	pulsar® med	40505880030812
cos30004-01va06	stellar® 190/65 med	40505880031284
cos30003-01va04	quasar® It med	40505880030294
cos30003-01va08	quasar® med OEM	40505880029786
cos30004-01va04	pulsar® It med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) Produktfamilie: treadmill h/p/cosmos 150/50 (locomotion) (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a))

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



D) Produktfamilie: treadmill h/p/cosmos 150/50 (pluto, mercury) (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® It med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® It med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



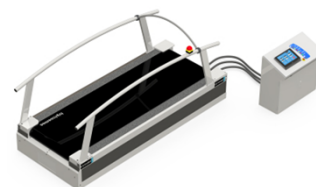
E) Produktfamilie: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va17	stellar® It med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® It med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® It	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) Produktfamilie: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® lt 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) Produktfamilie: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30005-01va05	venus® 200/75	40505880015758
cos30005-01va06	venus® 200/75r	40505880016298
cos30006-01va05	venus® 200/100	40505880016748
cos30006-01va06	venus® 200/100r	40505880016816
cos30007-01va05	saturn® 250/75	40505880017356
cos30007-01va06	saturn® 250/75r	40505880017424
cos30008-01va05	saturn® 250/100	40505880017974
cos30008-01va06	saturn® 250/100r	40505880018032
cos30009-01va03	saturn® 250/125r	40505880018346
cos30010-01va05	saturn® 300/75	40505880018896
cos30010-01va06	saturn® 300/75r	40505880018964
cos30011-01va05	saturn® 300/100	40505880019404
cos30011-01va06	saturn® 300/100r	40505880019572
cos30012-01va03	saturn® 300/125r	40505880019886

Vorschriften und Normen:

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


Wir erklären hiermit in alleiniger Verantwortung, dass die folgenden Geräte, die Gegenstand dieser Erklärung sind, mit der Medizinprodukteverordnung (EU) 2017/745 (MDR) und gegebenenfalls mit allen anderen einschlägigen Rechtsvorschriften der Union, die die Ausstellung einer EU-Konformitätserklärung vorsehen, übereinstimmen.

- A) Produktfamilie: treadmill h/p/cosmos 150/50 G7
- B) Produktfamilie: treadmill h/p/cosmos 170-190/65 MCU6

Wir erklären hiermit in alleiniger Verantwortung, dass die folgenden Geräte, die unter diese Erklärung fallen, mit der Medizinprodukteverordnung (EU) 2017/745 (in Anwendung der Übergangsbestimmungen MDR Art. 120 (3a)) und gegebenenfalls mit anderen einschlägigen Rechtsvorschriften der Union, die die Ausstellung einer EU-Konformitätserklärung vorsehen, übereinstimmen.

Gemäß EU 2023/607 hat die benannte Stelle (TÜV SÜD Product Service GmbH) das Bestätigungsschreiben CL 045283 0028 Rev. 00 ausgestellt, mit dem die Übergangsfrist bis zum 31.12.2028 verlängert wird.

- C) Produktfamilie: treadmill h/p/cosmos 150/50 (locomotion)
- D) Produktfamilie: treadmill h/p/cosmos 150/50 G6
- E) Produktfamilie family: treadmill h/p/cosmos 170-190/65
- F) Produktfamilie: treadmill h/p/cosmos 170-190/65 3p
- G) Produktfamilie treadmill h/p/cosmos 200-300/75-125

Das  0123 Zeichen wird auf den Produkten angebracht.

Diese Konformitätserklärung ist ein wichtiger Bestandteil unseres zertifizierten Qualitätsmanagementsystems gemäß der Norm ISO 13485 und gilt für alle oben aufgeführten Geräte, die von h/p/cosmos am oder nach dem 8. Juli 2025 hergestellt wurden.

Die Gültigkeit dieser Konformitätserklärung erlischt mit der Veröffentlichung einer neuen Konformitätserklärung, wenn dies aufgrund technischer Änderungen oder aufgrund gesetzlicher Änderungen der Normen und Standards erforderlich ist – spätestens jedoch mit Ablauf der Gültigkeitsdauer des EU-Qualitätsmanagementsystem-Zertifikats gemäß der Medizinprodukteverordnung (EU) 2017/745 mit der Zertifikatsnummer G10 045283 0027 Rev. 00 am 17.11.2027.

Auf der Grundlage der Richtlinie 2011/65/EU und (EU) 2015/863 (RoHS) sowie der Verordnung (EU) 2020/2096 (REACH)

Dieses Dokument bestätigt außerdem, dass nach aktuellem Kenntnisstand alle Rohstoffe, Teilkomponenten und Fertigprodukte, die im Herstellungsprozess der Produkte der h/p/cosmos sports & medical gmbh verwendet werden, den Anforderungen der Richtlinie 2011/65/EU und (EU) 2015/863 (RoHS) sowie der Verordnung (EU) 2020/2096 (REACH) zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe entsprechen.

Die h/p/cosmos sports & medical gmbh führt keine Tests an Komponenten durch und stützt sich bei der Erklärung der RoHS- und REACH-Konformität ausschließlich auf die von ihren Lieferanten bereitgestellten Informationen, Bestätigungen und Zertifikate.

Im Rahmen unserer Zertifizierung nach ISO 13485 stehen wir in ständigem Dialog mit unseren Lieferanten, auch um sicherzustellen, dass alle gelieferten Produkte RoHS- und REACH-konform sind.

BioComp-Erklärung:

Die h/p/cosmos sports & medical gmbh bestätigt die Biokompatibilität aller Produkte bei bestimmungsgemäßer Verwendung. Aufgrund langjähriger Erfahrung hat h/p/cosmos auf eine Einzelprüfung aller Komponenten gemäß ISO 10993 „Biologische Bewertung von Medizinprodukten“ verzichtet und erklärt, dass kein inakzeptables Risiko durch Hautkontakt mit irgendeinem Teil des Produkts besteht.

