



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-026

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia
SRN No.: SK-MF-000003702

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Non-active and Non-implantable Medical Devices: Sterile Syringes for Single Use
(For detailed list refer to Annex I)

Intended purpose: See Annex II
MD class IIa

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR077_2022 from 21.09.2022, MD Clinical Evaluation Report No. MDR077_2022 from 21.09.2022 and MD Audit Report No. SK-0655/22 from 21.09.2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **30.09.2022**
Valid until: **30.09.2027**
First issue: **30.09.2022**
Revision: **00**
History: **Annex III**

In Bratislava, Slovakia, 30.09.2022




3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-026

issued for the company

CHIRANA T. Injecta, a.s.

Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Sterile Hypodermic Syringe for Single use	CHIRANA	2part syringe – Luer – 2ml	CH002L
		2part syringe – Luer – 5ml	CH005L
		2part syringe – Luer – 10ml	CH010L
		2part syringe – Luer – 20ml	CH020L
		3part syringe – Luer – 1ml	CH03001L
		3part syringe – Luer – 2ml	CH03002L
		3part syringe – Luer – 3ml	CH03003L
		3part syringe – Luer – 5ml	CH03005L
		3part syringe – Luer – 10ml	CH03010L
		3part syringe – Luer – 20ml	CH03020L
		3part syringe – Luer – 30ml	CH03030L
		3part syringe – Luer – 50ml	CH03050L
		3part syringe – Luer-Lock – 1ml	CH03001LL
		3part syringe – Luer-Lock – 2ml	CH03002LL
		3part syringe – Luer-Lock – 3ml	CH03003LL
		3part syringe – Luer-Lock – 5ml	CH03005LL
		3part syringe – Luer-Lock – 10ml	CH03010LL
		3part syringe – Luer-Lock – 20ml	CH03020LL
		3part syringe – Luer-Lock – 20ml – Opaque	CH03020LLO
		3part syringe – Luer-Lock – 30ml	CH03030LL
Sterile Hypodermic Syringe for Single use	ECOJECT	2part syringe – Luer – 2ml	20002
		2part syringe – Luer – 5ml	20005
		2part syringe – Luer – 10ml	20010
		2part syringe – Luer – 20ml	20020

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Product	Trade Name	Models	REF code
Sterile Injection Set for Single Use	CHIRANA	2ml with needle 0,60 x 30 mm	CH002L0630
		2ml with needle 0,70 x 30 mm	CH002L0730
		5ml with needle 0,70 x 30 mm	CH005L0730
		5ml with needle 0,70 x 35 mm	CH005L0735
		10ml with needle 0,80 x 40 mm	CH010L0840
		20ml with needle 0,80 x 40 mm	CH020L0840
		2ml with needle 0,60 x 25 mm	CH03002L0625
		2ml with needle 0,60 x 30 mm	CH03002L0630
		2ml with needle 0,70 x 30 mm	CH03002L0730
		2ml with needle 0,80 x 40 mm	CH03002L0840
		5ml with needle 0,60 x 25 mm	CH03005L0625
		5ml with needle 0,70 x 30 mm	CH03005L0730
		5ml with needle 0,70 x 35 mm	CH03005L0735
		10ml with needle 0,80 x 40 mm	CH03010L0840
		20ml with needle 0,80 x 40 mm	CH03020L0840
		50ml Luer with needle 1,20 x 40 mm	CH03050L1240
		50ml Luer-Lock with needle 2,0 x 30 mm – transparent	CH030502030LL
		50ml Luer-Lock with needle 2,0 x 30 mm – opaque	CH030502030LLO

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Product	Trade Name	Models	REF code
Sterile Injection Set for Single Use	SYRISET	1ml with needle 0,45 x 12 mm and filter	10100
		1ml with needle 0,5 x 16 mm and filter	10200
		2ml with needle 0,45 x 12 mm and filter	10300
		2ml with needle 0,5 x 16 mm and filter	10400
Versions (CHIRANA / SYRISET):			
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, 0.3x40,			
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			

