



**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 01-2015)

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 HYPODERMIC SYRINGE**

versions: Luer - various sizes  
Luer-Lock - 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 2  
of the MDD 93/42/EEC

are in conformity:

- with provisions of Annex I of the EC Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 including revision 2007/47/EEC concerning medical devices which apply to them
- with provisions of technical specification TPF 320-0508-01, EN ISO 7886-1:1997, EN ISO 11135:2014, EN ISO 14971:2012, EN ISO 13485:2012/AC:2012, EN ISO 11607-1:2009/A1:2014, 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.5995-2007-CE-NOR 6.0 dated of 29<sup>th</sup> August 2014 and Certificate no.1037-2012-CE-CZS-NA 1.0 dated of 09<sup>th</sup> July 2013 for product.  
The products are marked with CE 0434.

in Stará Turá, date 03.08.2015



PaedDr. Zdenka Klbečková  
Regulatory Affairs Manager / QM ML

## EC DECLARATION OF CONFORMITY

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Product:

STERILE HYPODERMIC SYRINGE

### Versions:

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

3-parts - catheter with Luer adapter - 100ml

