

EU DECLARATION OF CONFORMITY

(no. EC 01-2022)

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:

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 purpose: 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 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.

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 Kíbečková
Regulatory Affairs Manager


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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	