



Declaration of Conformity | biocompatibility

manufacturer: h/p/cosmos sports & medical gmbh



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Statement on biocompatibility for h/p/cosmos treadmills including robowalk and unweighting devices:

All applicable models from the product families:

- treadmill h/p/cosmos 150/50 G6 (pluto, mercury) Basic UDI-DI: 4050588004002,
- treadmill h/p/cosmos 150/50 (locomotion), Basic UDI-DI 4050588004019,
- treadmill h/p/cosmos 170-190/65 (quasar, pulsar), Basic UDI-DI 4050588004026
- treadmill h/p/cosmos 170-190/65 3p (quasar 3p, pulsar 3p), Basic UDI-DI 4050588004033
- treadmill h/p/cosmos 170-190/65 MCU6 (quasar, pulsar), Basic UDI-DI 4050588cos30003-015X
- treadmill h/p/cosmos 200-300/75-125 (venus, saturn), Basic UDI-DI 4050588004040
- parallel bars h/p/cosmos (parawalk), Basic UDI-DI 4050588004071
- body weight support device h/p/cosmos (airwalk), Basic UDI-DI 4050588004064
- expander pulling unit h/p/cosmos (robomove), Basic UDI-DI 4050588004071

According to the intended use, the patient may come into contact with the following components:

Component	Body part	Material	Duration
Polar chest belt	Chest	Polyamid, Polyurethan, Elastan, Polyester	> 10 min
Powder-coating (Handrail)	Hands	Polyester PT-910	> 10 min
Emergency off button	Hands	Polyester	< 10 s

According to the intended use, the intended operator may come into contact with the following components, although they are not to be meant to be used on bare skin:

Component	Body part	Material	Duration
UserTerminal (Cockpit)	Hands	ABS/F	> 10 s, < 10 min
Keyboard surface	Hands	Polyester	> 10 s, < 10 min
Additional keyboard	Hands	Polyester foil, PC-ABS, Santoprene	> 10 s, < 10 min
Chest belt / safety harness	Hands	PES, Polypropylen, Polyamid	> 10 s, < 10 min
Unweighting vest / shorts	Hands	Polyester, solid plastic buckles	> 10 s, < 10 min
Leg cuffs (robowalk)	Hands	Neoprene, ND-PE Monofil	> 10 s, < 10 min
Handrails	Hands	S235/JR G2 blank	> 10 s, < 10 min
Keyboard foil / touch screen	Hands	Polyester, ABS/F	> 10 s, < 10 min
Handle (arm support)	Hands	Vinyl	> 10 s, < 10 min
Elbow rest (arm support)	Hands	Polyurethane	> 10 s, < 10 min
Emergency off button	Hands	Polyester	< 10 s
Safety lanyard (clip / waist belt)	Hands	Plastic	< 10 s
Rope (safety arch / airwalk)	Hands	Polyamide	< 10 s
Carabiner (safety arch / airwalk)	Hands	Aluminum	< 10 s

All components listed are freely available on the market and intended and for none of the components skin contact is excluded by the manufacturers of the components. Polar chest belts have been sold and used by millions of customers over more than 3 decades without known problems concerning biocompatibility. The same applies for the handrails which are powder coated.

There is extremely limited skin contact for intended use only for the patients for a few minutes of use. The usual duration of use of treadmills and/or unweighting devices is approx. 5 to 60 minutes training sessions 1 or 2 times per day.

h/p/cosmos performs a PMS post market surveillance for all devices on the market since 1988.

The post market surveillance, with more than 12,000 sports and medical h/p/cosmos treadmills and unweighting devices on the market currently, did not show any incidents caused by incompatibility of any component with human skin.

The maximum risk we could imagine would be minor temporary skin irritations for subjects/patients who have allergy against materials used.

The benefit of using treadmills and unweighting devices in applications of stress tests, gait training, gait correction, unweighted running and for safety while exercising on a treadmill fully outweighs the risk of possible minor skin irritations with extremely few people. Therefore we confirm the biocompatibility of our products to be used for the applications as mentioned above.

Based on the evidence listed above h/p/cosmos abstained from individual testing of the components acc. to ISO 10993 "Biological evaluation of medical devices" and declares, there is no unacceptable risk resulting from skin contact to any part of the device.

This declaration of conformity is valid for all above mentioned devices which have been produced by h/p/cosmos on 27.01.2021 or after 27.01.2021. 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.

DE 83365 Nussdorf-Traunstein, March 30, 2022

signed for and on behalf of h/p/cosmos sports & medical gmbh



Franz Harrer
President & CEO

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