CHIRANA T. Injecta
We supply values for life

CHIRANA T. Injecta, a.s.
Nám. Dr. Schweitzera 194
916 01 Stará Turá
Slovenská republika / Slovak Republic

IČO: **36794619**
IČ DPH/VAT No: **SK2022402822**

EU DECLARATION OF CONFORMITY

(no. EC 04-2024)

We, ***CHIRANA T. Injecta a.s.,***
nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Single registration number (SRN): SK-MF-000003702

manufacturer of: STERILE SINGLE USE MEDICAL DEVICES

declare in our own responsibility, that the product:

STERILE TUBERCULIN SYRINGE FOR SINGLE USE

Brand name: CHIRANA® / Acti-fine®

Versions: *various sizes and types*

intended use for: *Tuberculin syringe for single use is intended for administration of liquids and drugs into the body.*

Indication: *Tuberculin syringe is intended for injection of fluids or drugs into the body and for the administration of vaccines immediately after filling. It is not intended to store vaccines for prolonged period of time. A tuberculin syringe 1 ml is used in the combination with needle.*

classified as Class: IIa *according to classification set out in Annex VIII, Rule 6 of the EU Medical Device Regulation (MDR) 2017/745*

is in compliance:

- with provisions of Annex I of Regulation (EU) 2017/745 of the European parliament and of the council of 5th April 2017 on medical devices which apply to them
- with provisions of technical specification TPF 320-0404-02, EN ISO 8537:2016, EN ISO 7886-1:2018, EN ISO 7864:2016, EN ISO 11135:2014, EN ISO 14971:2019, EN ISO 13485:2016/AC:2018, EN ISO 11607-1:2020, standards selected from the group EN ISO 14644 and EN ISO 10993, European Pharmacopoeia actual edition and other relevant ISO/EN standards mentioned in product specification and list of standards for product
- have been subject to following conformity assessment procedure laid down in the Regulation (EU) 2017/745, Article 52 (6) relating to the Quality Management System and Technical Documentation set out in Annex IX.
- are certified by the Notified Body 3EC International a.s., identification number 2265

Product: STERILE TUBERCULIN SYRINGE FOR SINGLE USE – CHIRANA / ACTI-FINE

It was issued Certificate no. 2022-MDR/QS-026/A Rev.01 dated of 14.07.2023, valid till 30.09.2027 for product. Product models are marked with CE 2265.

EU declaration of conformity is issued under the sole responsibility of the manufacturer.
Signed for and on behalf of manufacturer.

in Stará Turá, date 02.02.2024

CHIRANA T.Injecta, a. s.
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IČO: 36794619
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CHIRANA T. Injecta
www.t-injecta.sk

Rastislav Broska, PhD.
Quality Manager

Product: STERILE TUBERCULIN SYRINGE FOR SINGLE USE – CHIRANA / ACTI-FINE

Versions:
Tuberculin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G
1 ml Luer

Product variants – CHIRANA:

Product REF code	***Product model***	***Basic UDI-DI (GMN)***
CHTUB01	*1 ml Luer*	*858601504TUBERCULIN04LN*
CHTUB0129	*1ml 29G x 1/2"*	

Product variants – ACTI-FINE:

Product REF code	***Product model***	***Basic UDI-DI (GMN)***
S381CE0T1	*1 ml Luer*	*858601504TUBERCULIN04LN*