

Management System Certificate

Certificate No.:
249018-2017-AQ-CZS-NA-PS Rev. 1.0

Project No.:
PRJC-231870-2010-MSV-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.

Nám. Dr. Alberta Schweitzera 194
916 01 Stará Turá
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:
Høvik, 27 February 2019



For:
DNV GL PRESAFE AS

Bjørge Synnøve Nesgård

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.:
11243-2017-CE-CZS-NA-PS Rev. 4.0

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
Slovakia (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, 18 July 2019



For:
DNV GL PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
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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
0.0	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

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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	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	
	Insulin Pen Needle - HARMOFINE	
	Sterile Perfusion Syringe – CHIRANA	
	Sterile Irrigation Syringe – CHIRANA	Is
	Sterile filter – STERIFILT, SYRIFILT, STERI5	
	Sterile Cup – SteriCUP, SteriMIX, MaxiCUP, MaxiMIX	

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,Slovakia (Slovak Republic)

EC Certificate

Full Quality Assurance System

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11243-2017-CE-CZS-NA-PS Rev. 4.0

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

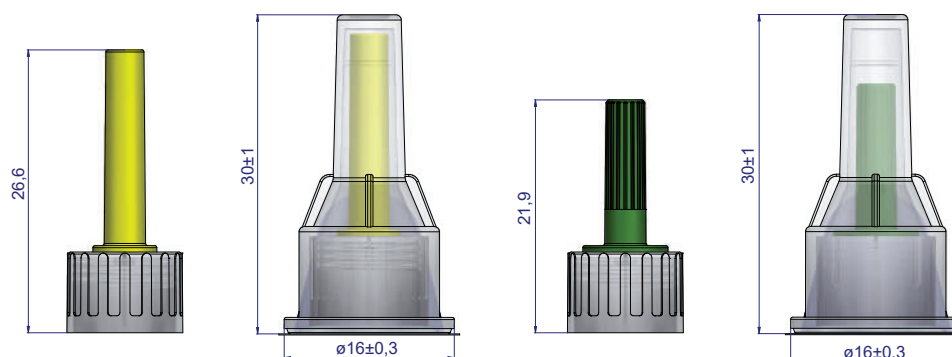
When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

MEDOJECT® fine Insulin Pen needles



**EUROPEAN
QUALITY**



Materials:

- ✓ Needle hub – PP
- ✓ Cannula – Stainless steel
- ✓ Silicone (medical grade)
- ✓ Glue (medical grade)
- ✓ Inner protective cap – PE + colour masterbatch
- ✓ Outer protective cap – PP
- ✓ Medical paper

Compatible with of type A Insulin pens

Sterilization:

- ✓ ETO

Packaging:

- ✓ Unit packaging
- ✓ Inner box for Insulin PEN needle - 100 pcs (129x70x68mm)
- ✓ Carton for Insulin PEN needle - 2 000 pcs (353x147x270mm)
- ✓ Pallet - 160 000 pcs

MEDOJECT® fine Insulin Pen needles

Size	Color code	Pieces per Box	Pieces per Case	Item Code
29G x10 mm	yellow	100	2000	CHPN2910
29G x 12,7 mm	pink	100	2000	CHPN29127
30G x 6 mm	dark blue	100	2000	CHPN3006
30G x 8 mm	light blue	100	2000	CHPN3008
31G x 4 mm	green	100	2000	CHPN3104
31G x 5 mm	dark violet	100	2000	CHPN3105
31G x 6 mm	dark blue	100	2000	CHPN3106
31G x 8 mm	light blue	100	2000	CHPN3108
32G x 4 mm	green	100	2000	CHPN3204
32G x 6 mm	dark blue	100	2000	CHPN3206

MEDOJECT fine® PEN needles are available in many sizes.
Ask your diabetes educator or pharmacist for advice.

TECHNICAL DATA

Intendend use	Insulin pen needles for single use used in medicine are intended for delivery of insulin in conjunction with injection pens.
Product properties	✓ Versatile needles, fit most commonly used insulin pens. ✓ Quality silicone treated needle for smooth penetration. ✓ Thin wall technology to ensure optimal insulin flow. ✓ Sterile, single use and disposable. ✓ Colour coding for easier identification of needle lengths. ✓ Easier twist-off cap design, when discarding the needle.
Shelf life	5 years
Product standard	EN ISO 11608-2:2012
Product classification	Medical Device acc. to MDD 93/42/EEC, class IIa
Quality certificate	EN ISO 13485:2012