

# 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.**  
N6m. Dr. Alberta Schweitzera 194  
916 01 Star6 Tur6  
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**

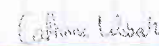
and found to comply.

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

Place and Date:  
Huvik, 09-10-2017



For:  
**DNV GL NEMKO PRESAFE AS**

  
**Cathrine Wisbech**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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

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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

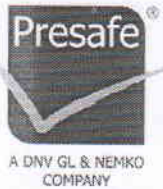
Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Single Use Medical Devices	Sterile Hypodermic Syringe <ul style="list-style-type: none"> <li>Luer</li> <li>Luer - Lock</li> </ul>	IIa
	Sterile Hypodermic Syringe with Integrated Needle <ul style="list-style-type: none"> <li>Insulin</li> <li>Tuberculin</li> </ul>	
	Sterile Hypodermic Needle – MEDOJECT	
	I.V. Cannula – CHIRAFLEX and CHIRAFLEX SAFETY	
	Mandrin - CHIRAFLEX	
	Infusion set - CHIRAPLUS G/P	
	Transfusion set - CHIRAHAM	
	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., Nám. Dr. Alberta Schweitzera 194, 916 01 Starý Turč, Slovak Republic



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10405-2017-CE-CZS-NA-PS Rev. 0.0

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

Valid Until:  
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



# 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

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**



For:  
**DNV GL NEMKO PRESAFE AS**

*Tone Kolpus*

**Tone Kolpus**

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# 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	<b>Extension in scope - new products</b> <b>Blood collection needle, Insulin Pen needle and Sterile Perfusion syringe added</b>	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	
	<b>Blood Collection Needle – CHIRAVAC</b>	
	<b>Insulin Pen Needle – MEDOJECT fine</b>	
	<b>Sterile Perfusion Syringe – CHIRANA</b>	



A DNV GL & NEMKO  
COMPANY

# EC Certificate

## Full Quality Assurance System

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Project No.:  
PRJC-92684-2008-PRC-SVK

Valid Until:  
09 October 2022

	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



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

### Terms and conditions

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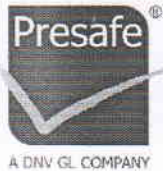
- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### 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.:  
249018-2017-AQ-CZS-NA-PS Rev. 1.0

Project No.:  
PRJC-231870-2010-MSK-SVK

Initial Certification Date:  
10 July 2004

Valid Until:  
27 February 2022

This is to certify that the management system of:

**CHIRANA T. Injecta, a. s.**  
N6m. Dr. Alberta Schweitzera 194  
916 01 Star6 Tur6  
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



For:  
DNV GL PRESAFE AS

*Bj6rg Synn6ve Nesgerd*

**Bj6rg Synn6ve Nesgerd**

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