



LEISTUNG

EC DECLARATION OF CONFORMITY

LUFT3 REV02

LEISTUNG EQUIPAMENTOS LTDA
202, João Ropelatto St.
Jaraguá do Sul – SC – Brazil
89265-520

European Representative: Donawa Lifescience Consulting Srl
10, Piazza Albania St.
Rome – Italy
00153

Declare under our sole responsibility that the product:

Manufacture: **LEISTUNG EQUIPAMENTOS LTDA.**

Product Description: **LUNG VENTILATOR**

Product Name: **LUFT3**

Class: **IIB**

Conformity Assessment Route: **The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices**

And in accordance with the following
Harmonized standards:

It bears the mark



EN ISO 5366-1:2009

Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)

EN ISO 5359:2008

Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)
EN ISO 5359:2008/A1:2011

EN ISO 7396-1:2007

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)

EN ISO 10993-1:2009

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-1:2009/AC:2010

EN 12342:1998+A1:2009

Breathing tubes intended for use with anaesthetic apparatus and ventilators

EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 13485:2016/AC:2016

EN ISO 14971:2012

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

EN ISO 15223-1:2012

Symbols to be used with medical device labels, labelling and information to be supplied (ISO 15223-1:2012)

EN ISO 17664:2004

Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)

EN ISO 17665-1:2006

Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)

EN ISO 23328-1:2008

Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003)
EN ISO 23328-2:2009

Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects (ISO 23328-2:2002)

EN 1041:2008

Information supplied by the manufacturer of medical devices

EN 60601-1:2006

Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

IEC 60601-1:2005

EN 60601-1:2006/AC:2010

EN 60601-1 Amendment 1:2013

IEC 60601-1 Amendment 1:2012

EN 60601-1-2:2015

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-2:2014

EN 60601-1-6:2010

Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010

EN 60601-1-8:2007

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 (IEC 60601-1-8:2006) EN 60601-1-8:2007/ AC:2010

EN 62304:2006

Medical device software -- Software life-cycle processes

IEC 62304:2006

EN 62304:2006/AC2008

EN 62366:2008

Medical device-- Application of usability engineer to medical devices.

IEC 62366:2007

DIRECTIVA 93-42 CE Harmonized Standards 17-11-17

Non-harmonized standards:

EN ISO 5356-1:2004

Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets (ISO 5356-1:2004)

ISO 80601-2-12:2011

Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.

EN ISO 780-2001 Packaging - Pictorial marking for handling of goods (ISO 780:1997)

Notified Body: DNV GL Nemko Presafe AS

Veritasveien 3

1363 Høvik

Country : Norway

Certificate No.: 199844-2016-CE-BRA-NA-PS

Issue date: 27 June 2017

Expiry date: 27 June 2022

I, signed below, through this, to declare that the above product conforms to the above referenced policy and standards when installed in accordance with the instructions contained in the product documentation,

Issued in Jaraguá do Sul/Brazil: October 17, 2018

Year of CE marking: 2017

Name: Marcelo Javier Fernandez

Title: Director -- Legal Responsible

Signature:

