

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
11243-2017-CE-CZS-NA-PS Rev. 5.0

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 (CL.IIA, IS)**

Has been assessed with respect to:

### **THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 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, 01 January 2020**

For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**



**Tone Elise Kolpus**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



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**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
0.0	Original 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	02-02-2018
1.0	Extension in scope - new products Blood collection needle, Pen needle and Perfusion syringes added	05-06-2018
2.0	Correction pagination	26-06-2018
3.0	New brand name of product Sterile Hypodermic needle- Harmofine	02-07-2019
4.0	Correction wrong name of added product -correct name - Insulin Pen Needle - HARMOFINE	18-07-2019
<b>5.0</b>	<b>New brand name of products - Sterile Hypodermic Syringe (Luer, Luer-Lock) – Ecoject, Sterile Perfusion Syringe – INFUJECT, Sterile Perfusion Syringe – PERFUJECT and Sterile Irrigation Syringe – CATHETER TIP SYRINGE</b>	<b>01-01-2020</b>

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Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Single Use Medical Devices	Sterile Hypodermic Syringe (Luer, Luer-Lock) – CHIRANA <b>Sterile Hypodermic Syringe (Luer, Luer-Lock) –Ecoject</b> 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 <ul style="list-style-type: none"> <li>• Straight</li> <li>• Bent</li> </ul> Blood Collection Needle – CHIRAVAC Insulin Pen Needle – MEDOJECT fine Insulin Pen Needle - HARMOFINE Sterile Perfusion Syringe – CHIRANA <b>Sterile Perfusion Syringe – INFUJECT</b> <b>Sterile Perfusion Syringe – PERFUJECT</b>	Ia
	Sterile Irrigation Syringe – CHIRANA <b>Sterile Irrigation Syringe – CATHETER TIP SYRINGE</b> Sterile filter – STERIFILT, SYRIFILT, STERI5 Sterile Cup – SteriCUP, SteriMIX, MaxiCUP, MaxiMIX	Is

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

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## 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