



DNV

EC CERTIFICATE

Production Quality Assurance

Certificate no.:
11166-2017-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.

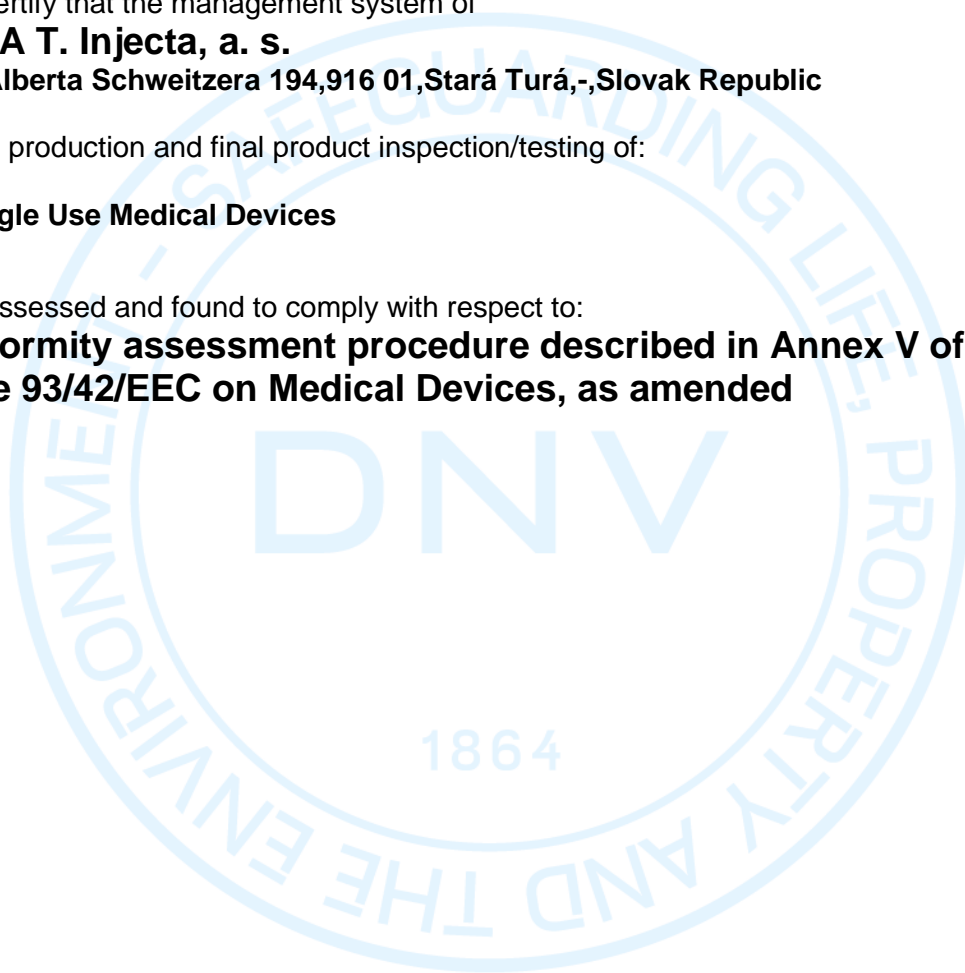
Nám. Dr. Alberta Schweitzera 194,916 01, Stará Turá, -, Slovak Republic

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 V 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.

Notified Body 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

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 | |
| | Infusion set - CHIRAPLUS G/P | |
| | Transfusion set - CHIRAHM | |
| | Extension line – CHIRALINE | |
| | Scalp Vein Set – CHIRAFLEX | |

| 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.