

# EC CERTIFICATE

Number: 3823682CE01

## Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

Manufacturer:

### Nihon Kohden OrangeMed Inc

1800 E. Wilshire Avenue  
Santa Ana, CA 92705  
United States Of America

For the product category(ies)

### Servo controlled ventilator to provide continuous ventilation for adult, pediatric and neonatal patients

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

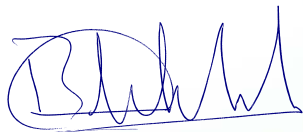
Documents that form the basis of this certificate:

### Certification Notice 3823327CN, initially dated 17 June 2019 Addendum, initially dated 30 September 2019

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: 27 May 2024  
Issued for the first time: 07 October 2019

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



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-product-safety.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 3823682CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Servo controlled ventilator to provide continuous ventilation for adult, pediatric and neonatal patients

Issued to:

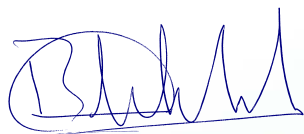
**Nihon Kohden OrangeMed Inc**  
1800 E. Wilshire Avenue  
Santa Ana, CA 92705  
United States Of America

This certificate covers the following product(s):

NKV 550 Ventilator System (Class IIb)

Initial date: 07 October 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

B.T.M. Holtus  
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-product-safety.com](http://www.dekra-product-safety.com) Company registration 09085396