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**EU DECLARATION OF CONFORMITY**  
**(no. EC 05-2022)**

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:

**STERILE HYPODERMIC NEEDLE FOR SINGLE USE**

brand name: **MEDOJECT**

versions: various sizes (14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G)

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

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 5th April 2017 on medical devices which apply to them
- with provisions of technical specification TPF 330-0508-01, EN ISO 7864:2016, 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



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Product:

STERILE HYPODERMIC NEEDLE FOR SINGLE USE - MEDOJECT

## Product variants:

Product REF code	Product model	Basic UDI-DI (GMN)
CH30012	0.3x12mm	858601504NEEDLE05V4
CH30100	0.3x25mm	
CH30112	0.3x40mm	
CH29012	0.33x12mm	
CH29100	0.33x25mm	
CH29112	0.33x40mm	
CH27012	0.4x12mm	
CH27058	0.4x16mm	
CH27034, CH27045	0.4x20mm	
CH27112	0.4x40mm	
CH26012	0.45x12mm	
CH26058	0.45x16mm	
CH26045	0.45x20mm	
CH26100	0.45x25mm	
CH26112	0.45x40mm	
CH25058	0.5x16mm	
CH25045	0.5x20mm	
CH25100	0.5x25mm	
CH25112	0.5x40mm	
CH25158	0.5x42mm	
CH25214	0.5x60mm	
CH24100	0.55x25mm	
CH24112	0.55x38mm	
CH24112	0.55x40mm	
CH23058	0.6x16mm	
CH23100	0.6x25mm	
CH23114	0.6x30mm	
CH23112	0.6x40mm	
CH23214	0.6x60mm	
CH23318	0.6x80mm	
CH22114	0.7x30mm	
CH22125	0.7x35mm	
CH22112	0.7x40mm	
CH22200	0.7x50mm	
CH22358	0.7x90mm	
CH21058	0.8x16mm	
CH21100	0.8x25mm	
CH21114	0.8x30mm	
CH21112	0.8x40mm	
CH21200	0.8x50mm	
CH21400	0.8x100mm	
CH21434	0.8x120mm	
CH20100	0.9x25mm	
CH20114	0.9x30mm	
CH20112	0.9x38mm	
CH20112	0.9x40mm	
CH20200	0.9x50mm	
CH20245	0.9x70mm	
CH19100	1.1x25mm	
CH19114	1.1x30mm	
CH19112	1.1x40mm	

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Product:

STERILE HYPODERMIC NEEDLE FOR SINGLE USE - MEDOJECT

CH19200	1.1x50mm	858601504NEEDLE05V4
CH18100	1.2x25mm	
CH18112	1.2x38mm	
CH18112	1.2x40mm	
CH18200	1.2x50mm	
CH18245	1.2x70mm	
CH18400	1.2x100mm	
CH17200	1.5x50mm	
CH17400	1.5x100mm	
CH16058	1.6x15mm	
CH16100	1.6x25mm	
CH16125	1.6x35mm	
CH16112	1.6x40mm	
CH16245	1.6x70mm	
CH16438	1.6x110mm	
CH15114	1.8x30mm	
CH15112	1.8x40mm	
CH15245	1.8x70mm	
CH15438	1.8x110mm	
CH14114	2.0x30mm	
CH14245	2.0x70mm	
CH14318	2.0x80mm	
CH14400	2.0x100mm	
CH14434	2.0x120mm	
CH14112	2.1x40mm	
CH14434	2.1x120mm	