



UKCA Declaration of Conformity

This declaration is issued according to the UK Conformity Assessed (UKCA) scheme for:

- **Manufacturer:** Tiny Air Limited
- **Address:** Ardwall Dairy House, Gatehouse of Fleet, Castle Douglas DG7 2EN
- **Device Name:** Tiny Air
- **Device Function:** Automated Pre-Cleaning Machine for Surgical Instruments
- **Model Number(s):** v2.1
- **Classification:** Class I Rule 1 Medical Device

This declaration confirms that the aforementioned device(s) comply with the following directives:

- **Machinery Directive 2006/42/EC (as amended by SI 2019/742)**
- **Low Voltage Directive 2014/35/EU (as amended by SI 2016/1107)**
- **Electromagnetic Compatibility Directive 2014/30/EU**
- **Medical Devices Regulation 2017/745 (as amended by SI 2020/1218)**
- **Noise Emission in the Environment Directive 2000/14/EC (as transposed by The Noise at Work Regulations 2005)**
- **Pressure Equipment Directive 2014/68/EU (as amended by SI 2016/1103)**

This declaration of conformity is made under the sole responsibility of the manufacturer.

This declaration is valid for a period of: 5 years from the date of issue

Issued Date: 9th May 2024

Standards Used:

- List the relevant harmonised standards used to demonstrate compliance with each directive. For example:
 - EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
 - EN 61000-6-3:2007 - Electromagnetic compatibility (EMC) - Generic standards - Emission standards for residential, commercial and light-industrial environments
 - BS EN ISO 12100:2010 - Safety of machinery - General principles for design and construction

Signed: **contact us for original document copy**

- **Name:** Christopher Helson
- **Title:** Director
- **Place:** Castle Douglas
- **Date:** 9th May 2024