

**The Appendix is an integral part of
Certificate of Accreditation No.: 384/2024 of 13/08/2024**

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 | Bílá Vchýnice 10, 533 16 Vápno u Přelouče |

Detailed information on activities within the scope of accreditation (source literature) is given in the section „Specification of the scope of accreditation“.

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. cl. 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. cl. 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, <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> sp.)	SOP-K.4.11 (ČSN EN ISO 11737-1; Ph. Eur. cl. 2.6.12, cl. 2.6.13; USP <61>; USP <62>)	Medical devices	-
4	Determination of microbiological contamination (monitoring) by culture - aeroscope - fall-outs - swabs - 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	Cleanrooms	-

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 valid edition of the specified procedure is used (including any changes)

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

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (source literature)
4	Ph. Eur. cl. 2.6.12, cl. 2.6.13; ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141

Sampling:

Ordinal number	Sampling procedure name	Sampling procedure identification ¹	Subject of sampling	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	Cleanrooms	-
2	Sampling of surfaces - swabs - 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	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)

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (source literature)
1, 2	ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141

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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.cl. 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, <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Salmonella sp.</i>)	SOP-K.4.11 (ČSN EN ISO 11737-1 Ph. Eur.cl. 2.6.12,cl. 2.6.13; USP <61>; USP <62>)	Medical devices	-
3	Determination of microbiological contamination (monitoring) by culture - aeroscope - fall-outs - swabs - 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	Cleanrooms	-

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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 valid edition of the specified procedure is used (including any changes)

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

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (source literature)
3	Ph. Eur. cl. 2.6.12, cl. 2.6.13; ČSN EN ISO 14698-1; ČSN EN ISO 14698-2; ČSN EN 17141

Explanations:

SOP Standard Operating Procedure
Ph. Eur. European Pharmacopoeia
USP US Pharmacopoeia
AAMI Association for the Advancement of Medical Instrumentation
ANSI American National Standard Institute

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."