

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

EU DECLARATION OF CONFORMITY
(no. EC 03-2024)

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 INJECTION SET FOR SINGLE USE

brand name: **CHIRANA / SYRISET**

versions: syringe with needle / syringe with needle and filter
- various sizes

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 6
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 320-0508-03, 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

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




Rastislav Broska, PhD.
Quality Manager

EU DECLARATION OF CONFORMITY

Product:

STERILE INJECTION SET FOR SINGLE USE – CHIRANA / SYRISET

Versions:

Combination a), b) and c)

a) Syringe (2-part / 3-part, Luer / Luer-Lock)
1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30 ml, 50ml

b) Needle (14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G)
0.3x12, 0.3x40,
0.33x12, 0.33x40,
0.4x12, 0.4x13, 0.4x16, 0.4x19, 0.4x20, 0.4x40,
0.45x12, 0.45x13, 0.45x16, 0.45x20, 0.45x25, 0.45x40,
0.5x16, 0.5x19, 0.5x20, 0.5x25, 0.5x42, 0.5x60,
0.55x25, 0.55x38, 0.55x40,
0.6x16, 0.6x25, 0.6x30, 0.6x40, 0.6x60,
0.7x30, 0.7x35, 0.7x40, 0.7x50, 0.7x90,
0.8x16, 0.8x25, 0.8x30, 0.8x38, 0.8x40, 0.8x50, 0.8x70, 0.8x100,
0.9x25, 0.9x38, 0.9x40, 0.9x50, 0.9x70,
1.1x25, 1.1x30, 1.1x38, 1.1x40, 1.1x50,
1.2x25, 1.2x30, 1.2x38, 1.2x40, 1.2x50, 1.2x65, 1.2x70, 1.2x100,
1.5x50, 1.5x100,
1.6x15, 1.6x25, 1.6x35, 1.6x40, 1.6x70, 1.6x110,
1.8x40, 1.8x50, 1.8x65, 1.8x70, 1.8x100, 1.8x110,
2.0x30, 2.0x40, 2.0x50, 2.0x65, 2.0x70, 2.0x100, 2.0x110, 2.0x120,
2.1x40, 2.1x50, 2.1x120

c) Filter

Product variants - CHIRANA:

Product REF code	Product model	Basic UDI-DI (GMN)
CH002L0630	2ml with needle 0,60 x 30 mm	858601504INJECTIONSET03PG
CH002L0730	2ml with needle 0,70 x 30 mm	
CH005L0730	5ml with needle 0,70 x 30 mm	
CH005L0735	5ml with needle 0,70 x 35 mm	
CH010L0840	10ml with needle 0,80 x 40 mm	
CH020L0840	20ml with needle 0,80 x 40 mm	
CH03002L0625	2ml with needle 0,60 x 25 mm	
CH03002L0630	2ml with needle 0,60 x 30 mm	
CH03002L0730	2ml with needle 0,70 x 30 mm	
CH03002L0840	2ml with needle 0,80 x 40 mm	
CH03005L0625	5ml with needle 0,60 x 25 mm	
CH03005L0730	5ml with needle 0,70 x 30 mm	
CH03005L0735	5ml with needle 0,70 x 35 mm	
CH03010L0840	10ml with needle 0,80 x 40 mm	
CH03020L0840	20ml with needle 0,80 x 40 mm	
CH03050L1240	50ml Luer with needle 1,20 x 40 mm	
CH030502030LL	50ml Luer-Lock with needle 2,0 x 30 mm – transparent	
CH030502030LLO	50ml Luer-Lock with needle 2,0 x 30 mm – opaque	

Product variants - SYRISET:

Product REF code	Product model	Basic UDI-DI (GMN)
10100	1ml with needle 0,45 x 12 mm and filter	858601504INJECTIONSET03PG
10200	1ml with needle 0,5 x 16 mm and filter	
10300	2ml with needle 0,45 x 12 mm and filter	
10400	2ml with needle 0,5 x 16 mm and filter	