DE 83365 Nussdorf-Traunstein, 8. Juli 2025

Unterszeichnet für und im Namen von h/p/cosmos sports & medical gmbh



Alexander Böck
Geschäftsführer



Nadine Schott
Qualitätsmanagerin und PRRC



Joschka Zimmer
Produktmanager und zur Erstellung der technischen Unterlagen befugte Person



Déclaration de conformité UE

attribué aux appareils médicaux et aux équipements de rééducation



Fabricant légal:

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**

organisme notifié:

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

produit:

Tapis roulant (machine à courir), y compris les options, les accessoires et les pièces détachées

Classification MDR (UE) 2017/745	<p>Classe de risque IIb selon la règle de classification 9 Les règles de classification 9 et la sous-règle 10 de l'annexe VIII, chapitres II et III, du règlement MDR s'appliquent.</p> <ul style="list-style-type: none"> • Les tapis roulants médicaux sont • des dispositifs médicaux actifs de classe IIb, classés comme • des dispositifs thérapeutiques actifs • et également comme • des dispositifs actifs destinés au diagnostic et à la surveillance
Évaluation de la conformité sur la base du RMD	<ul style="list-style-type: none"> • 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.
Certificat de système de gestion de la qualité de l'UE (MDR)	<p>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</p>
Classification selon ISO 20957-1	S, I
Classification selon ISO 20957-6	A
EUDAMED Code EMDN	Z129006 TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
Code UMDNS	14-141 Running Machine
Codes GMDN	33015 EXERCISER, TREADMILL, LINE-POWERED
Codes MDR	<p>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 MDT 2001: Devices manufactured using metal processing</p>

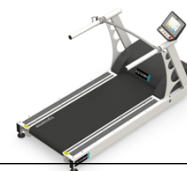
	MDT 2011: Devices which require packaging, including labelling
Objectif visé	<p>Les ergomètres médicaux sont destinés à</p> <ul style="list-style-type: none"> • Entraînement récréatif de la condition physique (y compris les athlètes) • Entraînement à la marche (avec ou sans soutien du poids du corps) <p>Les ergomètres médicaux peuvent être utilisés en combinaison avec des dispositifs externes pour la marche ou la course sur place en tant que</p> <ul style="list-style-type: none"> • Dispositifs de contrainte pour les mesures neuromusculaires et biomécaniques (par exemple EEG, EMG, analyse du mouvement) • Dispositifs de contrainte pour les mesures cardiovasculaires (par exemple ECG) • Dispositifs de contrainte pour les mesures cardio-pulmonaires (par exemple, ergospirométrie)
toute spécification commune (« CS ») (autre qu'une norme, voir l'article 9 MDR)	sans objet N/A
Durée d'utilisation prévue	peut suivre les deux, selon la prescription du médecin : Transitoire : Normalement destiné à une utilisation continue de moins de 60 minutes Court terme : Normalement destiné à une utilisation continue entre 60 minutes et 30 jours.
Mode d'emploi IFU téléchargeable	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Mise à jour des informations relatives à la sécurité, telles que les avis de sécurité sur le terrain (FSN), les actions correctives de sécurité sur le terrain (FSCA), etc. sur le site web.	https://www.hpcosmos.com/en/safety



A) famille de produits: treadmill h/p/cosmos 150/50 G7 (pluto, mercury)

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

article #	model name	UDI-DI
cos31002	pluto® lt med	40505880035862
cos31004	pluto® lt med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
cos31024	pluto® med OEM	40505880036852
cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) famille de produits: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

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

cos30003-01va04	quasar® It med	40505880030294
cos30003-01va08	quasar® med OEM	40505880029786
cos30004-01va04	pulsar® It med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) famille de produits: treadmill h/p/cosmos 150/50 (locomotion) (en application des dispositions transitoires MDR Art. 120 (3a))

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



D) famille de produits: treadmill h/p/cosmos 150/50 (pluto, mercury) (en application des dispositions transitoires MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® It med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® It med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



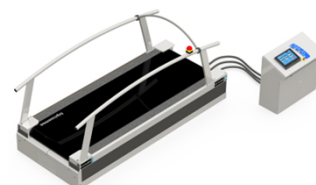
E) famille de produits: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (en application des dispositions transitoires MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va17	stellar® lt med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® lt med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® lt	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) famille de produits: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (en application des dispositions transitoires MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® lt 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) famille de produits: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (en application des dispositions transitoires MDR Art. 120 (3a))

article #	model name	UDI-DI
cos30005-01va05	venus® 200/75	40505880015758
cos30005-01va06	venus® 200/75r	40505880016298
cos30006-01va05	venus® 200/100	40505880016748
cos30006-01va06	venus® 200/100r	40505880016816
cos30007-01va05	saturn® 250/75	40505880017356
cos30007-01va06	saturn® 250/75r	40505880017424
cos30008-01va05	saturn® 250/100	40505880017974
cos30008-01va06	saturn® 250/100r	40505880018032
cos30009-01va03	saturn® 250/125r	40505880018346
cos30010-01va05	saturn® 300/75	40505880018896
cos30010-01va06	saturn® 300/75r	40505880018964
cos30011-01va05	saturn® 300/100	40505880019404
cos30011-01va06	saturn® 300/100r	40505880019572
cos30012-01va03	saturn® 300/125r	40505880019886

règlements et normes:

Numéro de référence	Date d'émission	Titre
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

Nous déclarons sous notre seule responsabilité que les dispositifs suivants, couverts par la présente déclaration, sont conformes au règlement (UE) 2017/745 relatif aux dispositifs médicaux (MDR) et, le cas échéant, à toute autre législation pertinente de l'Union prévoyant la délivrance d'une déclaration de conformité UE.

A) famille de produits: treadmill h/p/cosmos 150/50 G7

B) famille de produits: treadmill h/p/cosmos 170-190/65 MCU6

Nous déclarons sous notre seule responsabilité que les dispositifs suivants, couverts par la présente déclaration, sont conformes au règlement (UE) 2017/745 relatif aux dispositifs médicaux (en application des dispositions transitoires de l'article 120, paragraphe 3 bis, du règlement MDR) et, le cas échéant, à toute autre législation pertinente de l'Union prévoyant la délivrance d'une déclaration de conformité UE.

