

**EU DECLARATION OF CONFORMITY**  
**(no. EC 10-2022)**

We, **CHIRANA T. Injecta a.s.**,  
Nám. Dr. A. Schweitzera 194, 916 01 Stará Turá, Slovakia

Single registration number (SRN): SK-MF-000003702

manufacturer of: STERILE SINGLE USE MEDICAL DEVICES

declare in our own responsibility, that the product:

**BLOOD COLLECTION NEEDLE FOR SINGLE USE**

brand name: **CHIRAVAC™ / TECROM**

versions: various sizes (18G, 20G, 21G, 22G, 23G)

intended purpose: blood collection in connection with blood collection tube

classified as Class: **IIa** according to classification set out in Annex VIII, Rule 6  
of the EU Medical Device Regulation (MDR) 2017/745

is in compliance:

- with provisions of Annex I of the Regulation (EU) 2017/745 of the European parliament and of the council of 5<sup>th</sup> April 2017 on 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 6009:2016, EN ISO 11135:2014, EN ISO 14971:2019, EN ISO 13485:2016/AC:2018, EN ISO 11607-1:2020, 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 and list of standards for product
- have been subject to following conformity assessment procedure laid down in the Regulation (EU) 2017/745, Article 52 (6) relating to the Quality Management System and Technical Documentation set out in Annex IX.
- are certified by the Notified Body 3EC International a.s., identification number 2265

It was issued Certificate no. 2022-MDR/QS-025 Rev.00 dated of 30.09.2022, valid till 30.09.2027 for product. Product models are marked with CE 2265.

EU declaration of conformity is issued under the sole responsibility of the manufacturer.  
Signed for and on behalf of manufacturer.

in Stará Turá, date 01.10.2022



PaedDr. Zdenka Klbečková  
Regulatory Affairs Manager

## EU DECLARATION OF CONFORMITY

Product:

BLOOD COLLECTION NEEDLE FOR SINGLE USE – CHIRAVAC™ / TECROM

### Product variants - CHIRAVAC™:

<b>Product REF code</b>	<b>Product model</b>	<b>Basic UDI-DI (GMN)</b>
CHBCN23100	23G x 1" (0.6 x 25mm)	858601504BCN108L
CHBCN23112	23G x 1 1/2" (0.6 x 38mm)	
CHBCN22100	22G x 1" (0.7 x 25mm)	
CHBCN22112	22G x 1 1/2" (0.7 x 38mm)	
CHBCN21100	21G x 1" (0.8 x 25mm)	
CHBCN21112	21G x 1 1/2" (0.8 x 38mm)	
CHBCN20100	20G x 1" (0.9 x 25mm)	
CHBCN20112	20G x 1 1/2" (0.9 x 38mm)	
CHBCN18100	18G x 1" (1.2 x 25mm)	
CHBCN18112	18G x 1 1/2" (1.2 x 38mm)	

### Product variants - TECROM:

<b>Product REF code</b>	<b>Product model</b>	<b>Basic UDI-DI (GMN)</b>
TCBCN23100	23G x 1" (0.6 x 25mm)	858601504BCN108L
TCBCN23112	23G x 1 1/2" (0.6 x 38mm)	
TCBCN22100	22G x 1" (0.7 x 25mm)	
TCBCN22112	22G x 1 1/2" (0.7 x 38mm)	
TCBCN21100	21G x 1" (0.8 x 25mm)	
TCBCN21112	21G x 1 1/2" (0.8 x 38mm)	
TCBCN20100	20G x 1" (0.9 x 25mm)	
TCBCN20112	20G x 1 1/2" (0.9 x 38mm)	
TCBCN18100	18G x 1" (1.2 x 25mm)	
TCBCN18112	18G x 1 1/2" (1.2 x 38mm)	