

EU DECLARATION OF CONFORMITY
(no. EC 16-2022)

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:

SCALP VEIN SET FOR SINGLE USE

brand name: **CHIRAFLEX**

versions: various sizes (18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G)

intended purpose: access into the peripheral vascular system for administration of fluids and drugs and for withdrawal of blood at patient

classified as Class: **IIa** according to classification set out in Annex VIII, Rule 7 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 5th April 2017 on medical devices which apply to them
- with provisions of technical specification TPF 320-0209-01, EN ISO 7864:2016, EN ISO 9626:2016, EN ISO 8536-4:2020, 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 3EEC 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 Kibečková
Regulatory Affairs Manager



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Product:

SCALP VEIN SET FOR SINGLE USE – CHIRAFLEX

Product variants:

Product REF code	Product model	Basic UDI-DI (GMN)
CH260001118	18G	858601504SCALPVEINSET16T5
CH260001119	19G	
CH260001120	20G	
CH260001121	21G	
CH260001122	22G	
CH260001123	23G	
CH260001124	24G	
CH260001125	25G	
CH260001126	26G	
CH260001127	27G	