EC Certificate
Full Quality Assurance System

Certificate No.:
10405-2017-CE-CZS-NA-PS Rev. 0.0

Project No.:
PRJC-234834-2010-PRC-SVK

Valid Until:
09-10-2022

This is to certify that the quality system of:

CHIRANA T. Injecta, a. s.
Nбm. Dr. Alberta Schweitzera 194
916 01 Starб Turб
Slovak Republic

For design, production and final product inspection/testing of:

Sterile Single Use Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Digitally signed by Ermicev Alexandr
Date: 2019.10.25 16:33:29 EEST
Reason: MoldSign Signature
Location: Moldova

Place and Date:
Hшvik, 09-10-2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **10405-2017-CE-CZS-NA-PS Rev. 0.0**
Project No.: **PRJC-234834-2010-PRC-SVK**
Valid Until: **09-10-2022**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	**Supersedes DNV GL (NB0434) certificate No. 5995-2007-CE-NOR 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460) Recertification**	**2017-10-09**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Single Use Medical Devices	Sterile Hypodermic Syringe • Luer • Luer - Lock	IIa
	Sterile Hypodermic Syringe with Integrated Needle • Insulin • Tuberculin	
	Sterile Hypodermic Needle – MEDOJECT	
	I.V. Cannula – CHIRAFLEX and CHIRAFLEX SAFETY	
	Mandrin - CHIRAFLEX	
	Infusion set - CHIRAPLUS G/P	
	Transfusion set - CHIRAHEM	
	Scalp Vein Set – CHIRAFLEX	
	Three Way Stop Cock - CHIRAWAY	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

CHIRANA T. Injecta, a. s., Nőm. Dr. Alberta Schweitzera 194, 916 01 Starő Turő, Slovak Republic

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10405-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-234834-2010-PRC-SVK**	**09-10-2022**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

[redacted]

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
11243-2017-CE-CZS-NA-PS Rev. 1.0	**PRJC-92684-2008-PRC-SVK**	**09 October 2022**

This is to certify that the quality system of:

CHIRANA T. Injecta, a. s.
Nám. Dr. Alberta Schweitzera 194
916 01 Stará Turá
Slovak Republic

For design, production and final product inspection/testing of:

Sterile Single Use Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 08 June 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.: **11243-2017-CE-CZS-NA-PS Rev. 1.0**
Project No.: **PRJC-92684-2008-PRC-SVK**
Valid Until: **09 October 2022**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Supersedes DNV GL (NB0434) certificate No. 1037-2012-CE-CZS-NA 1.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460) Recertification	2018-02-02
1.0	**Extension in scope - new products Blood collection needle, Insulin Pen needle and Sterile Perfusion syringe added**	2018-06-05

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Single Use Medical Devices	Sterile Hypodermic Syringe (Luer, Luer-Lock) – CHIRANA	IIa
	Sterile Injection Set with Syringe and Needle / Needles (Sterile Filter) – CHIRANA, SYRISET	
	Insulin /Tuberculin syringe with/without integrated needle or side packed needle - CHIRANA	
	Sterile Hypodermic Needle – MEDOJECT	
	Sterile Ophthalmic Needle – INOX • Straight • Bent	
	Blood Collection Needle – CHIRAVAC	
	Insulin Pen Needle – MEDOJECT *fine*	
	Sterile Perfusion Syringe – CHIRANA	

	Sterile filter – STERIFILT, SYRIFILT, STERI5	Is
	Sterile Cup – SteriCUP, SteriMIX, MaxiCUP, MaxiMIX	
	Sterile Irrigation Syringe – CHIRANA	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CHIRANA T. Injecta, a. s.	Nám. Dr. Alberta Schweitzera 194, 916 01 Stará Turá, Slovak Republic

EC Certificate
Full Quality Assurance System

Certificate No.: **11243-2017-CE-CZS-NA-PS Rev. 1.0**
Project No.: **PRJC-92684-2008-PRC-SVK**
Valid Until: **09 October 2022**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
249018-2017-AQ-CZS-NA-PS Rev. 1.0	PRJC-231870-2010-MSC-SVK	10 July 2004	27 February 2022

This is to certify that the management system of:

CHIRANA T. Injecta, a. s.
Nбm. Dr. Alberta Schweitzera 194
916 01 Starб Turб
Slovakia

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, manufacturing, assembly, sterilization and sales of sterile and non sterile disposable medical devices, components incl. for OEM customers
- devices (syringes, syringe sets, needles, ophthalmic needles, insulin/tuberculin syringes, sterile filters/cups and sets, I.V. cannulas incl. accessories, infusion and transfusion sets incl. accessories, examination devices, lancets)
- components (lancets, cannulas, tubes).

Place and Date:
Huvik, 27 February 2019

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Bjbrg Synnbve Nesgård

Bjurg Synnuve Nesgerd

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info