

**The Appendix is an integral part of  
Certificate of Accreditation No: 220/2024 of 13/05/2024**

**Accredited entity according to ČSN EN ISO/IEC 17025:2018:**

**LABOX spol. s r.o.**  
CAB number 1313, LABOX Testing Laboratory  
Brandýská 8, 250 90 Jirny

*The laboratory provides opinions and interpretations of the test results.*

**Tests:**

Ordinal number <sup>1</sup>	Test procedure / method name	Test procedure / method identification <sup>2</sup>	Tested subject	Degrees of freedom <sup>3</sup>
1*	Determination of the mean airflow velocity and airflow volume in ducts and ventilation elements	SOP-Z001 (ČSN 12 4010; ČSN EN ISO 14644-3)	Air handling equipment and environment	-
2*	Measurements of aerosol particles in the air and gases based on the principle of light scattering	SOP-Z002 (ČSN EN ISO 14644-1; ČSN EN ISO 14644-3; IEST RP CC 006.2, cl. 6.3; FS 209 E; EU GMP Annex 1; VYR 32)	Equipment and premises with controlled cleanliness of air and gases	-
3*	Measurement of deviations of streamlines in unidirectional air flow	SOP-Z003 (ČSN EN ISO 14644-3; IEST RP CC 006.2, cl. 6.5; EU GMP Annex 1; VYR 32)	Equipment with laminar air flow	-
4*	Measurement of the overall filtration efficiency based on the principle of light scattering	SOP-Z004 (ASI directive, Part 3, Annex F)	Aerosol filter elements, filters and filtering equipment	-
5*	HEPA filter integrity test	SOP-Z005 (ČSN EN ISO 14644-3; IEST RP CC 006.2, cl. 6.2; EU GMP Annex 1; VYR 32)	High efficiency particle air filters and filter elements	-
6*	HEPA filter integrity test of free HEPA filters	SOP-Z006 (IEST RP CC 006.2, cl. 6.2)	High efficiency particle air filter elements	-
7*	Determination of recovery time of a ventilated room	SOP-Z007 (ČSN EN ISO 14644-3; IEST RP CC 006.2, cl. 6.7; EU GMP Annex 1; VYR 32)	Premises and equipment with controlled air cleanliness	-
8*	Determination of pressure pattern of a ventilated room	SOP-Z008 (ČSN EN ISO 14644-3; IEST RP CC 006.2, cl. 6.4; EU GMP Annex 1; VYR 32)	Premises and equipment with controlled cleanliness of air, ventilated and air-conditioned rooms	-
9*	Measurement of relative humidity	SOP-Z009 (ČSN EN ISO 7726)	Working environment	-

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Ordinal number <sup>1</sup>	Test procedure / method name	Test procedure / method identification <sup>2</sup>	Tested subject	Degrees of freedom <sup>3</sup>
10*	Measuring the resulting air temperature	SOP-Z010 (ČSN EN ISO 7726)	Working environment	-
11*	Temperature measurement by a data logger	SOP-Z011 (ČSN EN 285+A1; ČSN EN ISO 17665-1; instruction SÚKL DIS-15; EU GMP Annex 1; VYR 32)	Thermal devices	-
12*	Pressure measurement by a data logger	SOP-Z012 (ČSN EN 285+A1; ČSN EN ISO 17665-1; EU GMP Annex 1; VYR 32)	Thermal devices	-
13*	Determination of the average velocity and uniformity of airflow in a unidirectional air flow area	SOP-Z013 (ČSN EN ISO 14644-3; ČSN EN 12469; IEST RP CC 006.2, cl. 6.1; EU GMP Annex 1; VYR 32)	Equipment and premises with laminar air flow	-
14*	Auxiliary HEPA filter integrity test of clean room	SOP-Z014 (ČSN EN ISO 14644-3; IEST RP CC006.2, cl. 6.6; EU GMP Annex 1; VYR 32)	Premises with controlled air cleanliness	-
15*	Determination of air power and air reserve of the air handling system	SOP-Z015 (IEST RP CC 006.2, cl. 6.1)	Air handling systems	-

<sup>1</sup> asterisk at the ordinal number identifies the tests, which the laboratory is qualified to carry out outside the permanent laboratory premises

<sup>2</sup> if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest valid edition of the specified procedure is used (including any changes)

<sup>3</sup> the laboratory does not apply a flexible approach to the scope of accreditation

**Explanations and abbreviations:**

- ASI - Association of Mechanical Engineers
- ASTM - American Standard Test Method
- EU GMP - European Union Good Manufacturing Practices
- FS - Federal standard USA
- IEST - Institute of Environmental Science and Technology
- SOP - Standard Operating Procedure (Internal Test Procedure of the Laboratory)
- SÚKL - State Institute for Drug Control
- VYR - Guide to Good Manufacturing Practice