Conformément à la décision UE 2023/607, l'organisme notifié (TÜV SÜD Product Service GmbH) a émis la lettre de confirmation CL 045283 0028 Rev. 00, prolongeant la période de transition jusqu'au 31 décembre 2028.

C) famille de produits: treadmill h/p/cosmos 150/50 (locomotion)

D) famille de produits: treadmill h/p/cosmos 150/50 G6

E) famille de produits: treadmill h/p/cosmos 170-190/65

F) famille de produits: treadmill h/p/cosmos 170-190/65 3p

G) famille de produits: treadmill h/p/cosmos 200-300/75-125

The  0123 mark gets affixed to the products.

Cette déclaration de conformité est un élément important de notre système de gestion de la qualité certifié selon la norme ISO 13485 et s'applique à tous les dispositifs mentionnés ci-dessus qui ont été fabriqués par h/p/cosmos à compter du 8 juillet 2025.

La validité de cette déclaration de conformité expire avec la publication d'une nouvelle déclaration de conformité si celle-ci est requise en raison de modifications techniques ou de modifications juridiques des normes et standards – toutefois, au plus tard à la date d'expiration du certificat du système de gestion de la qualité de l'UE conformément au règlement sur les dispositifs médicaux (UE) 2017/745, portant le numéro G10 045283 0027 Rev. 00, le 17 novembre 2027.

Sur la base de la directive 2011/65/UE et (UE) 2015/863 (RoHS) et du règlement (UE) 2020/2096 (REACH)

Ce document confirme également que, selon les connaissances actuelles, toutes les matières premières, les composants partiellement finis et les produits finis utilisés dans le processus de fabrication des produits h/p/cosmos sports & medical gmbh sont conformes aux exigences de la directive 2011/65/UE et (UE) 2015/863 (RoHS) et du règlement (UE) 2020/2096 (REACH) relatives à la limitation de l'utilisation de certaines substances dangereuses.

h/p/cosmos sports & medical gmbh n'effectue aucun test sur les composants et se fie uniquement aux informations, confirmations et certificats fournis par ses fournisseurs pour déclarer la conformité RoHS et REACH.

Dans le cadre de notre certification selon la norme ISO 13485, nous sommes en dialogue constant avec nos fournisseurs, notamment pour garantir que tous les produits livrés sont conformes aux directives RoHS et REACH.

Déclaration BioComp :

h/p/cosmos sports & medical gmbh confirme la biocompatibilité de tous les produits destinés à être utilisés conformément à leur usage prévu. Sur la base de sa longue expérience, h/p/cosmos s'est abstenu de tester individuellement tous les composants conformément à la norme ISO 10993 « Évaluation biologique des dispositifs médicaux » et déclare qu'il n'existe aucun risque inacceptable résultant du contact cutané avec une quelconque partie du dispositif.

DE 83365 Nussdorf-Traunstein, le 8 juillet 2025

Signé pour et au nom de h/p/cosmos sports & medical gmbh



Alexander Böck
Directeur général



Nadine Schott
Responsable qualité et PRRC



Joschka Zimmer
Chef de produit et personne habilitée à constituer le dossier technique

ES atbilstības deklarācija

piešķirts medicīnas un rehabilitācijas iekārtu ierīcēm



Juridisks ražotājs:

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**

paziņotā iestāde:

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

produkts:

Skrejceļš, ieskaitot papildus aprīkojumu, piederumus un rezerves daļas

Atbilstības novērtēšana, pamatojoties uz MDR	<p>Risk class IIb based on classification rule 9</p> <p>classification rules 9 and sub-rule 10 of MDR Annex VIII chapter II and III apply.</p> <p>Medical treadmills are</p> <ul style="list-style-type: none"> • class IIb active medical devices, classified as • active therapeutic devices and also • active devices intended for diagnosis and monitoring
Atbilstības novērtēšana, pamatojoties uz MDR	<ul style="list-style-type: none"> • 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.
ES kvalitātes vadības sistēmas sertifikāts (MDR)	<p>No. G10 045283 0027 Rev. 00</p> <p>valid until November 17, 2027</p> <p>https://www.hpcosmos.com/sites/default/files/uploads/documents/20221118_hpcosmos_tuev_sued_mdr_eu2017-745_certificate_g100452830027_rev.00_en.pdf</p>
Klasifikācija saskaņā ar ISO 20957-1	S, I
Klasifikācija saskaņā ar ISO 20957-6	A
EUDAMED EMDN kods	Z129006 TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
UMDNS kods	14-141 Running Machine
GMDN kods	33015 EXERCISER, TREADMILL, LINE-POWERED
MDR kods	<p>MDA 0313: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</p> <p>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.</p> <p>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</p> <p>MDT 2001: Devices manufactured using metal processing</p> <p>MDT 2011: Devices which require packaging, including labelling</p>

Paredzētais mērķis	<p>medicīniskie ergometri ir paredzēti</p> <ul style="list-style-type: none"> • Atpūtas fitnesa treniņiem (tostarp sportistiem) • Gaitas treniņiem (ar vai bez ķermeņa svara atbalsta) <p>medicīniskos ergometrus var izmantot kopā ar ārējām ierīcēm, lai staigātu vai skrietu uz vietas kā</p> <ul style="list-style-type: none"> • Stresa ierīces neuro-muskuļu un biomehāniskajiem mērījumiem (piemēram, EEG, EMG, kustību analīze) • Stresa ierīcēm kardiovaskulāriem mērījumiem (piemēram, EKG) • Stresa ierīcēm kardiopulmonāliem mērījumiem (piemēram, ergospirometrija)
jebkādas kopējās specifikācijas („CS”) (izņemot standartu, skatīt MDR 9. pantu)	nepiemērojams N/A
Plānotais lietošanas ilgums	<p>atkarībā no ārsta norādījumiem var būt gan pārejošs, gan ilgstošs: Pārejošs: parasti paredzēts nepārtrauktai lietošanai mazāk nekā 60 minūtes. Īslaicīgs: parasti paredzēts nepārtrauktai lietošanai no 60 minūtēm līdz 30 dienām.</p>
IFU lietošanas instrukcijas lejupielādējamas	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Atjaunināta drošības informācija, piemēram, drošības paziņojumi FSN, drošības korektīvie pasākumi FSCA utt. tīmekļa vietnē	https://www.hpcosmos.com/en/safety



