



EU Declaration of Conformity

assigned to devices of medical and rehabilitation equipment



manufacturer:
(= EU representative)

h/p/cosmos sports & medical gmbh
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

product: expander pulling unit

Classification MDD Directive 93/42/EEC	Class I
Classification according to ISO 20957-1	S, I,C
UMDNS Code	11-623 + 15-326 exercisers
GMDN Codes	35060 EXERCISER, LEG + 11629 EXERCISER, HAND
NBOG Code	MD 103 Non-active orthopaedic and rehabilitation devices

product family: expander pulling unit h/p/cosmos (robowalk / robomove)

model name	article #	model name	article #
robowalk expander F 150/50	cos30022-02va01	robomove expander vh 1.2 m	cos101659va01
robowalk expander F 170-190/65	cos30022-02va02	robomove expander vh 2 m	cos101659va02
robowalk expander F aw se 135	cos30022-02va03		
robowalk expander F aw ap	cos30022-02va04		
robowalk expander F 150/50 LC	cos30022-02va05		
robowalk expander B	cos30023-03		

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

Annex I (essential requirements) + **Annex II** (full quality assurance system) 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.

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 01.04.2019. 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 EC-certificate according to medical device directive 93/42/EEC with the certificate number G1 045283 0022 Rev. 00 on 31.01.2024.

DE 83365 Nussdorf-Traunstein, April 1, 2019

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

Franz Harrer
President & CEO (Geschäftsführer)