The Appendix is an integral part of
Certificate of Accreditation No.: 88/2023 of 27/02/2023

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

ITEST plus, s.r.o.

CAB number 1678, ITEST plus Inspection Laboratory
Kladská 1032/44c, Slezské Předměstí, PSČ 500 03 Hradec Králové

Testing laboratory locations:

1.	**HK Inspection Laboratory**	**Kladská 1032/44c, Slezské předměstí, 500 03 Hradec Králové**
2.	**BV Inspection Laboratory**	**Bílé Vchýnice 10, 533 16 Vápno u Přelouče**

1. HK Inspection Laboratory

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested object	Degrees of freedom[3]
1	Determination of bacterial endotoxins, quantitative method Kinetic turbidimetric method	SOP-K.5.01 (Ph. Eur. p. 2.6.14, Method C; USP <85>; ČSN EN ISO 10993-12; ANSI/AAMI ST72)	Medical devices	-
2	Determination of bacterial endotoxins, limit test Gel method	SOP-K.5.02 (Ph. Eur. p. 2.6.14, Method A; USP <85>; ČSN EN ISO 10993-12; ANSI/AAMI ST72)	Medical devices	-
3	Determination of a population of microorganisms (bioburden) by culture (Bile tolerant G^- bacteria, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella sp.)*	SOP-K.4.11 (ČSN EN ISO 11737-1; Ph. Eur. p. 2.6.12, p. 2.6.13; USP <61>; USP <62>)	Medical devices	-
4	Determination of microbiological contamination (monitoring) by culture - aeroscope - fall-outs - smears - surface prints - finger prints	SOP-K.8.01, chap. 4.1.1.1; SOP-K.8.01, chap. 4.1.2.1; SOP-K.8.01, chap. 4.2.1; SOP-K.8.01, chap. 4.3.1.1; SOP-K.8.01, chap. 4.3.2.1; (Ph. Eur. p. 2.6.12, p. 2.6.13; VYR-36; ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141)	Cleanrooms	-

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[1] asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

[2] 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)

[3] the laboratory does not apply a flexible approach to the scope of accreditation

Sampling:

Ordinal number	Sampling procedure name	Sampling procedure identification[1]	Sampled object	Degrees of freedom[3]
1	Sampling of air - aeroscope - fall-outs	 SOP-K.8.01, chap. 4.1.1; SOP-K.8.01, chap. 4.1.2; (ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141)	Cleanrooms	-
2	Sampling of surfaces - smears - surface prints - finger prints - clothing prints	 SOP-K.8.01, chap. 4.2; SOP-K.8.01, chap. 4.3.1; SOP-K.8.01, chap. 4.3.2; SOP-K.8.01, chap. 4.3.3; (ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141)	Cleanrooms	-

[1] if the document identifying the sampling procedure is dated, only these specific procedures are used. If the document identifying the sampling procedure is not dated, the latest edition of the specified procedure is used (including any changes)

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2. BV Inspection Laboratory

Tests:

Ordinal number[1]	Test procedure/ method name	Test procedure/ method identification[2]	Tested object	Degrees of freedom[3]
1	Sterility test by culture	SOP-K.1.01 (Ph. Eur. p. 2.6.1; ČSN EN ISO 11737-2; USP <71>)	Medical devices	-
2	Determination of a population of microorganisms (bioburden) by culture (Bile tolerant G^- bacteria, *Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella sp.)*	SOP-K.4.11 (ČSN EN ISO 11737-1 Ph. Eur. p. 2.6.12, p. 2.6.13; USP <61>; USP <62>)	Medical devices	-
3	Determination of microbiological contamination (monitoring) by culture - aeroscope - fall-outs - smears - surface prints - finger prints	SOP-K.8.01, chap. 4.1.1.1; SOP-K.8.01, chap. 4.1.2.1; SOP-K.8.01, chap. 4.2.1; SOP-K.8.01, chap. 4.3.1.1; SOP-K.8.01, chap. 4.3.2.1; (Ph. Eur.: p. 2.6.12, p. 2.6.13; VYR-36; ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141)	Cleanrooms	-

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[3] the laboratory does not apply a flexible approach to the scope of accreditation

Explanations:

SOP - Standard Operating Procedure

Ph. Eur. - European Pharmacopoeia

USP - US Pharmacopoeia

ANSI/AAMI ST72 - Bacterial Endotoxins – Test Methodologies, Routine Monitoring

VYR - Instructions for Good Manufacturing Practice