

EU DECLARATION OF CONFORMITY

(no. EC 09-2022)

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: **SINGLE USE MEDICAL DEVICES**

declare in our own responsibility, that the product:

STERILE PERFUSION SYRINGE FOR SINGLE USE

brand name: **CHIRANA / INFUJECT / PERFUJECT**

versions: 3-part - Luer-Lock - various sizes (20, 30, 50ml) and types
- with/without needle: 18G-14G
- with/without stopper
- transparent/opaque/black

intended purpose: drug application into human body via syringe pumps.
Needle is for piercing the vials and bags and taking the drug into the syringe. Attached stopper is for temporarily closure of the syringe with prepared drug. Syringe opaque / black is for using with light sensitive drugs and solutions. Syringes can also be used for withdrawing fluids from human body or for administration of fluids into the human body.

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 310-0316-01, EN ISO 7886-1:2018, EN ISO 7886-2:1997, 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 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 Kibečková
Regulatory Affairs Manager



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Product:

STERILE PERFUSION SYRINGE FOR SINGLE USE – CHIRANA / INFUJECT / PERFUJECT

Product variants - CHIRANA:

Product REF code	Product model	Basic UDI-DI (GMN)
CH03020PT	20ml - Perfusion syringe Luer-Lock transparent with red stopper	858601504PERFSYRINGE09ZT
CH03030PT	30ml - Perfusion syringe Luer-Lock transparent with red stopper	
CH03050PT	50ml - Perfusion syringe Luer-Lock transparent	
CH03050PTB	50ml - Perfusion syringe Luer-Lock, BB transparent	
CH03050PTF	50ml - Perfusion syringe Luer-Lock, F transparent	
CH03050PTFS	50ml - Perfusion syringe Luer-Lock, F transparent with red stopper	
CH030502030PT	50ml - Perfusion syringe Luer-Lock transparent with needle 2,0x30mm	
CH030502030PTB	50ml - Perfusion syringe Luer-Lock, BB transparent with needle 2,0x30mm	
CH030501840PTF	50ml - Perfusion syringe Luer-Lock, F transparent with needle 1,8x40mm	
CH03050PO	50ml - Perfusion syringe Luer-Lock opaque	
CH03050POB	50ml - Perfusion syringe Luer-Lock, BB opaque	
CH03050POF	50ml - Perfusion syringe Luer-Lock, F opaque	
CH030502030PO	50ml - Perfusion syringe Luer-Lock opaque with needle 2,0x30mm	
CH030502030POB	50ml - Perfusion syringe Luer-Lock, BB opaque with needle 2,0x30mm	
CH030501840POF	50ml - Perfusion syringe Luer-Lock, F opaque with needle 1,8x40mm	
CH030502030POF	50ml - Perfusion syringe Luer-Lock, F opaque with needle 2,0x30mm	
CH03050PBB	50ml - Perfusion syringe Luer-Lock, BB black	
CH030502030PBB	50ml - Perfusion syringe Luer-Lock, BB black with needle 2,0x30mm	

Product variants – INFUJECT / PERFUJECT:

Product REF code	Product model	Basic UDI-DI (GMN)
21021	20ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT	858601504PERFSYRINGE09ZT
22030	30ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT	
22050	50ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT	
22054	50ml – syringe for infusion pumps Luer-Lock transparent (Kanüle:2,0x30) – INFUJECT	
22064	50ml – syringe for infusion pumps Luer-Lock amber (Kanüle:2,0x30) – INFUJECT	
22051	50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent – PERFUJECT	
22052	50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent (Kanüle:2,0x30) – PERFUJECT	
22063	50ml – syringe for infusion pumps Luer-Lock "Typ P" amber (Kanüle:2,0x30) – PERFUJECT	
22053	50ml – syringe for infusion pumps Luer-Lock "Typ P" black (Kanüle:2,0x30) – PERFUJECT	