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List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	CHIRANA	1ml 27G x 1/2"U100	CHINS0127
		1ml 29G x 1/2"U40	CHINS4129
		1ml 29G x 5/16"U100	CHINS01298
		1ml 29G x 1/2"U100	CHINS0129
		1ml 30G x 1/2"U100	CHINS0130
		1ml 30G x 5/16"U100	CHINS01308
		1ml 31G x 4/16"U100	CHINS01316
		1ml 31G x 5/16"U100	CHINS01318
		1 ml Luer – U100	CHINS01
		1ml Luer – U40	CHINS41
		0,5ml 29G x 1/2"U100	CHINS00529
		0,5ml 30G x 1/2"U100	CHINS00530
		0,5ml 30G x 5/16"U100	CHINS005308
		0,5ml 31G x 5/16"U100	CHINS005318
		0,5ml 31G x 4/16"U100	CHINS005316
		0,3ml 29G x 1/2"U100	CHINS00329
		0,3ml 30G x 1/2"U100	CHINS00330
		0,3ml 30G x 5/16"U100	CHINS003308
		0,3ml 31G x 5/16"U100	CHINS003318
		0,3ml 31G x 4/16"U100	CHINS003316
		1ml 27G x 1/2"U100	CHINS0127PB
		1ml 29G x 1/2"U40	CHINS4129PB
		1ml 29G x 5/16"U100	CHINS01298PB
		1ml 29G x 1/2"U100	CHINS0129PB
		1ml 30G x 1/2"U100	CHINS0130PB
		1ml 30G x 5/16"U100	CHINS01308PB
		1ml 31G x 4/16"U100	CHINS01316PB

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Product	Trade Name	Models	REF code
Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	CHIRANA	1ml 31G x 5/16"U100	CHINS01318PB
		0,5ml 29G x 1/2"U100	CHINS00529PB
		0,5ml 30G x 1/2"U100	CHINS00530PB
		0,5ml 30G x 5/16"U100	CHINS005308PB
		0,5ml 31G x 5/16"U100	CHINS005318PB
		0,5ml 31G x 4/16"U100	CHINS005316PB
		0,3ml 29G x 1/2"U100	CHINS00329PB
		0,3ml 30G x 1/2"U100	CHINS00330PB
		0,3ml 31G x 5/16"U100	CHINS003318PB
		0,3ml 31G x 4/16"U100	CHINS003316PB
Sterile Tubercilin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	CHIRANA	1 ml Luer	CHTUB01
		1ml 29G x 1/2"	CHTUB0129

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Product	Trade Name	Models	REF code
Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	HARMOFINE	1ml 27G x 1/2"U100	HFINS0127
		1ml 29G x 1/2"U40	HFINS4129
		1ml 29G x 5/16"U100	HFINS01298
		1ml 29G x 1/2"U100	HFINS0129
		1ml 30G x 1/2"U100	HFINS0130
		1ml 30G x 5/16"U100	HFINS01308
		1ml 31G x 4/16"U100	HFINS01316
		1ml 31G x 5/16"U100	HFINS01318
		1 ml Luer – U100	HFINS01
		1ml Luer – U40	HFINS41
		0,5ml 29G x 1/2"U100	HFINS00529
		0,5ml 30G x 1/2"U100	HFINS00530
		0,5ml 30G x 5/16"U100	HFINS005308
		0,5ml 31G x 5/16"U100	HFINS005318
		0,5ml 31G x 4/16"U100	HFINS005316
		0,3ml 29G x 1/2"U100	HFINS00329
		0,3ml 30G x 1/2"U100	HFINS00330
		0,3ml 30G x 5/16"U100	HFINS003308
		0,3ml 31G x 5/16"U100	HFINS003318
		0,3ml 31G x 4/16"U100	HFINS003316
		1ml 27G x 1/2"U100	HFINS0127PB
		1ml 29G x 1/2"U40	HFINS4129PB
		1ml 29G x 5/16"U100	HFINS01298PB
		1ml 29G x 1/2"U100	HFINS0129PB
		1ml 30G x 1/2"U100	HFINS0130PB
		1ml 30G x 5/16"U100	HFINS01308PB
		1ml 31G x 4/16"U100	HFINS01316PB

