

DECLARATION (no. EN 22-2022)

We, **CHIRANA T. Injecta a.s.**,

nám. Dr. A. Schweitzera 194
916 01 Stará Turá
Slovakia

manufacturer of:

STERILE SINGLE USE MEDICAL DEVICES

declare, that product

**Sterile perfusion syringe for single use
INFUJECT / PERFUJECT (DISPOMED)**

Types:

30ml – syringe for infusion pumps Luer-Lock transparent (Kappe) – INFUJECT (22030)
50ml – syringe for infusion pumps Luer-Lock transparent (Kappe) – INFUJECT (22050)
50ml – syringe for infusion pumps Luer-Lock transparent (Kanüle:2,0x30) – INFUJECT (22054)
50ml – syringe for infusion pumps Luer-Lock amber (Kanüle:2,0x30) – INFUJECT (22064)
50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent – PERFUJECT (22051)
50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent (Kanüle:2,0x30) –
PERFUJECT (22052)
50ml – syringe for infusion pumps Luer-Lock "Typ P" amber (Kanüle:2,0x30) – PERFUJECT
(22063)
50ml – syringe for infusion pumps Luer-Lock "Typ P" black (Kanüle:2,0x30) – PERFUJECT
(22053)

are suitable for use with infusion pumps defined in the table below.

in Stará Turá, date 07.12.2022



PaedDr. Zdenka Klbečková
Regulatory Affairs Manager

Product type (REF code)	Setting of the infusion pump	Suitable infusion pumps
30ml syringe for infusion pumps Luer-Lock transparent (Kappe) – INFUJECT (22030)	30 ml Fresenius Medical Heparin	ALARIS: GS, GH, GH plus, GH Guardrail, CC, CC plus, CC Guardrail, TIVA, PK, Asena, Asena CC ALARIS IVAC P1000, P2000, P3000 IVAC: 1000, 2000, 3000, 4000, 5000, 6000, 7000, PCA, IVAC: P4000 (if has defined setting) ASCOR: AP-12, AP-14, AP-22, SEP-11S, SEP-21S (if they have defined setting) TERUMO: TE-311, TE-312, TE-320, TE-331, TE-332, TE-371, TE-372 FRESENIUS: Pilot A2, Pilot C, Pilot Delta, Pilot Anaesthesia2, Orchestra Module DPS, Orchestra module DPS+, Injectomat Agilia, Injectomat MC Agilia, Injectomat TIVA Agilia B-Braun: PERFUSOR, PERFUSOR compact, PERFUSOR compact S, PERFUSOR Space MEDIMA: S1, S2, S300, SPCA MEDIPAN: 604 (if has defined setting) FRESENIUS: 4008S (dialysis machine): Gambro Prismaflex hemofiltration device
50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent – PERFUJECT (22051)	50 ml B-Braun Original Perfusor Spritze	ALARIS: GS, GH, GH plus, GH Guardrail, CC, CC plus, CC Guardrail, TIVA, PK, Asena, Asena CC ALARIS IVAC P1000, P2000, P3000 IVAC: 1000, 2000, 3000, 4000, 5000, 6000, 7000, PCA IVAC: P4000 (if has defined setting) ASCOR: AP-12, AP-14, AP-22, SEP-11S, SEP-21S (if they have defined setting) TERUMO: TE-311, TE-312, TE-320, TE-331, TE-332, TE-371, TE-372 FRESENIUS: Pilot A2, Pilot C, Pilot Delta, Pilot Anaesthesia2, Orchestra Module DPS, Orchestra module DPS+, Injectomat Agilia, Injectomat MC Agilia, Injectomat TIVA Agilia, Injectomat C-PS/CP-PS B-Braun: PERFUSOR, PERFUSOR compact, PERFUSOR compact S, PERFUSOR Space, PERFUSOR Secura FT, PERFUSOR F, PERFUSOR Secura FT µl, PERFUSOR Secura, PERFUSOR Secura P, PERFUSOR VII, PERFUSOR M, PERFUSOR Me, PERFUSOR M1, PERFUSOR ED, ED2, EDL, EDL2, PERFUSOR Bolustikolyse, PERFUSOR FM Clinico: Syritrol 12 MEDIMA: S1, S2, S300, SPCA MEDIPAN: 604 (if has defined setting) Gambro Prismaflex hemofiltration device
50ml – syringe for infusion pumps Luer-Lock "Typ P" transparent (Kanüle:2,0x30) – PERFUJECT (22052)		
50ml – syringe for infusion pumps Luer-Lock "Typ P" amber (Kanüle:2,0x30) – PERFUJECT (22063)		
50ml – syringe for infusion pumps Luer-Lock "Typ P" black (Kanüle:2,0x30) – PERFUJECT (22053)		
50ml – syringe for infusion pumps Luer-Lock transparent (Kappe) – INFUJECT (22050)	50ml Fresenius Kabi AG Injectomat	ALARIS: GS, GH, GH plus, GH Guardrail, CC, CC plus, CC Guardrail, TIVA, PK, Asena, Asena CC ALARIS IVAC P1000, P2000, P3000 IVAC: 1000, 2000, 3000, 4000, 5000, 6000, 7000, PCA IVAC: P4000 (if has defined setting) ASCOR: AP-12, AP-14, AP-22, SEP-11S, SEP-21S (if they have defined setting) TERUMO: TE-311, TE-312, TE-320, TE-331, TE-332, TE-371, TE-372 FRESENIUS: Pilot A2, Pilot C, Pilot Delta, Pilot Anaesthesia2, Orchestra Module DPS, Orchestra module DPS+, Injectomat Agilia, Injectomat MC Agilia, Injectomat TIVA Agilia, Injectomat S, Injectomat 50, Injectomat C-IS/CP-IS B-Braun: PERFUSOR, PERFUSOR compact, PERFUSOR compact S, PERFUSOR Space MEDIMA: S1, S2, S300, SPCA MEDIPAN: 604 (if has defined setting)
50ml – syringe for infusion pumps Luer-Lock transparent (Kanüle:2,0x30) – INFUJECT (22054)		
50ml – syringe for infusion pumps Luer-Lock amber (Kanüle:2,0x30) – INFUJECT (22064)		