

## EU Declaration of Conformity

assigned to devices of medical and rehabilitation equipment



**manufacturer:** **h/p/cosmos sports & medical gmbh**  
 (=EU representative) Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany, commercial register # HRB 7563 Traunstein  
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**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, www.tuev-sued.de




**product:** Treadmill Ergometer (running machine)



Risk Classification MDD 93/42/EEC	Risk class IIb   classification rules 9 + 10 of Annex IX apply
Risk Classification MDR (EU) 2017/745	Risk class IIb   classification rules 9 + 10 of Annex VIII apply legacy devices: implementation before January 31, 2024 EC certificate No. G1 045283 0022 Re. 00 based on MDD is valid until January 31, 2024
Classification according to ISO 20957-1	S, I
Classification according to EN 957-6	A
UMDNS Code	14-141 Running Machine
GMDN Codes	33015 EXERCISER, TREADMILL, LINE-POWERED
NBOG Code	36679 ERGOMETER, TREADMILL MD 1108 active rehabilitation devices

**A) product family: treadmill h/p/cosmos 150/50 G6 (pluto, mercury)**



Basic UDI-DI:  4050588004002

BfArM: DE/CA59/BS 5104/2020-R/Kn (initial registration date: October 30, 2019)

UDI-DI	model name	article #
 4050588002336	pluto® med	cos30026-01va02
 4050588002565	pluto® ef med	cos30027-01va14
 4050588002909	stratos® med	cos30000-02va10


UDI-DI	model name	article #
 4050588002435	pluto® lt med	cos30027-01va02
 4050588002619	mercury® med	cos30000-02va02

OEM Version: COSMED srl


 4050588002350	pluto®   COSMED T150 DE LC MED	cos30026-01va04
 4050588002848	mercury®   COSMED T150 DE MED	cos30000-02va04

 4050588002459	pluto®   COSMED T150 E LC MED	cos30027-01va04
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OEM Version: emotion fitness GmbH & Co. KG

 4050588002510	pluto®   motion sprint 600 PL med	cos30027-01va10
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OEM Version: Noraxon U.S.A. Inc.

 4050588002411	pluto®   PhysTread med	cos30026-01va10
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OEM Version: PHYSIOMED ELEKTROMEDIZIN AG

 4050588002374	pluto®   PHYSIORUN Trainer	cos30026-01va06
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OEM Version: Proxomed Medizintechnik GmbH

 4050588002398	pluto®   Kardiomed LC	cos30026-01va08
 4050588002886	mercury®   Kardiomed Mill S	cos30000-02va08


 4050588002541	pluto®   Kardiomed 521	cos30027-01va12
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OEM Version: SCHILLER AG

 4050588002473	pluto®   SCHILLER MTM-1400 MED	cos30027-01va06
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 4050588002862	mercury®   SCHILLER MTM- 1500 MED	cos30000-02va06
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OEM Version: Vyair Medical GmbH


 4050588002817	pluto®   LE 100CE	cos30026-01va11
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 4050588002824	pluto®   LE 200CE	cos30026-01va12
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**B) product family: treadmill h/p/cosmos 150/50 (locomotion)**

Basic UDI-DI:  4050588004019





BfArM: DE/CA59/BS 5102/2020-R/Kn (initial registration date: 12.11.2013)

UDI-DI	model name	article #
 4050588002305	locomotion® 150/50 DE med	cos30001-01va02


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

Basic UDI-DI:  4050588004026

BfArM: DE/CA59/BS 5060/2020-R/Kn (initial registration date: November 12, 2013)

UDI-DI	model name	article #
 4050588000493	stellar® lt med	cos30003va17
 4050588000516	quasar® lt med	cos30003va19
 4050588000554	pulsar® lt med	cos30004va01
 4050588002619	locomotion® 190/65 DE med	cos30024va03



**OEM Version: COSMED srl**




 4050588000431	COSMED T170 DE MED	cos30003va11
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**OEM Version: Noraxon U.S.A. Inc.**

 4050588002756	KinTread med	cos30003va28
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**OEM Version: Vyair Medical GmbH**

 4050588000332	LE 250CE 170/65	cos30003va01
 4050588000356	LE 500CE 170/65	cos30003va03

UDI-DI	model name	article #
 4050588000509	stellar® med	cos30003va18
 4050588000523	quasar® med	cos30003va20
 4050588000578	pulsar®	cos30004va03