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List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Sterile Insulin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	HARMOFINE	1ml 31G x 5/16"U100 0,5ml 29G x 1/2"U100 0,5ml 30G x 1/2"U100 0,5ml 30G x 5/16"U100 0,5ml 31G x 5/16"U100 0,5ml 31G x 4/16"U100 0,3ml 29G x 1/2"U100 0,3ml 30G x 1/2"U100 0,3ml 31G x 5/16"U100 0,3ml 31G x 4/16"U100	HFINS01318PB HFINS00529PB HFINS00530PB HFINS005308PB HFINS005318PB HFINS005316PB HFINS00329PB HFINS00330PB HFINS003318PB HFINS003316PB
Sterile Tuberculin Syringe with / without Integrated Needle or Side Packed Needle for Single Use	ACTI-FINE	1 ml Luer	S381CE0T1

Versions:

Insulin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G - U40/U100
1 ml Luer - U100

Tuberculin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G
1 ml Luer

- blister / polybag

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List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Sterile Perfusion Syringe for Single Use	CHIRANA	20ml - Perfusion syringe Luer-Lock transparent with red stopper	CH03020PT
		30ml - Perfusion syringe Luer-Lock transparent with red stopper	CH03030PT
		50ml - Perfusion syringe Luer-Lock transparent	CH03050PT
		50ml - Perfusion syringe Luer-Lock, BB transparent	CH03050PTB
		50ml - Perfusion syringe Luer-Lock, F transparent	CH03050PTF
		50ml - Perfusion syringe Luer-Lock, F transparent with red stopper	CH03050PTFS
		50ml - Perfusion syringe Luer-Lock transparent with needle 2,0x30mm	CH030502030PT
		50ml - Perfusion syringe Luer-Lock, BB transparent with needle 2,0x30mm	CH030502030PTB
		50ml - Perfusion syringe Luer-Lock, F transparent with needle 1,8x40mm	CH030501840PTF
		50ml - Perfusion syringe Luer-Lock opaque	CH03050PO
		50ml - Perfusion syringe Luer-Lock, BB opaque	CH03050POB
		50ml - Perfusion syringe Luer-Lock, F opaque	CH03050POF
		50ml - Perfusion syringe Luer-Lock opaque with needle 2,0x30mm	CH030502030PO
		50ml - Perfusion syringe Luer-Lock, BB opaque with needle 2,0x30mm	CH030502030POB
		50ml - Perfusion syringe Luer-Lock, F opaque with needle 1,8x40mm	CH030501840POF
		50ml - Perfusion syringe Luer-Lock, F opaque with needle 2,0x30mm	CH030502030POF
		50ml - Perfusion syringe Luer-Lock, BB black	CH03050PBB
		50ml - Perfusion syringe Luer-Lock, BB black with needle 2,0x30mm	CH030502030PBB

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List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Sterile Perfusion Syringe for Single Use	INFUJECT/ PERFUJECT	20ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT	21021
		30ml – syringe for infusion pumps Luer-Lock transparent (mit Kappe) – INFUJECT	22030
		50ml – syringe for infusion pumps Luer-Lock transparent (mit 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

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Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Sterile Hypodermic Syringe for Single Use: CHIRANA / ECOJECT - injection and taking off a blood and other liquids at patients

Sterile Injection Set for Single Use: CHIRANA / SYRISET - injection and taking off a blood and other liquids at patients

Sterile Insulin / Tuberculin Syringe With / Without Integrated Needle or Side Packed Needle for single Use: CHIRANA / ACTI-FINE / HARMOFINE – Insulin syringe - administration of 1 ml; 0,5 ml or 0,3 ml; that is 100, 50 or 30 units of U 100 insulin, or 1ml of 40 units of U 40 insulin. Tuberculin syringe - administration of vaccines immediately after filling, not to store vaccines for prolonged period of time

Sterile Perfusion Syringe for Single use: CHIRANA / INFUJECT / PERFUJECT - 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.

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Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-026	30.09.2022	MDR096_2022, MDR098_2022, MDR099_2022, MDR103_2022	Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR.

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