

Final Report

Virological Efficacy Assessment of a Thermal Virus-Inactivating Air Purification Device

1 Administrative Information

Item	Details
Project title	Virological Efficacy Assessment of a Thermal Virus-Inactivating Air Purification Device
Tested device	Thermal virus-inactivating air purification device / Air sterilisation apparatus
Device type	TAC-30
Client / Manufacturer	TAC-Thermal Air Cleaning Kft.
Testing organisation	RoLink Biotechnology Kft.
Contract / assignment reference	TAC-001 – Cooperation Agreement, 05 June 2025
Test location	University of Pécs National Laboratory of Virology, PTE SzKK C411 Laboratory
Biosafety level	BSL-2
Test period	05 June 2025 – 16 December 2025
Final report date	16 December 2025

The above administrative information applies to the full duration of the study and to all experimental results presented in this final report.

2 Purpose and Scope of the Study

Aspect	Description
Purpose of the study	The purpose of this study was to experimentally assess the virological and aerosol-related efficacy of the TAC-30 thermal virus-inactivating air purification device, with particular emphasis on the elimination of infectivity of airborne viruses under operational conditions.
Subject of the study	Verification of viral inactivation in air processed by the device, including separate evaluation of viral infectivity (cell culture, TCID ₅₀) and viral genome presence (PCR).
Scope of the study	The study covered the development and validation of the aerosolisation and sampling system, optimisation of downstream virus capture and recovery, chemical indicator-based (NaOH–AgNO ₃) assessment of outlet behaviour, and integrated inactivation testing using active virus.
Limitations of the study	The experiments were conducted under laboratory conditions using a defined model virus (Sindbis virus). The results are valid for the tested device, documented operating parameters, and experimental configuration; application under different conditions may require additional validation.
Application environment	The investigations were performed in a controlled BSL-2 laboratory environment, with the device operated at its designated operational temperature, modelling real-world usage conditions.

The purpose and scope of the study are consistent with the intended use of the device and enable an objective and reproducible evaluation of its virological performance.

14 Conclusion (MDR Annex II – Performance Evaluation)

Based on the investigations described in this technical documentation, it is concluded that the TAC-30 thermal virus-inactivating air purification device demonstrates effective virological performance under the defined and validated operating conditions.

Performance evaluation data show that, while viral genetic material may remain detectable at the device outlet by molecular methods (PCR), no replication-competent or infectious virus was detected using cell culture-based assays or TCID₅₀ testing. This differentiation confirms that the device achieves true viral inactivation rather than physical filtration or retention alone.

The applied test model, methodology, and analytical approaches were appropriate, reproducible, and conducted under controlled biosafety conditions. The results are consistent with the device's intended purpose and support the conclusion that the device performs as intended within its specified operational parameters.

This performance evaluation contributes to the overall benefit-risk assessment and supports conformity with applicable general safety and performance requirements, within the scope defined in this documentation.

15 Declaration

We hereby declare that:

- The investigations and performance evaluations described in this document were conducted in accordance with documented methodologies and applicable biosafety and quality management requirements.
- The results presented represent a true and accurate reflection of the data generated during testing.
- This conclusion is valid exclusively for the tested device configuration, operating conditions, and experimental setup as documented herein.
- This document is intended to support technical documentation, performance evaluation, and conformity assessment activities under Regulation (EU) 2017/745 and does not replace the final determination of conformity by a notified body or competent authority.

Place of issue: Pécs, Hungary

Date: 18 December 2025

Organisation: RoLink Biotechnology Kft.

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Dr. Roland Hetényi

Managing director