

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

## EU DECLARATION OF CONFORMITY

(no. EC 20-2024)

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:

### **SPIKE FOR SINGLE USE**

brand name: **CHIRAPLUS**

versions: various types

intended purpose: pharmaceutical preparations – transmit fluids from one container to another (e.g., transfer medication from the vial to the syringe or from the syringe to the vial), mixing fluids or dissolve dry substances in the vials

classified as Class: Is according to classification set out in Annex VIII, Rule 2 of the EU Medical Device Regulation (MDR) 2017/745

is in compliance:

- with provisions of Annex I of the Regulation (EU) 2017/745 of the European parliament and of the council of 5<sup>th</sup> April 2017 on medical devices which apply to them
- with provisions of internal technical specification PS 310-0116-01, EN ISO 22413: 2021, 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 (7a) 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

It was issued Certificate no. 2022-MDR/QS-024/A Rev.01 dated of 11.09.2023, 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



  
Rastislav Broska, PhD.  
Quality Manager

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Product:

SPIKE FOR SINGLE USE - CHIRAPLUS

**Product variants:**

<b>Product REF code</b>	<b>Product model</b>	<b>Basic UDI-DI (GMN)</b>
CHIS01	Infusion spike RED	858601504SPIKE20UA
CHIS02	Infusion spike BLUE	
CHIS03	Infusion spike GREEN	