



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 045283 0027 Rev. 00**

**Manufacturer:** **h/p/cosmos**  
**sports & medical gmbh**  
Am Sportplatz 8  
83365 Nussdorf - Traunstein  
GERMANY

**SRN Manufacturer:** DE-MF-000006147

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.  
For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 045283 0027 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_045283_0027_Rev._00)

**Report No.:** 713249132

**Valid from:** 2022-11-18

**Valid until:** 2027-11-17

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-11-18



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<b>Classification:</b>	IIb
<b>Device Group:</b>	Z129006 - TREADMILLS FOR PHYSIOTHERAPY AND/OR DIAGNOSTIC USES
<b>Intended Purpose:</b>	<p>h/p/cosmos medical treadmills are intended for walking or running in place for</p> <ul style="list-style-type: none"><li>- Recreational fitness training (incl. athletes)</li><li>- Gait training (with or without body weight support)</li></ul> <p>h/p/cosmos medical treadmills can be used in combination with external devices for walking or running in place as</p> <ul style="list-style-type: none"><li>- Stressing devices for neuromuscular and biomechanical measurements (e.g. EEG, EMG, motion analysis)</li><li>- Stressing devices for cardiovascular measurements (e.g. ECG)</li><li>- Stressing devices for cardiopulmonary measurements (e.g. ergospirometry).</li></ul> <p>Prescribed fall prevention device for any application where falling might cause an unacceptable risk (osteoporosis, high speed or special applications, applications with subjects not able to jump off the running belt such as children, physically impaired, etc.)</p>
<b>The validity of this certificate depends on conditions and/or is limited to the following:</b>	- none -