



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-024/A

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, Non-Implantable Medical devices: Sterile Medical Devices for Administration, Withdrawal and Collection
(For detailed list refer to Annex I)**

**Intended purpose: See Annex II
MD class Is**

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**

For class Is devices, the audit by the NB2265 of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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 Audit Report No. SK-0655/22 from 21.09.2022. Information on all examinations and tests performed is stated in the abovementioned report 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: **11.09.2023**
Valid until: **30.09.2027**
First issue: **30.09.2022**
Revision: **01**
History: **Annex III**

In Bratislava, Slovakia, 11.09.2023



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



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-024/A

issued for the company

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

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

Syringes

Product	Trade Name	Models	REF code
Sterile Irrigation Syringe for Single Use	CHIRANA	50ml catheter	CH03050C
		50ml catheter + Luer adapter	CH03050CLA
		100 ml catheter + Luer adapter	CH03100C
		150ml JANETTE	CH03150CS
		150ml JANETTE + Luer adapter	CH03150CSLA
Sterile Irrigation Syringe for Single Use	CATHETER TIP SYRINGE	50ml catheter tip syringe	22008
		50ml catheter tip syringe + adapter	22011

Syringes

Product	Trade Name	Models	REF code
Sterile Enteral Syringe for Single Use	CHIRANA	20ml	CH03020E
		60ml	CH03060E

Solution Filters

Product	Trade Name	Models	REF code
Spike for Single Use	CHIRAPLUS	Infusion spike RED	CHIS01
		Infusion spike BLUE	CHIS02
		Infusion spike GREEN	CHIS03

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

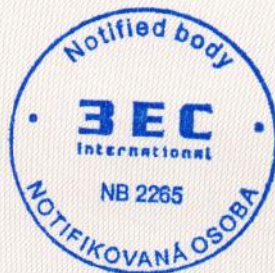
Solution Filters

Product	Trade Name	Models	REF code
Sterile filter for single use	SYRIFILT	N/A	10500
Sterile filter for single use	STERIFILT BASIC	N/A	AP02-001-00/CH
Sterile filter for single use	STERI5	N/A	AP02-003-00/CH
Sterile filter for single use	STERIFILT FAST	N/A	AP02-005-00/CH
Sterile filter for single use	STERIFILT +	N/A	AP02-006-00/CH

Needles

Product	Trade Name	Models	REF code
Sterile Blunt Fill Needle for Single Use	MEDOJECT	1,2x40mm (18G x 1 1/2")	CH18112BF
		1,2x50mm (18G x 2")	CH18200BF
		1,2x40mm with filter (18G x 1 1/2")	CH18112F
		1,2x50mm with filter (18G x 2")	CH18200F

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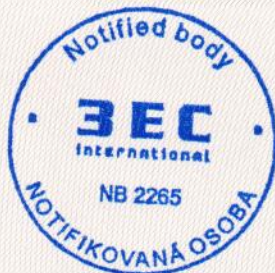
Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

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

Sterile Cup

Product	Trade Name	Models	REF code
Sterile cup for single use	Sterile Cup	Stericup (mix colour aluminum cup 2,5ml with attached holder, cotton swab, cotton filter)	AP01-118-99/CH
		Maxicup (mix colour aluminum cup 5ml with attached holder, cotton swab, cotton filter)	AP01-122-99/CH

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

Sterile Irrigation Syringe for Single Use: CHIRANA / CATHETER TIP SYRINGE - rinsing body cavities, washing a patient body and withdrawing body fluids, it can be used to deliver liquid food

Sterile filter for single use: SYRIFILT / STERIFILT BASIC/ STERI5 / STERIFILT FAST / STERIFILT + - filtering of impurities during suction of solution into syringe

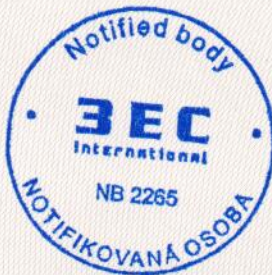
Spike for Single Use: CHIRAPLUS - pharmaceutical preparations – transmit fluids from one container to another (e.g., transfer medication from the vial to the syringe or from the syringe to the vial), mixing fluids or dissolve dry substances in the vials

Sterile Enteral Syringe for Single Use: CHIRANA - food or drug application via syringe pumps

Sterile Blunt Fill Needle for Single Use: MEDOJECT - to be attached to a syringe in order to aspiration fluids from vials or ampules during the preparation of medications

Sterile cup for single use - reduce the risk of transmission of viral infection, the preparation of active substances by drug users intravenously

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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-024	30.09.2022	MDR097_2022, MDR102_2022, MDR113_2022, MDR116_2022, MDR117_2022	Initially granted certification
01	2022-MDR/QS-024/A	11.09.2023	MDR087_2022/A MDR097_2022, MDR102_2022/A, MDR113_2022, MDR116_2022, MDR117_2022	Addition of MD Sterile cup for single use (Trade name: Sterile Cup) Addition of trade names for the product Sterile filter for single use, Trade name. STERIFILT FAST, STERIFILT + and changing the trade name from STERIFILT to STERIFILT BASIC

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