EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 11243-2017-CE-CZS-NA-PS Rev. 7.0 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 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 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

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

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
5.0	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	01-01-2020
6.0	Brand name addition via Two Notification of changes (no. 01/2021, 02/2021)	28-04-2021
7.0	**Extension in scope – new variant of existing product Sterile Irrigation Syringe CHIRANA with Luer Adaptor and new models of existing product 50ml Sterile Perfusion Syringe CHIRANA with or without needle, with or without stopper and colour variants added**	**18-05-2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Single Use Medical Devices	Sterile Hypodermic Syringe (Luer, Luer-Lock) – CHIRANA Sterile Hypodermic Syringe (Luer, Luer-Lock) – Ecoject Sterile Injection Set with Syringe and Needle / Needles (Sterile Filter) – CHIRANA, SYRISET Insulin /Tuberculin syringe with/without integrated needle or side packed needle – CHIRANA Insulin /Tuberculin syringe with/without integrated needle or side packed needle – Acti-fine Sterile Hypodermic Needle – MEDOJECT Sterile Ophthalmic Needle – INOX •Straight •Bent Blood Collection Needle – CHIRAVAC Insulin Pen Needle – MEDOJECT fine Insulin Pen Needle – HARMOFINE Insulin Pen Needle - DIABFINE Insulin Pen Needle - CleanFINE Insulin Pen Needle – CleanFINE penta Sterile Perfusion Syringe - CHIRANA Sterile Perfusion Syringe – INFUJECT Sterile Perfusion Syringe - PERFUJECT	IIa
	Sterile Irrigation Syringe – CHIRANA Sterile Irrigation Syringe – CATHETER TIP SYRINGE 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

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

End of Certificate