EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 88/2023

ITEST plus, s.r.o.
with registered office Kladská 1032/44c, Slezské Předměstí, 500 03 Hradec Králové,
Company Registration No. 62061828

to the Testing Laboratory No. **1678**
ITEST plus Inspection Laboratory

Scope of accreditation:

Microbiological monitoring of cleanrooms in the production of medical devices; tests for the presence of endotoxins and for sterility, microbial contamination of medical devices (bioburden) to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO/IEC 17025:2018

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 40/2022 of 31. 1. 2022, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **27. 2. 2028**

Prague: 27. 2. 2023

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN
-3-

Jan Velíšek
Director of the Department
of Testing and Calibration Laboratories
Czech Accreditation Institute
Public Service Company

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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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

[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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NÁRODNÍ AKREDITAČNÍ ORGÁN
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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

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	-

[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

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