

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 01-2023)

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 HYPODERMIC SYRINGE FOR SINGLE USE

brand name: **CHIRANA / ECOJECT**

versions: - 2-part / 3-part, - Luer / Luer-Lock,
- various sizes (1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50 ml)

intended use for: **injection and taking off a blood and other liquids at patients**

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 TPF 320-0508-01, EN ISO 80369-7:2021, EN ISO 7886-1:2018, 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 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

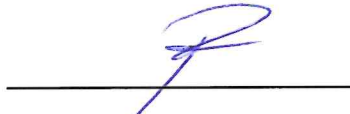
It was issued Certificate no. 2022-MDR/QS-026 Rev.00 dated of 30.09.2022, valid till 30.09.2027 for product. Product models are marked with CE 2265.

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EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of manufacturer.

in Stará Turá, date 04.05.2023


Rastislav Broska, PhD.
Quality Manager



Product:

STERILE HYPODERMIC SYRINGE FOR SINGLE USE – CHIRANA / ECOJECT

Product variants - CHIRANA:

Product REF code	Product model	Basic UDI-DI (GMN)
CH002L	2part syringe – Luer – 2ml	858601504SYRINGE0159
CH005L	2part syringe – Luer – 5ml	
CH010L	2part syringe – Luer – 10ml	
CH020L	2part syringe – Luer – 20ml	
CH03001L	3part syringe – Luer – 1ml	
CH03002L	3part syringe – Luer – 2ml	
CH03003L	3part syringe – Luer – 3ml	
CH03005L	3part syringe – Luer – 5ml	
CH03010L	3part syringe – Luer – 10ml	
CH03020L	3part syringe – Luer – 20ml	
CH03030L	3part syringe – Luer – 30ml	
CH03050L	3part syringe – Luer – 50ml	
CH03001LL	3part syringe – Luer-Lock – 1ml	
CH03002LL	3part syringe – Luer-Lock – 2ml	
CH03003LL	3part syringe – Luer-Lock – 3ml	
CH03005LL	3part syringe – Luer-Lock – 5ml	
CH03010LL	3part syringe – Luer-Lock – 10ml	
CH03020LL	3part syringe – Luer-Lock – 20ml	
CH03020LLO	3part syringe – Luer-Lock – 20ml – Opaque	
CH03030LL	3part syringe – Luer-Lock – 30ml	
CH03050LL	3part syringe – Luer-Lock – 50ml	
CH03050LLO	3part syringe – Luer-Lock – 50ml – Opaque	

Product variants - ECOJECT:

Product REF code	Product model	Basic UDI-DI (GMN)
20002	2part syringe – Luer – 2ml	858601504SYRINGE0159
20005	2part syringe – Luer – 5ml	
20010	2part syringe – Luer – 10ml	
20020	2part syringe – Luer – 20ml	

