NIHON KOHDEN
OrangeMed Inc.

EC DECLARATION of CONFORMITY

MANUFACTURER :

Nihon Kohden OrangeMed, Inc.
1800 E. Wilshire Ave
Santa Ana, CA 92705
USA

AUTHORIZED REPRESENTATIVE EC REP :

Nihon Kohden Europe GmbH
Raiffeisenstrasse 10
D-61191 Rosbach
Germany

DECLARATION of SOLE RESPONSIBILITY:

We declare, that this Declaration of Conformity is under the sole responsibility Nihon Kohden OrangeMed, Inc.

MODEL NUMBERS and UNIQUE DEVICE IDENTIFIER (UDI):

Model	Type	U.P.C. Company Prefix (7 Digits)	UDI – DI GTIN	UDI – DI GTIN-12 (U.P.C.)
NKV-550-S	Standard	8436851	00843685100005	843685100005
NKV-550-U	Universal	8436851	00843685100012	843685100012
NKV-550-N	Neonate	8436851	00843685100029	843685100029

PRODUCT NAME:

Trade Name: Nihon Kohden NKV-550 Series Ventilator System
Common Name: Ventilator, Intensive Care

GMDN CODE:

42411 – Intensive Care Ventilator, Adult/Infant

UMDNS CODE:

17429 – Ventilators, Intensive Care

RISK CLASSIFICATION:

Class IIb (Rule 9)

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DECLARATION STATEMENT OF CONFORMITY:

The undersigned hereby declares, on behalf of Nihon Kohden OrangeMed, Inc. that the medical devices included in this EC Declaration of Conformity:

(1) complies with applicable Essential Requirements as specified in MDD 93/42/EEC Annex I;

(2) has been classified according to the classification rules as specified in MDD 93/42/EEC Annex IX; and

(3) complies with all applicable conformity assessment elements under the MDD 93/42/EEC.

REFERENCES:

See attached list of Harmonized Standards and Common Technical Specifications (CTS)

NOTIFIED BODY:

Notified Body Number: **0344**
DEKRA Certification B.V.
Meander 1051, 6825 MJ Arnhem,
Netherlands

CONFORMITY ASSESSMENT PROCEDURE:

MDD 93/42/EEC - Annex II, excluding section 4; Class IIb active device

CERTIFICATE(s):

EC Certificate - MDD 93/42/EEC:

Certificate Number	Initial Date	Renewal Date	Revision Date	Expiry Date
3823682CE01	Oct. 7, 2019	NA	NA	May 27, 2024

Quality System Standard

Certificate Number	Standard	Initial Date	Effective Date	Expiry Date
3823327	ISO 13485:2016	Jun 17, 2019	Jun 17, 2019	Jun 17, 2022

ADDITIONAL INFORMATION:

N/A

AUTHORIZED SIGNATORY:

Signed this **8th** day of **October, 2019** in Santa Ana, CA:

Sheryl W. Higgins
Vice President of Regulatory Affairs and Quality Assurance
Nihon Kohden OrangeMed, Inc.

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List of Applicable Standards

Standard	Version	Title
ISO 13485	2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 14971	2012-07	Medical devices - Application of risk management to medical devices
IEC 60601-1	2005+AC1; A2 (R2012)	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	Ed. 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6	2010+AM1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8	Ed. 2.1 2006 (2nd Ed) + Am.1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-12	Ed. 1 2011-04	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators [Including: Technical Corrigendum 1 (2011)]
IEC 62133	Ed. 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]
ISO 80601-2-55	Ed. 1. 2011	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (O2)
ISO 80601-2-61	2011	Medical Electrical Equipment – Particular Requirements for basic safety and essential performance of pulse oximeter equipment
BS EN ISO 10993-1 (series)	Ed. 4 2009-10	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
EN 62304	2006	Medical Device Software – Software Lifecycle processes
IEC 62366-1	Ed. 1.0 2015 COR1:2016	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 15223-1	Ed. 3 2016-11	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041	2008	Information supplied by the manufacturer of medical devices
ISO 5356-1	Ed. 4 2015-03	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
ISO 5356-2	Ed. 3 2012-11	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors