EMC TEST CERTIFICATE PAGE 1 OF 3

ISSUED BY:
Cranage EMC Testing Limited, Wallace Way, Tern Valley Business Park, Market Drayton, Shropshire. TF9 3AG.

This Certificate can only be reproduced in its entirety.

UKAS TESTING 1833

Certificate No: **E9359C** Date of Issue: **23rd December 2020**

The item detailed below has been tested in accordance with:

EN 60601-1-2: 2015 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The results contained within this Certificate only apply to this specific Equipment Under Test.

This certificate is issued in conjunction with EMC test report E9359R.

All measurements were taken using calibrated equipment traceable to National Standards.

1) **EN 60601-1-2: 2015** – (EN 55011: 2009) – Conducted Emissions. The EUT met the specified Group 1 Class A limits in the frequency range 0.15 MHz to 30.0 MHz when tested in mode 1. The 95% confidence measurement uncertainty for this test was 4.0 dB.

2) **EN 60601-1-2: 2015** – (EN 55011: 2009) – Radiated Emissions. The EUT met the specified Group 1 Class A limits in the frequency range 30 MHz to 1000 MHz when tested in mode 1. The 95% confidence measurement uncertainty for this test was 5.6 dB in the frequency range 30 MHz to 300 MHz and 6.3 dB in the frequency range 300 MHz to 1000 MHz.

3) **EN 60601-1-2: 2015** – (EN 61000-3-2: 2014) – Harmonic Current Emissions. This test was not applicable due to the measured power consumption of EUT 1 being less than 75 Watts AC in mode 1.

4) **EN 60601-1-2: 2015** – (EN 61000-3-3: 2013) – Voltage Fluctuations and Flicker. This test was not applicable due to the measured Inrush Current of EUT 1 being less than 20 Amps and the measured Constant Current of EUT 1 being less than 1.5 Amps in mode 1.

5) **EN 60601-1-2: 2015** – (EN 61000-4-3: 2006 + A1: 2008 + A2: 2010) – Radiated RF Immunity (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The 95% confidence measurement uncertainty for this test was 2.3 dB.

6) **EN 60601-1-2: 2015** – Proximity Fields RF immunity (Table 9 of EN 60601-1-2: 2015 only). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1.

Manufacturer:	Palliare Ltd. Galway Business Park, Dangan, Galway. H91 P2DK. Ireland.
Test Dates:	4th December 2020 to 11th December 2020.
Date of Receipt of Test Item:	2nd December 2020.
EUT Description:	Laparo-Endoscopic Insufflator.
EUT Manufacturer:	Palliare Ltd.
EUT Model Number:	EVA-15.
EUT Serial Number:	102520201117-05.
EUT Software revision:	00.12.
Operating Conditions:	**Mode 1:** 240V AC 50 Hz supplied to the EUT (unless stated otherwise). The EUT displayed a steady pressure of 15 mmHg and the Flow mode indicated a reading of 02 to 08 SLPM as the pressure was maintained. Cavity size: Large. Insufflation: Maintain. The EUT was identified as Class 1 earthed equipment. **Basic Safety and Essential Performance (as Declared by the Manufacturer)** Patient pressure shall not vary from its target setting by more than 5 mmHg for more than 5 sec when measured in a vessel with compliance 7ml/mmHg or less. A leak of at least 1 L/min will be created in the test apparatus to ensure that there is continuous delivery of gas. In the case of loss of power or a fuse blowing, no gas shall be delivered to the patient.

Approved Signatories: K.G. Richens - Managing Director

K.G. Richens

APPROVED SIGNATORY

Verification Signatories: M. Richens - Technical Director

VERIFICATION SIGNATORY

EMC TEST CERTIFICATE PAGE 2 OF 3

ISSUED BY:
Cranage EMC Testing Limited, Wallace Way, Tern Valley Business Park, Market Drayton, Shropshire. TF9 3AG.

This Certificate can only be reproduced in its entirety.

UKAS TESTING 1833

Certificate No: **E9359C** Date of Issue: **23rd December 2020**

The item detailed below has been tested in accordance with:

EN 60601-1-2: 2015 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The results contained within this Certificate only apply to this specific Equipment Under Test.

This certificate is issued in conjunction with EMC test report E9359R.

All measurements were taken using calibrated equipment traceable to National Standards.

7) **EN 60601-1-2: 2015** – (IEC 61000-4-6: 2013) – Conducted RF Immunity (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The 95% confidence measurement uncertainty for this test was 1.6 dB.

