EU Declaration of Conformity

assigned to devices of medical and rehabilitation equipment

CE

Legal manufacturer: **h/p/cosmos sports & medical gmbh**

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EUDAMED SRN: **single registration number: DE-MF-000006147**

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

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

Classification MDR (EU) 2017/745	**Risk class I** based on **classification rule 13** (All other active devices) **Active Therapeutic Device**
EU Quality Management System Certificate (MDR)	**n.a. for class I devices**
Classification according to ISO 20957-1	**S, I**
Classification according to ISO 20957-6	not applicable
EUDAMED EMDN Code	**Z120602** PHYSIOTHERAPY EQUIPMENT **Y050201** STANDING SUPPORT GAIT TRAINERS
UMDNS Code	**11-623** exercisers
GMDN Codes	**58876** Gait rehabilitation system harness
MDR Codes	**MDA 0313**: Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport **MDS 1011**: Devices in systems or procedure packs (unweighting devices can be stand alone devices or can be within / combined to / be part of a system, e.g. gait training system consisting of unweighting device and treadmill, stress test system consisting of unweighting device, treadmill with ECG, CPET, VO2max. Heart Rate Monitor, etc.) **MDT 2001**: Devices manufactured using metal processing **MDT 2011**: Devices which require packaging, including labelling
Intended purpose	• Body weight support of a subject (during treadmill therapy / training) • Fall protection of a subject (during treadmill therapy / training) • Emergency stop in case of falling during treadmill therapy / training • Balance training under unweighted and/or secured conditions • Functional movement and gait training under unweighted and/or secured conditions • Overspeed / hyperspeed and excess frequency training in athletics (only for sports applications) Prescribed fall prevention device for any application where falling might cause an unacceptable risk (e.g. high speed or special applications, applications with subjects not able to support their weight properly, physically impaired, newly operated hip patients, invasive probes, osteoporosis, etc.)
any Common Specifications ('CS') (other than a standard, see Article 9 MDR)	not applicable N/A
IFU instructions for use downloadable	https://www.hpcosmos.com/en/contact-support/media-downloads/manuals
Updated safety information such as Field Safety Notices FSN, Field Safety Corrective Actions FSCA, etc. on website	https://www.hpcosmos.com/en/safety

A) product family: body weight support device h/p/cosmos (airwalk)

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

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

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

regulations and standards:

Reference Number	Date of Issue	Title
Regulation (EU) 2017/745	5 April 2017	Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. (**MDR**) Medical Device Regulation
Directive 2006/42/EC	17 May 2006	DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast). "**Machinery Directive**"
Directive 2011/65/EU and (EU) 2015/863	8 June 2011 and 31 March 2015	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. **RoHS**. COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.
Regulation (EU) 2020/2096	15 December 2020	COMMISSION REGULATION (EU) 2020/2096 of 15 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants.
DIN EN ISO 14971	2020	Medical devices - Application of risk management to medical devices
IEC 62366-1	2015 + COR1:2016	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 62366-2	2021	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
ISO 10993-1	2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10);
ISO 20957-1	2013	Stationary training equipment - Part 1: General safety requirements and test methods

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

The CE mark gets affixed to the products.

This declaration of conformity is an important part of our certified Quality Management System according to the ISO 13485 standard and it is valid for all above listed devices which have been produced by h/p/cosmos on or after January 25, 2024.
The validity of this declaration of conformity expires with the release of a new declaration of conformity if this is required due to technical amendments or due to legal amendments of the norms and standards – however, at the latest on the expiry date of the EU Quality Management System Certificate according to medical device regulation (EU) 2017/745 with the certificate number G10 045283 0027 Rev. 00 on 17.11.2027.

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

Alexander Böck	Nadine Schott	Joschka Zimmer
Managing Director Sales Director	Quality Manager and PRRC	Product Manager and person authorized to compile the technical file