

# CERTIFICATE

Number: 65611CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**GymnaUniphy N.V.**

**Pasweg 6A  
3740 Bilzen  
Belgium**

For the product category:

**Electromedical devices intended for electrotherapy, ultrasound therapy, laser therapy or combinations of these therapies**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 2002487CN, initially dated 26 June 2000  
Addendum, initially dated 1 March 2001**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 24 November 2014  
Issued for the first time: 26 June 1997  
Reissued: 24 November 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

# ADDENDUM

Belonging to certificate: 65611CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

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This certificate covers the following product(s):

Phyaction C	Electrotherapy, ultrasound and combination therapy, including the matching ultrasound treatment heads
Phyaction E and I	Electrotherapy
Phyaction U	Ultrasound therapy, including the matching ultrasound treatment heads and combination therapy when coupled to a Phyaction E or I
Phyaction V	Vacuum unit for electrotherapy
Duo 200 and 500	Electrotherapy
Combi 200	Electrotherapy, ultrasound and combination therapy, including the matching ultrasound treatment heads
Combi 500	Electrotherapy, ultrasound, combination and laser therapy, including the matching ultrasound and laser treatment heads
Pulson 200	Ultrasound therapy, including the matching ultrasound treatment heads
Vaco 500	Vacuum unit for electrotherapy

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Combi 200 L	Electrotherapy ultrasound laser unit. Combined apparatus for electrotherapy, ultrasound and lasertherapy
Phyaction CL	Combined device for electrotherapy, ultrasound and laser therapy.
Phyaction Ub	Ultrasound therapy devices intended for rehabilitation, pain treatment and inflammation Treatment
Pulson 100	Ultrasound therapy devices intended for rehabilitation, pain treatment and inflammation treatment
Vaco 200	Electrotherapy devices with vacuum electrodes
Myo 200	Device for combination of electrotherapy stimulation and feedback
Combi 400	Device for Electrotherapy, ultrasound, combination and laser therapy, including the matching ultrasound and laser treatment heads
Combi 400V	Device for Electrotherapy, ultrasound, combination and laser therapy, including the matching ultrasound and laser treatment heads and vacuum module
Duo 400	Device for electrotherapy
Duo 400V	Device for electrotherapy and vacuum module
Pulson 400	Device for ultrasound therapy

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Guidance C	Device for electrotherapy, ultrasound, combination and laser therapy, including the matching ultrasound and laser treatment heads
Guidance CV	Device for electrotherapy, ultrasound, combination and laser therapy, including the matching ultrasound and laser treatment heads and vacuum module
Guidance E	Device for electrotherapy
Guidance EV	Device for electrotherapy and vacuum module
Guidance U	Device for ultrasound therapy

Initial date: 1 March 2001

Revision date: 24 November 2011

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