



SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

Karloveská 63, 840 00 Bratislava 4, Slovenská republika

## CERTIFICATE OF ACCREDITATION

**No. S-264**

**The Slovak National Accreditation Service based on the decision  
No. 364/9420/2021/1 dated 04.08.2021 certifies that**

**CHIRANA T.Injecta, a. s.**

**Microbiological laboratory**

Nám. Dr. Alberta Schweitzera 194, 916 01 Stará Turá

ID Number: 36 794 619


is competent to perform microbiological, biological, physical testing of medical devices and injection and infusion solutions, to perform sampling and analyses of air in clean rooms and imprints/drosses from surfaces, areas, objects and devices within the accreditation scope delineated in the Annex to this Certificate. The Annex is an integral part of Certificate of Accreditation.

*The accredited body gives evidence of competence to perform the accredited activity impartially and trustworthily by meeting the requirements of the **ISO/IEC 17025: 2017 Standard.***

Accreditation granted on 05.11.2021 is valid until 05.11.2026.

Bratislava 04.08.2021



  
Martin Senčák  
director

**Accreditation scope**

Name of the accredited subject: **CHIRANA T.Injecta, a. s.**  
**Microbiological laboratory**  
Nám. Dr. Alberta Schweitzera 194, 916 01 Stará Turá

**Laboratory with a fixed accreditation scope.**

| Item no. | Test subject  |   | Established method                        |   | Other specifications<br>(range, uncertainty, purpose,<br>modification / validation,<br>opinions/interpretations, etc.) |
|----------|---|---|---|---|--|
|          | Subject /<br>Matrix /<br>Environment                | Property /<br>Parameter /<br>Indicator /<br>Analyte | Principle /<br>Kind of /<br>Type          | Prescription                              |  |
| 1.       | Medical devices                                     | Sterility   | Cultivation method<br>(Qualitative test)  | EuPh 2.6.1<br>(SOP 4420)                  | SL   |
|          | Injection and<br>infusion<br>solutions              | Bioburden   | Cultivation method<br>(Quantitative test) | EN ISO 11737-1,2<br>(SOP 4421)            | SL   |
| 3.       |   | Bacterial<br>endotoxin                              | Gel method<br>(Qualitative test)          | EuPh 2.6.14<br>(SOP 4430)                 | Limited test   |
| 4.       |   | Invisible<br>particles in fluid                     | Optical method<br>(Quantitative test)     | EuPh 2.9.19<br>(SOP 4438)                 | SL   |
| 5.       | Air in the clean<br>and<br>air-conditioned<br>rooms | Non-viable partical<br>contamination                |   | EN ISO 14644<br>part 1-5, 7<br>(SOP 4441) | VSM  |
| 6.       |   | Viable partical<br>contamination                    | Cultivation method<br>(Quantitative test) | EN 17141<br>(SOP 4439)                    | OVM  |
| 7.       | Prints/swabs<br>from surfaces<br>and equipments     | Microbial<br>contamination<br>of surfaces           |   | EN 17141<br>(SOP 4439)                    | OVM  |

## Abbreviations:

SL - test performed in laboratory,

VSM - test performed in place,

OVM - samples selection in place

**Sampling:**

| Item no. | Object   |                                 |  | Method                 |   | Other specifications |
|----------|--|---------------------------------|--|------------------------|---|----------------------|
|          | Subject  | Property                        | Sampling place                                   | Kind of /<br>Principle | Prescription                              |                      |
| 1.       | Air  | Test<br>performance –<br>item 5 | Air in the clean and<br>air-conditioned<br>rooms | Point sampling         | EN ISO 14644-1<br>(SOP 4440, SOP<br>4441) |                      |
| 2.       |  | Test<br>performance –<br>item 6 |  |                        | EN 17141<br>(SOP 4439, SOP<br>4440)       |                      |
| 3.       | Prints/swab<br>s from<br>surfaces<br>and<br>equipments | Test<br>performance –<br>item 7 | Prints/swabs from<br>surfaces and<br>equipments  | Print/swab method      | EN 17141<br>(SOP 4439, SOP<br>4440)       |                      |

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