EU Declaration of Conformity

assigned to devices of medical and

rehabilitation equipment

CE 0123

manufacturer: h/p/cosmos sports & medical gmbh

(=EU representative) Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany, commercial register # HRB 7563 Traunstein

phone +49 86 69 86 42 0 fax +49 86 69 86 42 49 email@hpcosmos.com www.hpcosmos.com

BfArM 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

sales & service: proxomed Medizintechnik GmbH

proxomed®

Daimlerstraße 6, DE 63755 Alzenau, Germany

phone +49 60 23 91 68 0 fax +49 60 23 91 68 68 info@proxomed.com

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)

OEM Version: Proxomed Medizintechnik GmbH

UDI-DI	model name	article #
4050588002398	pluto® | Kardiomed LC	cos30026-01va08
4050588002886	mercury® | Kardiomed Mill S	cos30000-02va08

UDI-DI	model name	article #
4050588002541	pluto® | Kardiomed 521	cos30027-01va12

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
Person Responsible for Regulatory Compliance Art. 15 MDR
Quality Management Representative,
Safety Officer Medical Devices