

EC CERTIFICATE

Number: 86443CE11

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)

Body wearable devices for the measurement or determination of the following physiological parameters: heart rate, resting heart rate, body movement and energy expenditure, for adults at risk of or suffering lifestyle related diseases

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 6 July 2016

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 2019
Issued for the first time: 6 July 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 86443CE11

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Body wearable devices for the measurement or determination of the following physiological parameters: heart rate, resting heart rate, body movement and energy expenditure, for adults at risk of or suffering lifestyle related diseases

Issued to:

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

This certificate covers the following product(s):

Health Watch (DL8790)
Health Band (DL7411, DL7412)

Initial date: 6 July 2016
Revision date: 17 July 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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