



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-025

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 Needles 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-025

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 Needle for Single Use	MEDOJECT	0.3x12mm	CH30012
		0.3x25mm	CH30100
		0.3x40mm	CH30112
		0.33x12mm	CH29012
		0.33x25mm	CH29100
		0.33x40mm	CH29112
		0.4x12mm	CH27012
		0.4x16mm	CH27058
		0.4x20mm	CH27034, CH27045
		0.4x40mm	CH27112
		0.45x12mm	CH26012
		0.45x16mm	CH26058
		0.45x20mm	CH26045
		0.45x25mm	CH26100
		0.45x40mm	CH26112
		0.5x16mm	CH25058
		0.5x20mm	CH25045
		0.5x25mm	CH25100
		0.5x40mm	CH25112
		0.5x42mm	CH25158
		0.5x60mm	CH25214
		0.55x25mm	CH24100
		0.55x38mm	CH24112
		0.55x40mm	CH24112
		0.6x16mm	CH23058
		0.6x25mm	CH23100
		0.6x30mm	CH23114
0.6x40mm	CH23112		
0.6x60mm	CH23214		
0.6x80mm	CH23318		

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In Bratislava, Slovakia, 30.09.2022
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Product	Trade Name	Models	REF code
Sterile Hypodermic Needle for Single Use	MEDOJECT	0.7x30mm	CH22114
		0.7x35mm	CH22125
		0.7x40mm	CH22112
		0.7x50mm	CH22200
		0.7x90mm	CH22358
		0.8x16mm	CH21058
		0.8x25mm	CH21100
		0.8x30mm	CH21114
		0.8x40mm	CH21112
		0.8x50mm	CH21200
		0.8x100mm	CH21400
		0.8x120mm	CH21434
		0.9x25mm	CH20100
		0.9x30mm	CH20114
		0.9x38mm	CH20112
		0.9x40mm	CH20112
		0.9x50mm	CH20200
		0.9x70mm	CH20245
		1.1x25mm	CH19100
		1.1x30mm	CH19114
		1.1x40mm	CH19112
		1.1x50mm	CH19200
		1.2x25mm	CH18100
		1.2x38mm	CH18112
1.2x40mm	CH18112		
1.2x50mm	CH18200		
1.2x70mm	CH18245		
1.2x100mm	CH18400		
1.5x50mm	CH17200		
1.5x100mm	CH17400		

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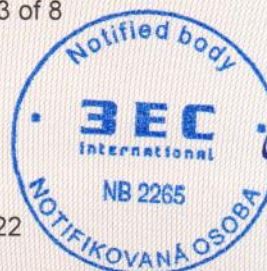
Product	Trade Name	Models	REF code
Sterile Hypodermic Needle for Single Use	MEDOJECT	1.6x15mm	CH16058
		1.6x25mm	CH16100
		1.6x35mm	CH16125
		1.6x40mm	CH16112
		1.6x70mm	CH16245
		1.6x110mm	CH16438
		1.8x30mm	CH15114
		1.8x40mm	CH15112
		1.8x70mm	CH15245
		1.8x110mm	CH15438
		2.0x30mm	CH14114
		2.0x70mm	CH14245
		2.0x80mm	CH14318
		2.0x100mm	CH14400
		2.0x120mm	CH14434
2.1x40mm	CH14112		
2.1x120mm	CH14434		

Product	Trade Name	Models	REF code
Sterile Ophthalmic Needle for Single Use	INOX – Straight	0.4x20mm	CHOP27045S
		0.4x25mm	CHOP27100S
		0.5x20mm	CHOP25045S
		0.5x25mm	CHOP25100S
		0.6x20mm	CHOP23045S
Sterile Ophthalmic Needle for Single Use	INOX – Bent	0.4x20mm	CHOP27045B
		0.5x22mm	CHOP25045B
		0.6x20mm	CHOP23045B
		0.6x22mm	CHOP23045B

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

Product	Trade Name	Models	REF code
Blood Collection Needle for Single Use	CHIRAVAC™	23G x 1" (0.6 x 25mm)	CHBCN23100
		23G x 1 1/2" (0.6 x 38mm)	CHBCN23112
		22G x 1" (0.7 x 25mm)	CHBCN22100
		22G x 1 1/2" (0.7 x 38mm)	CHBCN22112
		21G x 1" (0.8 x 25mm)	CHBCN21100
		21G x 1 1/2" (0.8 x 38mm)	CHBCN21112
		20G x 1" (0.9 x 25mm)	CHBCN20100
		20G x 1 1/2" (0.9 x 38mm)	CHBCN20112
		18G x 1" (1.2 x 25mm)	CHBCN18100
		18G x 1 1/2" (1.2 x 38mm)	CHBCN18112
Blood Collection Needle for Single Use	TECROM	23G x 1" (0.6 x 25mm)	TCBCN23100
		23G x 1 1/2" (0.6 x 38mm)	TCBCN23112
		22G x 1" (0.7 x 25mm)	TCBCN22100
		22G x 1 1/2" (0.7 x 38mm)	TCBCN22112
		21G x 1" (0.8 x 25mm)	TCBCN21100
		21G x 1 1/2" (0.8 x 38mm)	TCBCN21112
		20G x 1" (0.9 x 25mm)	TCBCN20100
		20G x 1 1/2" (0.9 x 38mm)	TCBCN20112
		18G x 1" (1.2 x 25mm)	TCBCN18100
		18G x 1 1/2" (1.2 x 38mm)	TCBCN18112

