

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
 4050588002602	mercury® med	cos30000-02va02

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




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


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)

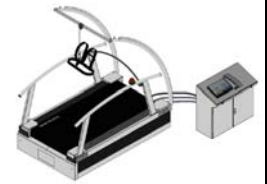


UDI-DI	model name	article #
 4050588001544	quasar® med 3p	cos30003va26
 4050588000561	pulsar® lt 3p	cos30004va02
 4050588000585	pulsar® 3p	cos30004va04





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



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

 4050588001889	saturn [®] 300/75	cos30010-01va05
 4050588001940	saturn [®] 300/100	cos30011-01va05

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
 4050588001957	saturn [®] 300/100r	cos30011-01va06
 4050588001988	saturn [®] 300/125r	cos30012-01va06

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 (MDR).

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 10.03.2021. The validity of this declaration of conformity expires with the release of a new declaration of conformity if this is required due to technical amendments or due to legal amendments of the norms and standards – 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, March 10, 2021

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
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Compliance Art. 15 MDR
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