A) produktu grupa: treadmill h/p/cosmos 150/50 G7 (pluto, mercury)

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

raksts #	modeļa nosaukums	UDI-DI
cos31002	pluto® lt med	40505880035862
cos31004	pluto® lt med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
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cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) produktu grupa: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

raksts #	modeļa nosaukums	UDI-DI
cos30003-01va02	quasar® med	40505880029540
cos30003-01va06	stellar® med	40505880030058
cos30004-01va02	pulsar® med	40505880030812
cos30004-01va06	stellar® 190/65 med	40505880031284
cos30003-01va04	quasar® lt med	40505880030294
cos30003-01va08	quasar® med OEM	40505880029786
cos30004-01va04	pulsar® lt med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) produktu grupa: treadmill h/p/cosmos 150/50 (locomotion) (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a)

raksts #	modeļa nosaukums	UDI-DI
cos30001-01va02	locomotion® 150/50 DE med	40505880023050



D) produktu grupa: treadmill h/p/cosmos 150/50 (pluto, mercury) (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktu)

raksts #	modeļa nosaukums	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® lt med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® lt med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



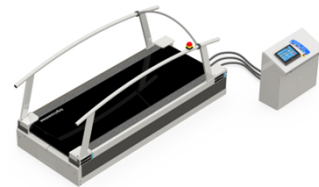
E) produktu grupa: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktu)

raksts #	modeļa nosaukums	UDI-DI
cos30003va17	stellar® It med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® It med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® It	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) produktu grupa: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktu)

raksts #	modeļa nosaukums	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® It 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) produktu grupa: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktu)

raksts #	modeļa nosaukums	UDI-DI
cos30005-01va05	venus [®] 200/75	40505880015758
cos30005-01va06	venus [®] 200/75r	40505880016298
cos30006-01va05	venus [®] 200/100	40505880016748
cos30006-01va06	venus [®] 200/100r	40505880016816
cos30007-01va05	saturn [®] 250/75	40505880017356
cos30007-01va06	saturn [®] 250/75r	40505880017424
cos30008-01va05	saturn [®] 250/100	40505880017974
cos30008-01va06	saturn [®] 250/100r	40505880018032
cos30009-01va03	saturn [®] 250/125r	40505880018346
cos30010-01va05	saturn [®] 300/75	40505880018896
cos30010-01va06	saturn [®] 300/75r	40505880018964
cos30011-01va05	saturn [®] 300/100	40505880019404
cos30011-01va06	saturn [®] 300/100r	40505880019572
cos30012-01va03	saturn [®] 300/125r	40505880019886

noteikumi un standarti:

Atsauces numurs	Izdošanas datums	Nosaukums
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

Ar šo mēs uzņemamies pilnu atbildību un apliecinām, ka šajā deklarācijā minētās ierīces atbilst šai MDR Medicīnas ierīču regulai (ES) 2017/745 un, ja piemērojams, jebkuriem citiem attiecīgiem Savienības tiesību aktiem, kas paredz ES atbilstības deklarācijas izsniegšanu.

- A) produktu grupa: treadmill h/p/cosmos 150/50 G7
- B) produktu grupa: treadmill h/p/cosmos 170-190/65 MCU6

Ar šo mēs uzņemamies pilnu atbildību un apliecinām, ka šajā deklarācijā minētās ierīces atbilst MDR Medicīnas ierīču regulai (ES) 2017/745 (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktā) un, ja piemērojams, jebkuriem citiem attiecīgiem Savienības tiesību aktiem, kas paredz ES atbilstības deklarācijas izsniegšanu.

Saskaņā ar ES 2023/607 paziņotā iestāde (TÜV SÜD Product Service GmbH) izsniedza apstiprinājuma vēstuli CL 045283 0028 Rev. 00, pagarinot pārejas periodu līdz 2028. gada 31. decembrim.

- C) produktu grupa: treadmill h/p/cosmos 150/50 (locomotion)
- D) produktu grupa: treadmill h/p/cosmos 150/50 G6
- E) produktu grupa: treadmill h/p/cosmos 170-190/65
- F) produktu grupa: treadmill h/p/cosmos 170-190/65 3p
- G) produktu grupa: treadmill h/p/cosmos 200-300/75-125

Produktiem tiek pievienota  0123 zīme.

Šī atbilstības deklarācija ir svarīga daļa no mūsu sertificētās kvalitātes vadības sistēmas saskaņā ar ISO 13485 standartu, un tā ir spēkā visām iepriekš minētajām ierīcēm, kuras h/p/cosmos ir ražojis 2025. gada 8. jūlijā vai pēc šā datuma.

Šīs atbilstības deklarācijas derīgums beidzas ar jaunas atbilstības deklarācijas izdošanu, ja tas nepieciešams tehnisku grozījumu vai normu un standartu juridisku grozījumu dēļ, bet ne vēlāk kā ES kvalitātes vadības sistēmas sertifikāta derīguma termiņa beigās saskaņā ar medicīnas ierīču regulu (ES) 2017/745 ar sertifikāta numuru G10 045283 0027 Rev. 00 2027. gada 17. novembrī.