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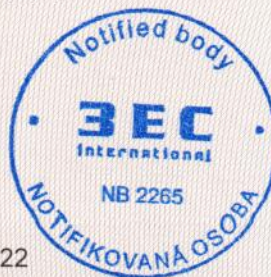
List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Insulin Pen Needle for Single Use	MEDOJECTfine	29G x 10 mm	CHPN2910
		29G x 12,7 mm	CHPN29127
		30G x 6 mm	CHPN3006
		30G x 8 mm	CHPN3008
		31G x 4 mm	CHPN3104
		31G x 5 mm	CHPN3105
		31G x 6 mm	CHPN3106
		31G x 8 mm	CHPN3108
		32G x 4 mm	CHPN3204
		32G x 5 mm	CHPN3205
		32G x 6 mm	CHPN3206
		32G x 8 mm	CHPN3208
		33G x 4 mm	CHPN3304
Insulin Pen Needle for Single Use	HARMOFINE®	29G x 10 mm	HFPN2910
		29G x 12,7 mm	HFPN29127
		30G x 6 mm	HFPN3006
		30G x 8 mm	HFPN3008
		31G x 4 mm	HFPN3104
		31G x 5 mm	HFPN3105
		31G x 6 mm	HFPN3106
		31G x 8 mm	HFPN3108
		32G x 4 mm	HFPN3204
		32G x 5 mm	HFPN3205
		32G x 6 mm	HFPN3206
		33G x 4 mm	HFPN3304
		Insulin Pen Needle for Single Use	DIABFINE
31G x 8 mm	DBF831		
32G x 4 mm	DBF432		

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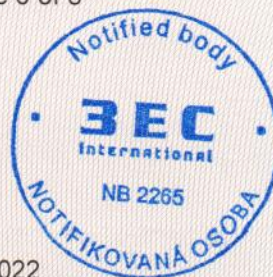
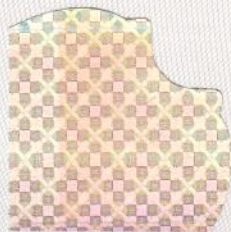
List of medical devices covered by the EU Quality Management System Certificate:

Product	Trade Name	Models	REF code
Insulin Pen Needle for Single Use	cleanFINE	31G x 4 mm	A067040TREN-TR01X
		31G x 5 mm	A067050TREN-TR01X
		31G x 6 mm	A067060TREN-TR01X
		31G x 8 mm	A067080TREN-TR01X
Insulin Pen Needle for Single Use	cleanFINE penta	31G x 4 mm	A068040DEEN-XX00X
		31G x 6 mm	A068060DEEN-XX00X
		31G x 8 mm	A068080DEEN-XX00X

Product	Trade Name	Models	REF code
Scalp Vein Set for Single Use	CHIRAFLEX	18G	CH260001118
		19G	CH260001119
		20G	CH260001120
		21G	CH260001121
		22G	CH260001122
		23G	CH260001123
		24G	CH260001124
		25G	CH260001125
		26G	CH260001126
27G	CH260001127		

Product	Trade Name	Models	REF code
Sterile Safety Hypodermic Needle for Single Use	MEDOJECT	0,6x30mm (23G x 1 1/4")	CHS23114
		0,7x40mm (22G x 1 1/2")	CHS22112
		0,8x40mm (21G x 1 1/2")	CHS21112
		0,9x40mm (20G x 1 1/2")	CHS20112

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

Sterile Hypodermic Needle for Single Use: MEDOJECT - injection and taking off a blood and other liquids at patients

Sterile Ophthalmic Needle for Single Use: INOX (Straight, Bent) - administration of fluids in the eye (ocular irrigation canals) patients

Blood Collection Needle for Single Use: CHIRAVACT™ / TECROM - blood collection in connection with blood collection tube

Insulin Pen Needle for Single Use: MEDOJECTfine / HARMOFINE® / DIABFINE / cleanFINE / cleanFINE penta - delivery of insulin in conjunction with injection pens

Scalp Vein Set for Single Use: CHIRAFLEX - access into the peripheral vascular system for administration of fluids and drugs and for withdrawal of blood at patient

Sterile Safety Hypodermic Needle for Single Use: MEDOJECT - injection and taking off a blood and other liquids at patients

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-025

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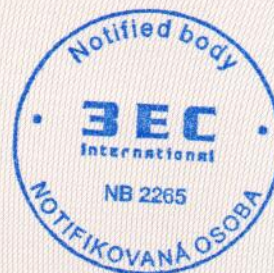
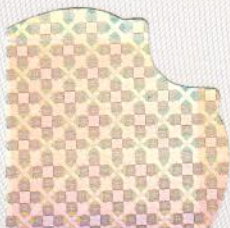
CHIRANA T. Injecta, a.s.

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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-025	30.09.2022	MDR077_2022, MDR100_2022, MDR101_2022, MDR104_2022, MDR110_2022 MDR112_2022	Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR.

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