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)

Electrical medical devices intended for electrotherapy, ultrasound therapy, laser therapy, cryo therapy, shockwave therapy and diathermy or combinations of those 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 2022
Issued for the first time: 26 June 1997
Reissued: 1 December 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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
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ADDENDUM

Belonging to certificate: 65611CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Electrical medical devices intended for electrotherapy, ultrasound therapy, laser therapy, cryo therapy, shockwave therapy and diathermy or combinations of those therapies

Issued to:

GymnaUniphy N.V.
Pasweg 6A
3740 Bilzen
Belgium

This certificate covers the following product(s):

Phyaction C	Device for electrotherapy, ultrasound and combination therapy, including the matching ultrasound treatment heads
Phyaction E and I	Device for electrotherapy
Phyaction U	Device for 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 using vacuum electrodes
Duo 200	Device for electrotherapy
Combi 200	Combined device for electrotherapy, ultrasound and combination therapy, including the matching ultrasound treatment heads
Pulson 200	Device for ultrasound therapy, including the matching ultrasound treatment heads
Combi 200 L	Combined device for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads
Phyaction CL	Combined device for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads
Phyaction Ub	Device for ultrasound therapy, including the matching ultrasound treatment heads
Pulson 100	Device for ultrasound therapy, including the matching ultrasound treatment heads
Vaco 200	Vacuum unit for electrotherapy using vacuum electrodes
Myo 200	Device for combination of electrotherapy stimulation and feedback
Combi 400	Combined device for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads
Combi 400V	Combined device with vacuum module for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads

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ADDENDUM

Belonging to certificate: 65611CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Electrical medical devices intended for electrotherapy, ultrasound therapy, laser therapy, cryo therapy, shockwave therapy and diathermy or combinations of those therapies

Issued to:

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Duo 400	Device for electrotherapy
Duo 400V	Device with vacuum module for electrotherapy
Pulson 400	Device for ultrasound therapy, including the matching ultrasound treatment heads
Guidance C	Combined device for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads
Guidance CV	Combined device with vacuum module for electrotherapy, ultrasound and laser therapy, including the matching ultrasound and laser treatment heads
Guidance E	Device for electrotherapy
Guidance EV	Device with vacuum module for electrotherapy
Guidance U	Device for ultrasound therapy, including the matching ultrasound treatment heads
Cryoflow ICE-CT	Cold air cryo therapy device for pain relief, anti-inflammation,muscle detonising and reducing swelling or bleeding
ShockMaster 300	Extracorporeal shockwave device for activation of muscles and connective tissue
ShockMaster 500	Extracorporeal shockwave device with external compressor for activation of muscles and connective tissue
Thermo 500	Shortwave diathermy device with matching applicators (thermoplodes)

Initial date: 1 March 2001
Revision date: 1 December 2017

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