Atestado/Certificate

Campinas, 02 de Abril de 2024
Campinas, April 02, 2024

Processo / Process:
87828/24.1

Norma avaliada / Evaluated standard:
RTCA DO-160G

Solicitante / Applicant:
Razão social / Corporate name:
Magnamed Tecnologia Médica S/A
Endereço / Address:
Rua Santa Mônica 801/831, Capuava, Cotia, SP, CEP: 0671-865, Brasil
CNPJ: 34.192.854/0001-39

Unidade Fabril / Factory Unit:
Razão social / Corporate name:
Magnamed Tecnologia Médica S/A
Endereço / Address:
Rua Santa Mônica 801/831, Capuava, Cotia, SP, CEP: 0671-865, Brasil
CNPJ: 34.192.854/0001-39

Produto / Product:
Ventilador de Transporte e Emergência

Nome Comercial / Commercial Name:
Ventilador de Transporte e Emergência OxyMag

Modelo / Model:
OxyMag

Características Técnicas / Technical Characteristics:
Profundity (with handle) x Height (with handle) x Width (mm):
134(185) x 176(231) x 254
Weight (approximate maximum approximate): 3,0 kg
Connection to external source: AC/DC (100-240 VAC – 50/60 Hz → +12 VDC)

1. **Objetivo / Objective**:
   Evaluate if the above-mentioned product complies with the RTCA DO-160G standard.

2. **Análise / Analysis:**
   According the Operation Manual, the evaluated product consists of an Electronic Transport and Emergency Ventilator that belongs to the family of equipment for ventilatory support of patients with respiratory failure, controlled by volume, pressure and cycled in time, which caters for neonatal, infant, adult and morbidly obese patients. Oxymag interacts with the

patient via an invasive or non-invasive interface that delivers air from the ventilator to the patient's airways.
Oxymag delivers a mixture of ambient air and oxygen in concentrations adjusted by the operator using the System for Obtaining Precise Oxygen Concentrations using the "venturi" principle. The O2 concentration is obtained via a galvanic cell or, optionally, a paramagnetic cell through indirect contact with the patient's gas, by passing gas through the sensor. It also controls flows and pressures in the respiratory circuit in order to provide ventilation modes that are appropriate for the patient's condition.
Pulmonary ventilation can be performed under the following conditions:
- In emergency medicine for care in the field, primary care, rescues in which the patient can be transported by land or air, including fixed-wing aircraft and helicopters;
- In the post-operative period, in the post-anesthetic recovery room (RPA);
- Intra-hospital transportation: The patient can be transported internally, from one department to another;
- Inter-hospital transportation: The patient can be transported by land or air.

The OxyMag is considered to be airborne equipment, since it can be used for airborne assistance. It was assessed in accordance with RTCA standard DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment, in the sections shown in Table 1. This standard defines test procedures that determine the performance characteristics of airborne equipment in environmental conditions that represent those found in an airborne operation.

Table 1. Sections of the RTCA DO-160G standard evaluated for OxyMag.

Section	Description
8	Vibration in fixed wing aircrafts (Category S) Vibration in helicopters (Category U)
16.6	Voltage fluctuations, ripple voltage
17	Voltage spikes
18.3.1	Audio frequency susceptibility, DC power input
20	Radio frequency susceptibility (radiated and conducted)
21	Emission of radio frequency energy
25	Electrostatic discharge (ESD)

Test report(s):

Report N.	Standard	Laboratory	Issue date
9279.23EE_00	RTCA DO-160G Seção 8 (Categoria S)	Scitec	05/10/2023
9472.23EE_00	RTCA DO-160G Seção 8 (Categoria U)	Scitec	06/11/2023
MGNMD02-R01	RTCA DO-160G Seções 16.6, 18.3.1, 20, 21 e 25	INPE	06/02/2020

Equipment descriptional documents (confidential):

Document	Description	Revision
1600185-10	Manual do usuário	26

3. **Conclusão / Conclusion**:
   We certify that OxyMag equipment has been evaluated and meets the requirements of Sections 8, 16.6, 17, 18.3.1, 20, 21 and 25 of the RTCA DO-160G standard.

This analysis was made based on the existing technical descriptions of the product and the information declared to be the responsibility of the applicant, which were received by NCC. Any changes to the product, its documentation and/or identification provided invalidate this declaration, and it is also subject to the decisions of the Regulatory Body that may, at any time, demand compulsory certification of the product in question.

We make ourselves available for further clarification.

Best Regards,

GUISLA FILOMENA LANGHAMER MARTINS:30314134824

Assinado de forma digital por GUISLA FILOMENA LANGHAMER MARTINS:30314134824

Guisla Martins
Gerente de Processos
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