

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

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IČ DPH/VAT No: **SK2022402822**

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Sídlo/Branch:  
SWIFT/BIC:  
Č.ú./Account No/IBAN:

## EC DECLARATION OF CONFORMITY

(no. EC 33-2018)

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:

**BLOOD COLLECTION NEEDLE – CHIRAVAC**

versions: various sizes

intended use for: blood collection in connection with blood collection tube

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 14<sup>th</sup> June 1993 including revision 2007/47/EEC concerning medical devices which apply to them
- with provisions of technical specification TPF 310-1016-01, EN ISO 7864:2016, EN ISO 9626:2016, 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 Full Quality Assurance System set out in Annex II
- are under the supervision of DNV GL NEMKO PRESAFE as a Notified Body of No. 2460

It was edited Certificate no.11243-2017-CE-CZS-NA-PS Rev.1.0 dated of 08<sup>th</sup> June 2018 for product.

The products are marked with CE 2460.

We are solely responsible for this declaration.

in Stará Turá, date 11.06.2018



  
PaedDr. Zdenka Klbečková  
Regulatory Affairs Manager

## EC DECLARATION OF CONFORMITY

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Product:

BLOOD COLLECTION NEEDLE - CHIRAVAC

### Versions (Item code):

23G x 1" (0.6 x 25mm) (CHBCN23100),  
23G x 1 1/2" (0.6 x 38mm) (CHBCN23112),  
22G x 1" (0.7 x 25mm) (CHBCN22100),  
22G x 1 1/2" (0.7 x 38mm) (CHBCN22112),  
21G x 1" (0.8 x 25mm) (CHBCN21100),  
21G x 1 1/2" (0.8 x 38mm) (CHBCN21112),  
20G x 1" (0.9 x 25mm) (CHBCN20100),  
20G x 1 1/2" (0.9 x 38mm) (CHBCN20112),  
18G x 1" (1.2 x 25mm) (CHBCN18100),  
18G x 1 1/2" (1.2 x 38mm) (CHBCN18112)

