



CHIRANA T. Injecta, a. s.
 Nám. Dr. Schweitzera 194
 916 01 Stará Turá
 Slovenská republika / Slovak Republic
 Certifikované / Certified by:



IČO: 36794619
 IČ DPH/VAT No: SK2022402822
 Banka/Bank:
 Sídlo/Branch:
 SWIFT/BIC:
 Č.ú./Account No/IBAN:

EC DECLARATION OF CONFORMITY

(no. EC 03-2013)

We, **CHIRANA T. Injecta a.s.**,

nám. Dr. A. Schweitzera 194
 916 01 Stará Turá
 Slovakia

manufacturer of:

STERILE SINGLE USE MEDICAL DEVICES

declare, that product:

STERILE INJECTION SET

versions: syringe with needle - various sizes
 syringe with needle and filter - various sizes

intended use for: injection and taking off a blood and other liquids at patients

classified as Class: **IIa** according to classification in Annex IX, Rule 6
 of the MDD 93/42/EEC

are in conformity:

- with provisions of Annex I of the EC Council Directive 93/42/EEC of 14th June 1993 including revision 2007/47/EEC concerning medical devices which apply to them
- with provisions of technical specification TPF 320-0508-03, EN ISO 7886-1:1997, EN ISO 7864:1995, EN ISO 11135-1:2007, EN ISO 14971:2012, EN ISO 13485:2012/AC:2012, EN ISO 11607-1:2009; standards selected from the group EN ISO 14644 and EN ISO 10993, European Pharmacopoeia actual edition and other relevant ISO/EN standards mentioned in product specification
- have been subject to following conformity assessment procedure laid down in the EC Council Directive 93/42/EEC Article 11.3(a) relating to the Production Quality Assurance set out in Annex II
- are under the supervision of Det Norske Veritas as a Notified Body of No. 0434

It was edited Certificate no.1037-2012-CE-CZS-NA dated of 25th July 2012 for product.

The products are marked with CE 0434.

in Stará Turá, date 17.01.2013



Rastislav Broska, PhD.
 Quality manager & regulatory

EC DECLARATION OF CONFORMITY

Product:

STERILE INJECTION SET

Versions:

Combination a), b) and c)

a) Syringe

2-parts - Luer - 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30 ml, 50ml

2-parts - Luer-Lock - 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml

3-parts - Luer - 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30 ml, 50ml

3-parts - Luer-Lock - 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml

b) Needle

0.4x12, 0.4x16, 0.4x20, 0.4x40,

0.45x12, 0.45x16, 0.45x20, 0.45x25,

0.5x16, 0.5x20, 0.5x25,

0.55x25, 0.55x38, 0.55x40,

0.6x25, 0.6x30, 0.6x40, 0.6x60,

0.7x30, 0.7x35, 0.7x40, 0.7x50, 0.7x90,

0.8x25, 0.8x30, 0.8x40, 0.8x50, 0.8x70,

0.9x25, 0.9x40, 0.9x50, 0.9x70,

1.1x25, 1.1x30, 1.1x40, 1.1x50,

1.2x25, 1.2x30, 1.2x40, 1.2x50, 1.2x65, 1.2x70, 1.2x100,

1.5x50, 1.5x100,

1.8x50, 1.8x65, 1.8x70, 1.8x100, 1.8x110,

2.0x40, 2.0x50, 2.0x65, 2.0x70, 2.0x100, 2.0x110

2.1x50



c) Filter