# The Appendix is an integral part of Certificate of Accreditation No. 62/2023 of 09/02/2023

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

## TRIGON PLUS s.r.o.

CAB number 1679, TRIGON PLUS, Testing Laboratory Západní 93, 251 01 Čestlice

The laboratory provides opinions and interprets test results.

### **Tests:**

Ordinal number <sup>1</sup>	Test procedure / method name	Test procedure / method identification <sup>2</sup>	Subject of the test	Degrees of freedom <sup>3</sup>
1*	Determination of mean flow velocity and flow uniformity	ZL-PP-01 (ČSN EN 12469; ČSN EN ISO 14644-3; EU GMP Annex 1; VYR-32 Appendix 1)	Clean rooms and equipment with air and gas cleanliness control	-
2*	Enumeration of aerosol particles in air and gas with a laser particle counter	ZL-PP-02 (ČSN EN ISO 14644-1; ČSN EN ISO 14644-3; EU GMP Annex 1; VYR-32 Appendix 1)	Clean rooms and equipment with air and gas cleanliness control	-
3*	Non destructive inspection of filters by a laser particle counter	ZL-PP-03 (ČSN EN 12469; ČSN EN ISO 14644-3)	High performance aerosol filter cartridges	-

- asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent Laboratory premises
- 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 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

### Explanatory notes:

ZL-PP: Test Procedure TRIGON PLUS, Testing Laboratory

GMP: European Commission regulations for good manufacturing practice for medicinal products for human and

VYR: regulations of the State Institute for Drug Control for good manufacturing practice for medicinal products

for human and veterinary use