 4050588000448	COSMED T170 DE sportmed	cos30003va12
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 4050588000349	LE 300CE 170/65	cos30003va02
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D) product family: treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p)

Basic UDI-DI:  4050588004033

BfArM: DE/CA59/BS 5057/2020-R/Kn (initial registration date: November 12, 2013)

UDI-DI	model name	article #
 4050588001544	quasar® med 3p	cos30003va26
 4050588000561	pulsar® lt 3p	cos30004va02
 4050588000585	pulsar® 3p	cos30004va04

UDI-DI	model name	article #
 4050588002114	locomotion® 190/65 3p DE med	cos30024va04





OEM Version: COSMED srl


 4050588001537	COSMED T170 DE 3p sportmed	cos30003va25
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E) product family: treadmill h/p/cosmos 200-300/75-125 (venus, saturn)

Basic UDI-DI:  4050588004040

BfArM: DE/CA59/BS 5103/2020-R/Kn (initial registration date: November 12, 2013)

UDI-DI	model name	article #
 4050588001612	venus® 200/75	cos30005-01va05
 4050588001674	venus® 200/100	cos30006-01va05
 4050588001735	saturn® 250/75	cos30007-01va05
 4050588001797	saturn® 250/100	cos30008-01va05

UDI-DI	model name	article #
 4050588001629	venus® 200/75r	cos30005-01va06
 4050588001681	venus® 200/100r	cos30006-01va06
 4050588001742	saturn® 250/75r	cos30007-01va06
 4050588001803	saturn® 250/100r	cos30008-01va06
 4050588001834	saturn® 250/125r	cos30009-01va06
 4050588001896	saturn® 300/75r	cos30010-01va06

 4050588001889	saturn® 300/75	cos30010-01va05
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 4050588001940	saturn® 300/100	cos30011-01va05
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 4050588001957	saturn® 300/100r	cos30011-01va06
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 4050588001988	saturn® 300/125r	cos30012-01va06
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**OEM Version: COSMED srl**


 4050588001599	COSMED® T200 S	cos30005-01va03
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 4050588001650	COSMED T200 M	cos30006-01va03
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 4050588001780	COSMED T250 MR	cos30008-01va04
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**OEM Version: Vyair Medical GmbH**


 4050588001575	LE 580CE 200/75	cos30005-01va01
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 4050588001582	LE 580CE 200/75 R	cos30005-01va02
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 4050588001636	LE 590CE 200/100	cos30006-01va01
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 4050588001643	LE 590CE 200/100 R	cos30006-01va02
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 4050588001698	LE 600CE 250/75	cos30007-01va01
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 4050588001704	LE 600CE 250/75 R	cos30007-01va02
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 4050588001759	LE 650CE 250/100	cos30008-01va1
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 4050588001766	LE 650CE 250/100 R	cos30008-01va02
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 4050588001810	LE 680CE 250/125 R	cos30009-01va01
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 4050588001841	LE 690CE 300/75	cos30010-01va01
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 4050588001858	LE 690CE 300/75 R	cos30010-01va02
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 4050588001902	LE 700CE 300/100	cos30011-01va01
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 4050588001919	LE 700CE 300/100 R	cos30011-01va02
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 4050588001964	LE 720CE 300/125 R	cos30012-01va01
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We herewith declare under our sole responsibility that the above models / types meet the essential requirements of:

**Annex I** (essential requirements) + **Annex II** (full quality assurance system) of the European Council Directive 93/42/EEC (MD

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

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

The **CE** 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 mentioned devices which have been produced by h/p/cosmos on or after 12.10.2020. The validity of this declaration of conformity expires with the release of a new declaration of conformity if this is required due to technical amendments or due to legal amendments of the norms and standards – however, at the latest on the expiry date of the EC-certificate according to medical device directive 93/42/EEC with the certificate number G1 045283 0022 Rev. 00 on 31.01.2024.

**DE 83365 Nussdorf-Traunstein, October 12, 2020**

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



**Franz Harrer**  
President & CEO (Geschäftsführer)



**Joschka Zimmer**  
Dipl.-Ing. (FH)  
R & D Manager (Leiter Entwicklung)

**Nadine Schott**  
B.Sc. Healthcare Management  
Person Responsible for Regulatory  
Compliance Art. 15 MDR  
Quality Management Representative,  
Safety Officer Medical Devices