Pamatojoties uz Direktīvu 2011/65/ES un (ES) 2015/863 (RoHS) un Regulu (ES) 2020/2096 (REACH)

Šis dokuments arī apstiprina, ka saskaņā ar pašreizējām zināšanām visas izejvielas, daļēji pabeigtie komponenti un gatavie izstrādājumi, kas tiek izmantoti h/p/cosmos sports & medical gmbh izstrādājumu ražošanas procesā, atbilst Direktīvas 2011/65/ES un (ES) 2015/863 (RoHS) un Regulas (ES) 2020/2096 (REACH) noteiktām prasībām par dažu bīstamu vielu lietošanas ierobežojumiem.

h/p/cosmos sports & medical gmbh neveic komponentu testēšanu un RoHS un REACH atbilstības deklarēšanai paļaujas vienīgi uz informāciju, apstiprinājumiem un sertifikātiem, ko sniedz tā piegādātāji.

Saskaņā ar mūsu sertifikāciju atbilstoši ISO 13485 mēs pastāvīgi uzturam dialogu ar saviem piegādātājiem, lai nodrošinātu, ka visi piegādātie produkti atbilst RoHS un REACH prasībām.

BioComp paziņojums:

h/p/cosmos sports & medical gmbh apstiprina visu produktu bioloģisko saderību ar paredzēto lietojumu. Pamatojoties uz ilgstošas pieredzes liecībām, h/p/cosmos atturējās no atsevišķu komponentu testēšanas saskaņā ar ISO 10993 „Medicīnisko ierīču bioloģiskā novērtēšana” un paziņo, ka nav pieļaujama nekāda riska, kas varētu rasties no saskares ar ādu jebkurai ierīces daļai.

DE 83365 Nussdorf-Traunstein, July 8, 2025

parakstīts h/p/cosmos sports & medical gmbh vārdā un uzdevumā



Alexander Böck
izpilddirektors



Nadine Schott
Kvalitātes vadītājs un PRRC



Joschka Zimmer
Produktu vadītājs un persona, kas pilnvarota
sastādīt tehnisko dokumentāciju



EU izjava o skladnosti

dodeljeno napravam medicinske in rehabilitacijske opreme



Zakoniti proizvajalec: **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**

notificirani organ: **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

izdelek: **Tekalna steza (tekalni stroj) vključno z dodatki, priborom in rezervnimi deli**

Razvrstitev 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 <ul style="list-style-type: none"> • class IIb active medical devices, classified as • active therapeutic devices and also • active devices intended for diagnosis and monitoring
Ocena skladnosti na podlagi MDR	<ul style="list-style-type: none"> • 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.
Certifikat sistema vodenja kakovosti EU (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
Razvrstitev v skladu s standardom ISO 20957-1	S, I
Razvrstitev v skladu s standardom ISO 20957-6	A
EUDAMED Koda EMDN	Z129006 TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
Koda UMDNS	14-141 Running Machine
Kode GMDN	33015 EXERCISER, TREADMILL, LINE-POWERED
Kode MDR	<p>MDA 0313: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</p> <p>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.</p> <p>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</p> <p>MDT 2001: Devices manufactured using metal processing</p> <p>MDT 2011: Devices which require packaging, including labelling</p>

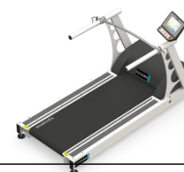
Predvideni namen	<p>medicinski ergometri so namenjeni za</p> <ul style="list-style-type: none"> rekreativno vadbo v fitnesu (vključno s športniki) Trening hoje (s podporo telesne teže ali brez nje) <p>medicinski ergometri se lahko uporabljajo v kombinaciji z zunanjimi napravami za hojo ali tek na mestu kot</p> <ul style="list-style-type: none"> Napetostne naprave za živčno-mišične in biomehanske meritve (npr. EEG, EMG, analiza gibanja) obremenilne naprave za meritve srca in ožilja (npr. EKG) obremenilne naprave za kardiopulmonalne meritve (npr. ergospirometrija)
vse skupne specifikacije („CS“) (razen standarda, glej člen 9 MDR).	se ne uporablja N/A
Predvideno trajanje uporabe	lahko oboje, odvisno od zdravnikovega recepta: Prehodno: Običajno je namenjena neprekinjeni uporabi za manj kot 60 minut Kratkotrajna: Običajno je namenjena neprekinjeni uporabi med 60 minutami in 30 dnevi
IFU navodila za uporabo, ki jih je mogoče prenesti	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Posodobljene varnostne informacije , kot so obvestila o varnosti na terenu FSN, korektivni ukrepi za varnost na terenu FSCA itd. na spletni strani	https://www.hpcosmos.com/en/safety



A) produktu grupa: treadmill h/p/cosmos 150/50 G7 (pluto, mercury)

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

članek #	ime modela	UDI-DI
cos31002	pluto® lt med	40505880035862
cos31004	pluto® lt med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
cos31024	pluto® med OEM	40505880036852
cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) produktu grupa: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

članek #	ime modela	UDI-DI
cos30003-01va02	quasar® med	40505880029540
cos30003-01va06	stellar® med	40505880030058
cos30004-01va02	pulsar® med	40505880030812
cos30004-01va06	stellar® 190/65 med	40505880031284
cos30003-01va04	quasar® lt med	40505880030294

cos30003-01va08	quasar® med OEM	40505880029786
cos30004-01va04	pulsar® lt med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) produktu grupa: treadmill h/p/cosmos 150/50 (locomotion) (ob uporabi prehodnih določb MDR, čl. 120 (3a))

članek #	ime modela	UDI-DI
cos30001-01va02	locomotion® 150/50 DE med	40505880023050



D) produktu grupa: treadmill h/p/cosmos 150/50 (pluto, mercury) (ob uporabi prehodnih določb MDR, čl. 120 (3a))

članek #	ime modela	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® lt med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® lt med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



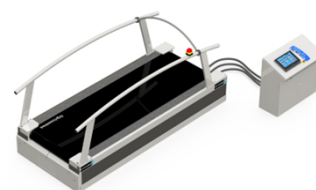
E) produktu grupa: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (ob uporabi prehodnih določb MDR, čl. 120 (3a))

