EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 – Medical Devices Regulation (MDR)

This EU Declaration of Conformity is issued under the **sole responsibility of the manufacturer**.

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1. Manufacturer

Legal Manufacturer:
Tiny Air Limited
Ardwall Dairy House
Gatehouse of Fleet
Castle Douglas
DG7 2EN
United Kingdom

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2. EU Authorised Representative (Article 11 MDR)

EU Authorised Representative:
Israel Pecharromán Herrero (DNI: 29126592J)
Registered Industrial Engineer (19068) Meditrust.Solutions
Calle Monte Archanda nº 29. 28660 Boadilla del Monte (Madrid)
Spain

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3. Product Identification

Device Name: Tiny Air
Intended Purpose: Automated pre-cleaning machine for surgical instruments
Model Number(s): v2.1
Medical Device Classification: Class I medical device
Classification Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI: [If applicable / to be assigned]

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4. Declaration

Tiny Air Limited hereby declares that the medical device identified above **conforms to the requirements of Regulation (EU) 2017/745 (Medical Devices Regulation)**.

This declaration covers compliance with:

- The **General Safety and Performance Requirements (GSPR)** set out in **Annex I**
- The **technical documentation requirements** of **Annex II and Annex III**

This declaration is issued under the **exclusive responsibility of the manufacturer**.

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5. Applicable Union Legislation

The device complies with the following Union legislation:

- **Regulation (EU) 2017/745 – Medical Devices Regulation (MDR)**

Where applicable, compliance with relevant aspects of the following legislation has been demonstrated **through conformity with the MDR Annex I requirements**:

- **Electromagnetic Compatibility Directive 2014/30/EU**
- **Pressure Equipment Directive 2014/68/EU**

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6. Harmonised Standards and Common Specifications

The following harmonised standards have been applied, in whole or in part, to demonstrate conformity:

- **EN ISO 13485:2016**
  Medical devices – Quality management systems – Requirements for regulatory purposes
- **EN ISO 14971:2019**
  Medical devices – Application of risk management to medical devices
- **BS EN ISO 12100:2010**
  Safety of machinery – General principles for design – Risk assessment and risk reduction
- **EN 61000-6-3:2007 + A1:2011**
  Electromagnetic compatibility (EMC) – Emission standard for residential, commercial and light industrial environments
- **EN 61000-6-1:2007**
  Electromagnetic compatibility (EMC) – Immunity standard for residential, commercial and light industrial environments

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7. CE Marking

The medical device described above bears the **CE marking** in accordance with Article 20 of Regulation (EU) 2017/745.

8. Validity

This Declaration of Conformity is valid for a period of **five (5) years** from the date of issue, unless superseded by a revised declaration due to changes in the device, applicable legislation, or standards.

9. Place and Date of Issue

Place: Castle Douglas, United Kingdom
Date of Issue: 4th Jan 2026

10. Signature

Signed on behalf of the manufacturer:

Signature:

contact us for original copy

Name: Christopher Helson
Title: Director
Company: Tiny Air Limited