



EU Declaration of Conformity

assigned to devices of medical and
rehabilitation equipment



manufacturer: h/p/cosmos sports & medical gmbh

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

product: expander pulling unit

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	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 (robomove)		
Basic UDI-DI:		4050588004071
UDI-DI	model name	article #
	robomove expander vh 1.2 m	cos101659va01
4050588002725		
UDI-DI	model name	article #
	robomove expander vh 2 m	cos101659va02
4050588002732		

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