članek #	ime modela	UDI-DI
cos30003va17	stellar® lt med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® lt med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® lt	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) produktu grupa: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (ob uporabi prehodnih določb MDR, čl. 120 (3a))

članek #	ime modela	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® lt 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) produktu grupa: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (ob uporabi prehodnih določb MDR, čl. 120 (3a))

članek #	ime modela	UDI-DI
cos30005-01va05	venus® 200/75	40505880015758
cos30005-01va06	venus® 200/75r	40505880016298
cos30006-01va05	venus® 200/100	40505880016748
cos30006-01va06	venus® 200/100r	40505880016816
cos30007-01va05	saturn® 250/75	40505880017356
cos30007-01va06	saturn® 250/75r	40505880017424
cos30008-01va05	saturn® 250/100	40505880017974
cos30008-01va06	saturn® 250/100r	40505880018032
cos30009-01va03	saturn® 250/125r	40505880018346
cos30010-01va05	saturn® 300/75	40505880018896
cos30010-01va06	saturn® 300/75r	40505880018964
cos30011-01va05	saturn® 300/100	40505880019404
cos30011-01va06	saturn® 300/100r	40505880019572
cos30012-01va03	saturn® 300/125r	40505880019886

noteikumi un standarti:

Referenčna številka	Datum izdaje	Naslov
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

Ar šo mēs uzņemamies pilnu atbildību un apliecinām, ka šajā deklarācijā minētās ierīces atbilst MDR Medicīnas ierīču regulai (ES) 2017/745 un, ja piemērojams, jebkuriem citiem attiecīgiem Savienības tiesību aktiem, kas paredz ES atbilstības deklarācijas izsniegšanu.

A) produktu grupa: treadmill h/p/cosmos 150/50 G7

B) produktu grupa: treadmill h/p/cosmos 170-190/65 MCU6

Ar šo mēs uzņemamies pilnu atbildību un apliecinām, ka šajā deklarācijā minētās ierīces atbilst MDR Medicīnas ierīču regulai (ES) 2017/745 (piemērojot pārejas noteikumus MDR 120. panta 3. punkta a) apakšpunktā) un, ja piemērojams, jebkuriem citiem attiecīgiem Savienības tiesību aktiem, kas paredz ES atbilstības deklarācijas izsniegšanu.

Saskaņā ar ES 2023/607 paziņotā iestāde (TÜV SÜD Product Service GmbH) izsniedza apstiprinājuma vēstuli CL 045283 0028 Rev. 00, pagarinot pārejas periodu līdz 2028. gada 31. decembrim.

C) produktu grupa: treadmill h/p/cosmos 150/50 (locomotion)

D) produktu grupa: treadmill h/p/cosmos 150/50 G6

E) produktu grupa: treadmill h/p/cosmos 170-190/65

F) produktu grupa: treadmill h/p/cosmos 170-190/65 3p

G) produktu grupa: treadmill h/p/cosmos 200-300/75-125

Produktiem tiek pievienota  0123 zīme.

Šī atbilstības deklarācija ir svarīga daļa no mūsu sertificētās kvalitātes vadības sistēmas saskaņā ar ISO 13485 standartu, un tā ir spēkā visām iepriekš minētajām ierīcēm, kuras h/p/cosmos ir ražojis 2025. gada 8. jūlijā vai pēc šā datuma.

Šīs atbilstības deklarācijas derīgums beidzas ar jaunas atbilstības deklarācijas izdošanu, ja tas nepieciešams tehnisku grozījumu vai normu un standartu juridisku grozījumu dēļ, bet ne vēlāk kā ES kvalitātes vadības sistēmas sertifikāta derīguma termiņa beigās saskaņā ar medicīnas ierīču regulu (ES) 2017/745 ar sertifikāta numuru G10 045283 0027 Rev. 00 2027. gada 17. novembrī.

Na podlagi direktiv 2011/65/EU in (EU) 2015/863 (RoHS) ter Uredbe (EU) 2020/2096 (REACH)

Ta dokument tudi potrjuje, da po trenutnem znanju vse surovine, polizdelki in končni izdelki, ki se uporabljajo v proizvodnem procesu izdelkov podjetja h/p/cosmos sports & medical gmbh, izpolnjujejo zahteve direktiv 2011/65/EU in (EU) 2015/863 (RoHS) ter Uredbe (EU) 2020/2096 (REACH) glede omejitev uporabe nekaterih nevarnih snovi.

Podjetje h/p/cosmos sports & medical gmbh ne izvaja testiranja sestavnih delov in se pri izjavi o skladnosti z RoHS in REACH zanaša izključno na informacije, odobritve in certifikate, ki jih zagotovijo dobavitelji.

V skladu z našim certifikatom ISO 13485 vzdržujemo stalen dialog z dobavitelji, da bi zagotovili skladnost vseh dobavljenih izdelkov z RoHS in REACH.

Izjava o biokompatibilnosti:

h/p/cosmos sports & medical gmbh potrjuje biokompatibilnost vseh izdelkov za predvideno uporabo. Podjetje h/p/cosmos se je na podlagi dokazov iz dolgoletnih izkušenj vzdržalo testiranja posameznih sestavnih delov v skladu s standardom ISO 10993 „Biološko vrednotenje medicinskih pripomočkov“ in izjavlja, da tveganje zaradi stika s kožo ni sprejemljivo za noben del pripomočka.

