EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
10405-2017-CE-CZS-NA-PS

Initial certification date:
10 October 2017

Valid Until:
09 October 2022

This is to certify that the management 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 and found to comply 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

Place and date:
Høvik, 23 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

Lack of fulfilment of conditions as set out in the Certification Agreement 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**	**Issued Date**
0.0	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
1.0	Editorial Changes and blockchain information	2021-05-23

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	

Sites covered by this certificate	
Site Name	**Site 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. 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.