8) **EN 60601-1-2: 2015** – (EN 61000-4-4: 2012) – Electrical Fast Transient Burst Immunity (Professional Healthcare Facility Environment Healthcare immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The generator meets the specified requirements in the standard with at least 95% confidence.

9) **EN 60601-1-2: 2015** – (EN 61000-4-5: 2006) – Surge Immunity (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The Generator meets the specified requirements with at least 95% confidence.

10) **EN 60601-1-2: 2015** – (EN 61000-4-11: 2004) – Voltage Dips and Interruptions Immunity (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The EUT was tested with a supply voltage of 100V AC 50 Hz as well as 240V AC 50 Hz. The Generator meets the specified requirements of the standard with at least 95% confidence.

11) **EN 60601-1-2: 2015** – (EN 61000-4-2: 2009) – Electrostatic Discharge Immunity (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The Generator meets the specified requirements of the standard with at least 95% confidence.

Manufacturer:	Palliare Ltd. Galway Business Park, Dangan, Galway. H91 P2DK. Ireland.
Test Dates:	4th December 2020 to 11th December 2020.
Date of Receipt of Test Item:	2nd December 2020.
EUT Description:	Laparo-Endoscopic Insufflator.
EUT Manufacturer:	Palliare Ltd.
EUT Model Number:	EVA-15.
EUT Serial Number:	102520201117-05.
EUT Software revision:	00.12.
Operating Conditions:	**Mode 1:** 240V AC 50 Hz supplied to the EUT (unless stated otherwise). The EUT displayed a steady pressure of 15 mmHg and the Flow mode indicated a reading of 02 to 08 SLPM as the pressure was maintained. Cavity size: Large. Insufflation: Maintain. The EUT was identified as Class 1 earthed equipment. **Basic Safety and Essential Performance (as Declared by the Manufacturer)** Patient pressure shall not vary from its target setting by more than 5 mmHg for more than 5 sec when measured in a vessel with compliance 7ml/mmHg or less. A leak of at least 1 L/min will be created in the test apparatus to ensure that there is continuous delivery of gas. In the case of loss of power or a fuse blowing, no gas shall be delivered to the patient.

Approved Signatories: K.G. Richens - Managing Director

K.G. Richens

APPROVED SIGNATORY

Verification Signatories: M. Richens - Technical Director

VERIFICATION SIGNATORY

EMC TEST CERTIFICATE PAGE 3 OF 3

ISSUED BY:
Cranage EMC Testing Limited, Wallace Way, Tern Valley Business Park, Market Drayton, Shropshire. TF9 3AG.

This Certificate can only be reproduced in its entirety.

UKAS TESTING 1833

Certificate No: **E9359C** Date of Issue: **23rd December 2020**

The item detailed below has been tested in accordance with:

EN 60601-1-2: 2015 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The results contained within this Certificate only apply to this specific Equipment Under Test.

This certificate is issued in conjunction with EMC test report E9359R.

All measurements were taken using calibrated equipment traceable to National Standards.

12) **EN 60601-1-2: 2015** – (EN 61000-4-8: 2010) – Power Frequency Magnetic Field Immunity. (Professional Healthcare Facility Environment immunity levels). The EUT met the manufacturer's declared basic safety and essential performance when tested in mode 1. The Generator meets the specified requirements of the standard with at least 95% confidence.

Manufacturer:	Palliare Ltd. Galway Business Park, Dangan, Galway. H91 P2DK. Ireland.
Test Dates:	4th December 2020 to 11th December 2020.
Date of Receipt of Test Item:	2nd December 2020.
EUT Description:	Laparo-Endoscopic Insufflator.
EUT Manufacturer:	Palliare Ltd.
EUT Model Number:	EVA-15.
EUT Serial Number:	102520201117-05.
EUT Software revision:	00.12.
Operating Conditions:	**Mode 1:** 240V AC 50 Hz supplied to the EUT (unless stated otherwise). The EUT displayed a steady pressure of 15 mmHg and the Flow mode indicated a reading of 02 to 08 SLPM as the pressure was maintained. Cavity size: Large. Insufflation: Maintain. The EUT was identified as Class 1 earthed equipment. **Basic Safety and Essential Performance (as Declared by the Manufacturer)** Patient pressure shall not vary from its target setting by more than 5 mmHg for more than 5 sec when measured in a vessel with compliance 7ml/mmHg or less. A leak of at least 1 L/min will be created in the test apparatus to ensure that there is continuous delivery of gas. In the case of loss of power or a fuse blowing, no gas shall be delivered to the patient.

Approved Signatories: K.G. Richens - Managing Director

K.G. Richens

APPROVED SIGNATORY

Verification Signatories: M. Richens - Technical Director

VERIFICATION SIGNATORY