DE 83365 Nussdorf-Traunstein, 8. julij 2025

podpisano za in v imenu družbe h/p/cosmos sports & medical gmbh



Alexander Böck
Izvršni direktor



Nadine Schott
Vodja kakovosti in PRRC



Joschka Zimmer
Vodja izdelka in oseba, pooblaščen za pripravo tehnične dokumentacije



AB uygunluk beyanı

tıbbi ve rehabilitasyon ekipmanlarına atanan cihazlar

CE 0123



Yasal üretici:

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**

onaylanmış kuruluş:

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

ürün:

Koşu bandı (koşu makinesi), seçenekler, aksesuarlar ve yedek parçalar dahil

Sınıflandırma MDR (AB) 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 <ul style="list-style-type: none">• class IIb active medical devices, classified as• active therapeutic devices and also• active devices intended for diagnosis and monitoring
MDR'ye dayalı uygunluk değerlendirmesi	<ul style="list-style-type: none">• 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) <ul style="list-style-type: none">• Chapter III (ADMINISTRATIVE PROVISIONS) archiving period for documentation.
AB Kalite Yönetim Sistemi Sertifikası (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
ISO 20957-1'e göre sınıflandırma	S, I
ISO 20957-6'ya göre sınıflandırma	A
EUDAMED EMDN Kodu	Z129006 TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
UMDNS Kodu	14-141 Running Machine
GMDN Kodu	33015 EXERCISER, TREADMILL, LINE-POWERED
MDR Kodu	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 MDT 2001 : Devices manufactured using metal processing MDT 2011 : Devices which require packaging, including labelling

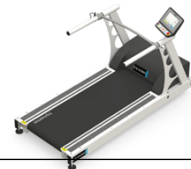
Amaçlanan amaç	Tıbbi ergometreler aşağıdaki amaçlar için tasarlanmıştır <ul style="list-style-type: none"> • Rekreatif fitness eğitimi (sporcular dahil) • Yürüyüş eğitimi (vücut ağırlığı desteği ile veya olmadan) Tıbbi ergometreler, yerinde yürüme veya koşma için harici cihazlarla birlikte aşağıdaki amaçlarla kullanılabilir <ul style="list-style-type: none"> • Nöromusküler ve biyomekanik ölçümler için stres cihazları (ör. EEG, EMG, hareket analizi) • Kardiyovasküler ölçümler için stres cihazları (örn. EKG) • Kardiyopulmoner ölçümler için stres cihazları (örn. ergospirometri)
herhangi bir Ortak Spesifikasyon ("CS") (standart hariç, bkz. MDR Madde 9)	uygulanamaz N/A
Kullanım süresi	Tıbbi doktorun reçetesine bağlı olarak her ikisi de uygulanabilir: Geçici: Normalde 60 dakikadan az süreli sürekli kullanım için tasarlanmıştır. Kısa süreli: Normalde 60 dakika ile 30 gün arasında sürekli kullanım için tasarlanmıştır.
IFU kullanım talimatları indirilebilir	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Web sitesinde FSN (Saha Güvenliği Bildirimleri), FSCA (Saha Güvenliği Düzeltici Eylemler) vb. gibi güncellenmiş güvenlik bilgileri	https://www.hpcosmos.com/en/safety



A) ürün ailesi: treadmill h/p/cosmos 150/50 G7 (pluto, mercury)

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

makale #	model adı	UDI-DI
cos31002	pluto® lt med	40505880035862
cos31004	pluto® lt med OEM	40505880036098
cos31012	pluto® ef med	40505880036234
cos31014	pluto® ef med OEM	40505880036470
cos31022	pluto® med	40505880036616
cos31024	pluto® med OEM	40505880036852
cos31032	stratos® med	40505880037088
cos31034	stratos® med OEM	40505880037224
cos31042	mercury® med	40505880037460
cos31044	mercury® med OEM	40505880037606



B) ürün ailesi: treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar)

Basic UDI-DI code: 4050588cos30003-015X / GTIN-14 GS1

makale #	model adı	UDI-DI
cos30003-01va02	quasar® med	40505880029540
cos30003-01va06	stellar® med	40505880030058
cos30004-01va02	pulsar® med	40505880030812
cos30004-01va06	stellar® 190/65 med	40505880031284
cos30003-01va04	quasar® lt med	40505880030294
cos30003-01va08	quasar® med OEM	40505880029786

cos30004-01va04	pulsar® lt med	40505880031420
cos30004-01va08	pulsar® med OEM	40505880031048



C) ürün ailesi: treadmill h/p/cosmos 150/50 (locomotion) (geçiş hükümlerinin uygulanmasında MDR Md. 120 (3a))

makale #	model adı	UDI-DI
cos30001-01va02	locomotion® 150/50 DE med	40505880023050



D) ürün ailesi: treadmill h/p/cosmos 150/50 (pluto, mercury) (geçiş hükümlerinin uygulanmasında MDR Md. 120 (3a))

makale #	model adı	UDI-DI
cos30026-01va02	pluto® med	40505880023364
cos30026-01va14	pluto® med OEM	40505880031734
cos30027-01va02	pluto® lt med	40505880024354
cos30027-01va14	pluto® ef med	40505880025658
cos30027-01va16	pluto® lt med OEM	40505880032106
cos30000-02va02	mercury® med	40505880026020
cos30000-02va10	stratos® med	40505880028932
cos30000-02va12	mercury® med OEM	40505880031970



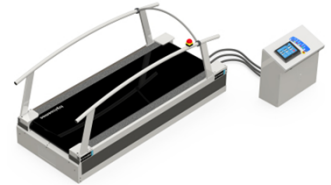
E) ürün ailesi: treadmill h/p/cosmos 170-190/65 (quasar, pulsar) (geçiş hükümlerinin uygulanmasında MDR Md. 120 (3a))

makale #	model adı	UDI-DI
cos30003va17	stellar® lt med	40505880004936
cos30003va18	stellar® med	40505880005094
cos30003va19	quasar® lt med	40505880005162
cos30003va20	quasar® med	40505880005230
cos30004va01	pulsar® lt	40505880005544
cos30004va02	pulsar®	40505880005780
cos30024va01	locomotion® 190/65 E med	40505880020844
cos30024va03	locomotion® 190/65 DE med	40505880021070



F) ürün ailesi: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p) (geçiş hükümlerinin uygulanmasında MDR Md. 120 (3a))

makale #	model adı	UDI-DI
cos30003va26	quasar® med 3p	40505880015444
cos30004va02	pulsar® lt 3p	40505880005612
cos30004va04	pulsar® 3p	40505880005858
cos30024va02	locomotion® 190/65 3p E med	40505880020912
cos30024va04	locomotion® 190/65 3p DE med	40505880021148



