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 CE 2460

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 (ISO17665-1:2006)

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 medival 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)

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

ISO 80601-2-12:2011
Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.

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 Responsable

Signature:

LEISTUNG

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid:
199844-2016-CE-BRA-NA-PS	PRJC-522222-2015-MSL-BRA	27 June 2022

This is to certify that the quality system of:

LEISTUNG EQUIPAMENTOS LTDA.

Rua João Ropelatto, 202, 89.265-520 Jaraguá Do Sul, Brazil

For design, production and final product inspection/testing of:

LUNG VENTILATOR

Has been assessed with respect to:

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, as amended
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 27 June 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: 199844-2016-CE-BRA-NA-PS
Project No.: PRJC-522222-2015-MSL-BRA
Valid: 27 June 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	Original Certificate	2017-06-27

Products covered by this Certificate:

Product Description	Product Name	Class
LUNG VENTILATOR	▪ LUFT3	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

LEISTUNG EQUIPAMENTOS LTDA.
RUA JOÃO ROPELATTO, 202, 89.265-520 JARAGUÁ DO SUL, BRAZIL

EU Representative

DONAWA LIFESCIENCE CONSULTING Srl
Piazza Albania street, 10
Rome – Italy, 00153

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid:
199844-2016-CE-BRA-NA-PS	PRJC-522222-2015-MSL-BRA	27 June 2022

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
216741-2017-AQ-BRA-NA-PS Rev. 1.0	**PRJC-522222-2015-MSL-BRA**	**29 SEPTEMBER 2015**	**29 SEPTEMBER 2021**

This is to certify that the management system of:

LEISTUNG EQUIPAMENTOS LTDA.

Rua João Ropelatto 202
89265-520 Jaraguá do Sul
Brazil

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

DEVELOPMENT, PRODUCTION, SALES, DISTRIBUTION, INSTALLATION AND SERVICE OF LUNG VENTILATORS AND ACCESSORIES

Place and Date:
Høvik, 17 October 2018

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info