



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

**BfArM / DIMDI:** Federal Institute for Drugs and Medical Devices registration number: DE/0000012774 (since 02.06.1999)

**product:** body weight support device

Risk Classification MDD 93/42/EEC	Risk class I   classification rule 12 of Annex IX apply
Risk Classification MDR (EU) 2017/745	Risk class I   classification rule 13 of Annex VIII apply
Classification according to ISO 20957-1	S, I
Classification according to EN 957-6	not applicable
UMDNS Code	11-623 exercisers
GMDN Codes	30928 training aid, physical, arm / trunk / leg
NBOG Code	MD 1108 active rehabilitation devices

product family: body weight support device h/p/cosmos (airwalk)						
UDI-DI:  4050588004064		initial registration date: November 12, 2013				
BfArM: DE/CA59/BS 5123/2020-R/Kn						
UDI-DI	model name	article #		UDI-DI	model name	article #
 4050588002305	airwalk® ap	cos30028		 4050588002312	airwalk® ap It	cos30028-It

We herewith declare under our sole responsibility that the above models / types meet the essential requirements of:

**Annex I** (essential requirements) + **Annex VII** (EC DECLARATION OF CONFORMITY) of the European Council Directive 93/42/EEC.

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

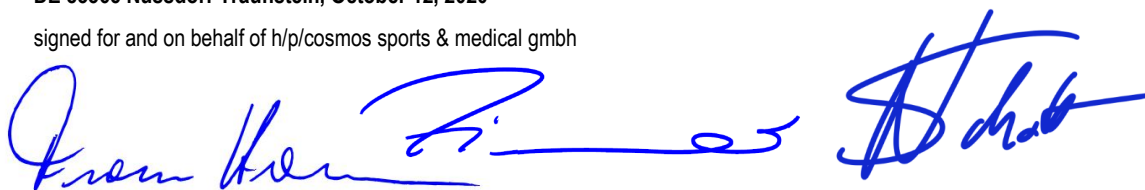
We herewith declare under our sole responsibility that h/p/cosmos sports & medical gmbh meets the applicable requirements of MDR (EU) 2017/745.

The **CE** - 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.

**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