



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: parallel bars

Risk Classification MDD 93/42/EEC	Risk class I classification rule 1 of Annex IX apply
Risk Classification MDR (EU) 2017/745	Risk class I classification rule 1 of Annex VIII apply
Classification according to ISO 20957-1	S, I
Classification according to EN 957-6	not applicable
UMDNS Code	12-957 Parallel Bars
GMDN Codes	30926 Parallel Bars, non-powered
NBOG Code	MD 103 Non-active orthopaedic and rehabilitation devices

product family: parallel bars h/p/cosmos (parawalk)		
Basic UDI-DI:  4050588004071		
UDI-DI	model name	article #
 4050588002015	parawalk 3m with wooden plate	cos30018va01
UDI-DI	model name	article #
 4050588002022	parawalk 3m	cos30018va02
UDI-DI	model name	article #
 4050588002039	parawalk 4m with wooden plate	cos30019va01
UDI-DI	model name	article #
 4050588002046	parawalk 4m	cos30019va02

UDI-DI	model name	article #	UDI-DI	model name	article #
 4050588002053	parawalk 5m with wooden plate	cos30020va01	 4050588002060	parawalk 5m	cos30020va02

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)



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

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