

# EC CERTIFICATE

Number: 2183975CE01

## Production Quality Assurance

**Directive 93/42/EEC on Medical devices, Annex V**

(Devices in Class IIa, IIb or III)

Manufacturer:

**Photonics Healthcare B.V.**

**Koningin Wilhelminalaan 8**

**3527 LD Utrecht**

**The Netherlands**

For the product category(ies)

**Noninvasive measuring system to locally determine cellular oxygen availability in human skin cells with a high concentration of protoporphyrin IX**

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 2183975CN, initially dated 18 April 2016**

**Addendum, initially dated 18 April 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 September 2023

Issued for the first time: 18 April 2016

Reissued: 24 September 2018

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, consisting of a stylized 'Z' followed by 'oetbrood'.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized 'J' followed by 'A. van Vugt'.

J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2183975CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Noninvasive measuring system to locally determine cellular oxygen availability in human skin cells with a high concentration of protoporphyrin IX

Issued to:

**Photonics Healthcare B.V.**  
Koningin Wilhelminalaan 8  
3527 LD Utrecht  
The Netherlands

This certificate covers the following product(s):

COMET measurement system

Initial date: 18 April 2016

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, the Managing Director of DEKRA Certification B.V.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager of DEKRA Certification B.V.

J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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