Compliance

Make: ORSIM™ Model: 1.x

The ORSIM Bronchoscopy Simulator is in conformity with the applicable requirements of the following documents:

**EMC:** Tested fully to the emission and immunity requirements of IEC 60601-1-2 which includes emission testing to EN 55011 as a Class B device.

**FCC:** This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**Class B warning to users:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**Warning to users:** Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment and invalidate the certification.

The computer that accompanies this device is required to be a class B computer that has been either FCC certified or is covered by an FCC declaration of conformity or similar.

**ICES-003:** This Class B digital apparatus complies with Canadian ICES-003.

**LVD:** 5V USB and therefore is SELV (Safety Extra Low Voltage)

**LASER:** Full compliance with IEC60825-1:2007

**Important**

This product contains a high power embedded laser, and therefore it must NOT be opened while it is powered via the USB connector. Doing this could risk optical injury. Opening the unit without Airway Limited’s express written permission is prohibited and will void the warranty. **CAUTION:** Making internal adjustments or performing procedures other than those described in this manual may cause hazardous radiation exposure and is not permitted.