G) ürün ailesi: treadmill h/p/cosmos 200-300/75-125 (venus, saturn) (geçiş hükümlerinin uygulanmasında MDR Md. 120 (3a))

makale #	model adı	UDI-DI
cos30005-01va05	venus® 200/75	40505880015758
cos30005-01va06	venus® 200/75r	40505880016298
cos30006-01va05	venus® 200/100	40505880016748
cos30006-01va06	venus® 200/100r	40505880016816
cos30007-01va05	saturn® 250/75	40505880017356
cos30007-01va06	saturn® 250/75r	40505880017424
cos30008-01va05	saturn® 250/100	40505880017974
cos30008-01va06	saturn® 250/100r	40505880018032
cos30009-01va03	saturn® 250/125r	40505880018346
cos30010-01va05	saturn® 300/75	40505880018896
cos30010-01va06	saturn® 300/75r	40505880018964
cos30011-01va05	saturn® 300/100	40505880019404
cos30011-01va06	saturn® 300/100r	40505880019572
cos30012-01va03	saturn® 300/125r	40505880019886

yönetmelikler ve standartlar:

Referans Numarası	Yayın Tarihi	Başlık
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

İşbu belge ile, aşağıda belirtilen ve bu beyanın kapsamına giren cihazların, MDR Tıbbi Cihaz Yönetmeliği (AB) 2017/745 ile ve varsa, AB uygunluk beyanının düzenlenmesini öngören diğer ilgili Birlik mevzuatı ile uyumlu olduğunu, tüm sorumluluk bize ait olmak üzere beyan ederiz.

A) ürün ailesi: treadmill h/p/cosmos 150/50 G7

B) ürün ailesi: treadmill h/p/cosmos 170-190/65 MCU6

İşbu belge ile, aşağıda belirtilen cihazların, işbu beyanın kapsamına giren cihazlar olup, MDR Tıbbi Cihaz Yönetmeliği (AB) 2017/745 (MDR Madde 120 (3a) geçiş hükümlerinin uygulanmasıyla) ile ve varsa, AB uygunluk beyanının düzenlenmesini öngören diğer ilgili Birlik mevzuatı ile uyumlu olduğunu, tamamen kendi sorumluluğumuz altında beyan ederiz.

AB 2023/607 uyarınca, Onaylanmış Kuruluş (TÜV SÜD Product Service GmbH) CL 045283 0028 Rev. 00 numaralı Onay Mektubu düzenleyerek geçiş süresini 31.12.2028 tarihine kadar uzatmıştır.


C) ürün ailesi: treadmill h/p/cosmos 150/50 (locomotion)

D) ürün ailesi: treadmill h/p/cosmos 150/50 G6

E) ürün ailesi: treadmill h/p/cosmos 170-190/65

F) ürün ailesi: treadmill h/p/cosmos 170-190/65 3p

G) ürün ailesi: treadmill h/p/cosmos 200-300/75-125

Ürünler  0123 işareti yapıştirilir.

Bu uygunluk beyanı, ISO 13485 standardına göre sertifikalı Kalite Yönetim Sistemimizin önemli bir parçasıdır ve h/p/cosmos tarafından 8 Temmuz 2025 tarihinde veya sonrasında üretilen yukarıda listelenen tüm cihazlar için geçerlidir.

Bu uygunluk beyanının geçerliliği, teknik değişiklikler veya norm ve standartların yasal değişiklikleri nedeniyle yeni bir uygunluk beyanının yayınlanmasıyla sona erer – ancak en geç 17.11.2027 tarihinde tıbbi cihaz yönetmeliği (AB) 2017/745 uyarınca, sertifika numarası G10 045283 0027 Rev. 00 olan AB Kalite Yönetim Sistemi Sertifikasının son geçerlilik tarihi olan 17.11.2027 tarihinde sona erer.

2011/65/EU ve (AB) 2015/863 (RoHS) Direktifleri ile (AB) 2020/2096 (REACH) Yönetmeliği temel alınarak

Bu belge ayrıca, mevcut bilgilere göre h/p/cosmos sports & medical gmbh ürünlerinin üretim sürecinde kullanılan tüm hammaddeler, kısmen tamamlanmış bileşenler ve tamamlanmış ürünlerin 2011/65/EU ve (AB) 2015/863 (RoHS) Direktifleri ile (AB) 2020/2096 (REACH) Yönetmeliği'nin belirli tehlikeli maddelerin kullanımının kısıtlanmasına ilişkin gerekliliklerine uygun olduğunu teyit etmektedir.

h/p/cosmos sports & medical gmbh, bileşenlerin testlerini gerçekleştirmez ve RoHS ve REACH uygunluğu beyanı için yalnızca tedarikçileri tarafından sağlanan bilgiler, onaylar ve sertifikalara güvenir.


ISO 13485 sertifikamız kapsamında, tedarikçilerimizle sürekli iletişim halindeyiz ve teslim edilen tüm ürünlerin RoHS ve REACH uyumlu olmasını sağlamak için çalışıyoruz.

BioComp açıklaması:

h/p/cosmos sports & medical gmbh, tüm ürünlerin kullanım amacına uygun olarak biyolojik uyumluluğunu onaylar. Uzun yıllara dayanan deneyimlere dayanarak, h/p/cosmos, ISO 10993 "Tıbbi cihazların biyolojik değerlendirilmesi" standardına göre tüm bileşenlerin ayrı ayrı test edilmesinden kaçınmış ve cihazın herhangi bir parçasıyla cilt teması sonucu kabul edilemez bir risk bulunmadığını beyan eder.

DE 83365 Nussdorf-Traunstein, July 8, 2025

h/p/cosmos sports & medical gmbh adına ve hesabına imzalanmıştır.



Alexander Böck
Genel Müdür



Nadine Schott
Kalite Müdürü ve PRRC



Joschka Zimmer
Ürün Müdürü ve teknik dosyayı derlemeye yetkili kişi