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SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

CHIRANA T.Injecta, a. s.

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

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, MANUFACTURING, ASSEMBLY, STERILIZATION AND SALES OF STERILE AND NON STERILE DISPOSABLE MEDICAL DEVICES AND COMPONENTS:
- DEVICES (SYRINGES, SYRINGE SETS, NEEDLES, OPHTHALMIC NEEDLES, INSULIN/TUBERCULIN SYRINGES, STERILE FILTERS/CUPS AND SETS, I.V. CANNULAS INCLUDING ACCESSORIES, INFUSION AND TRANSFUSION SETS INCLUDING ACCESSORIES, EXAMINATION DEVICES, LANCETS)
- COMPONENTS (LANCETS, CANNULAS, TUBES)

Certificate No.: M-0521/24 **Date of issuance: December 18th, 2024** **Original date of approval: January 25th, 2022**

This certificate is valid from **January 25th, 2025** to **January 24th, 2028** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a. s.

Certification body 3EC International a. s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.

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