Signed by /
Podpisano przez:

Radosław Żywicki

Date / Data:
2023-10-18 08:58

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

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

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 30.09.2022

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

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

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:

Syringes

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

Syringes

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

Solution Filters

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

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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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	N/A	AP02-001-00
Sterile filter for single use	STERI5	N/A	AP02-003-00

Needles

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

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

issued for the company

CHIRANA T. Injecta, a.s.

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

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 / STERIFLIT / STERI5 - 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

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In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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

issued for the company

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-024	30.09.2022	MDR097_2022, MDR102_2022, MDR113_2022, MDR116_2022, MDR117_2022	Initially granted certification, sampling of technical documentation according to art. 52 (6) MDR.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 30.09.2022
Valid until 30.09.2027

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