# EC CERTIFICATE

Number: 86443CE03

## Production Quality Assurance

**Directive 93/42/EEC on Medical devices, Annex V**
(Devices in Class IIa, IIb or III)

Manufacturer:

## Philips Consumer Lifestyle B.V.

**Tussendiepen 4**
**9206 AD Drachten**
**The Netherlands**

For the product category(ies)

**Transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulation (EMS) for the treatment of mild to moderate chronic musculoskeletal pain and acute mild to moderate postsurgical pain and muscle strengthening**

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 86443CN, initially dated 29 June 1998**
**Addendum, initially dated 8 July 2013**

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 the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
The necessary information related to the quality assurance 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 July 2016
Issued for the first time: 8 July 2013
Revised: 13 November 2014

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

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# ADDENDUM

Belonging to certificate: 86443CE03 

# CE MARKING OF CONFORMITY
## MEDICAL DEVICES

Transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulation (EMS) for the treatment of mild to moderate chronic musculoskeletal pain and acute mild to moderate postsurgical pain and muscle strengthening

Issued to:

**Philips Consumer Lifestyle B.V.**
**Tussendiepen 4**
**9206 AD Drachten**
**The Netherlands**

This certificate covers the following product(s):

- Wireless TENS (PR3093) TENS
- Wireless TENS pro with wireless TENS PC application (PR3094) TENS
- PulseRelief TENS (PR3840) TENS and EMS

Initial date: 8 July 2013
Revision date: 13 November 2014

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