

EU DECLARATION OF CONFORMITY

(no. EC 21-2022)

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:

STOPPER FOR SINGLE USE

brand name: **CHIRAPLUS**

versions: various types

intended purpose: closure of Luer Lock connectors

classified as Class: **IIa** 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 5th April 2017 on medical devices which apply to them
- with provisions of technical specification PS 310-0918-05, EN ISO 80369-1:2018, EN ISO 80369-7:2017, 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

It was issued Certificate no. 2022-MDR/QS-027 Rev.00 dated of 30.09.2022, 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 01.10.2022



PaedDr. Zdenka Klbečková
Regulatory Affairs Manager

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Product:

STOPPER FOR SINGLE USE - CHIRAPLUS

Product variants:

Product REF code	Product model	Basic UDI-DI (GMN)
<i>CHLL01</i>	<i>Stopper Luer-Lock</i>	<i>858601504STOPPER215Z</i>
<i>CHCS01</i>	<i>Combistopper red</i>	
<i>CHCS02</i>	<i>Combistopper blue</i>	
<i>CHCS03</i>	<i>Combistopper white</i>	