

EC CERTIFICATE

Number: 65611CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

GymnaUniphy N.V.

**Pasweg 6A
3740 Bilzen
Belgium**

For the product category(ies)

Electro medical 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 Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities 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: 1 December 2017
Issued for the first time: 26 June 1997
Reissued: 24 November 2014

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 65611CE01

1/3

CE MARKING OF CONFORMITY MEDICAL DEVICES

Electro medical devices intended for electrotherapy, ultrasound therapy, laser therapy or combinations of these therapies

Issued to:

GymnaUniphy N.V.

Pasweg 6A
3740 Bilzen
Belgium

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	Electrotherapy
Combi 200	Electrotherapy, ultrasound and combination therapy, including the matching ultrasound treatment heads
Pulson 200	Ultrasound therapy, including the matching ultrasound treatment heads

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ADDENDUM

Belonging to certificate: 65611CE01

2/3

CE MARKING OF CONFORMITY MEDICAL DEVICES

Electro medical devices intended for electrotherapy, ultrasound therapy, laser therapy or combinations of these therapies

Issued to:

GymnaUniphy N.V.

**Pasweg 6A
3740 Bilzen
Belgium**

Combi 200 L	Electrotherapy ultrasound laser unit. Combined apparatus for electrotherapy, ultrasound and lasertherapy
Phyaction CL Phyaction Ub	Combined device for electrotherapy, ultrasound and laser therapy. 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
Guidance U	Device for ultrasound therapy

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ADDENDUM

Belonging to certificate: 65611CE01

3/3

CE MARKING OF CONFORMITY MEDICAL DEVICES

Electro medical devices intended for electrotherapy, ultrasound therapy, laser therapy or combinations of these therapies

Issued to:

GymnaUniphy N.V.

**Pasweg 6A
3740 Bilzen
Belgium**

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 2014

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan
Certification Manager

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