

**EU DECLARATION OF CONFORMITY**  
**(no. EC 11-2022)**

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:

**INSULIN PEN NEEDLE FOR SINGLE USE**

brand names: **MEDOJECTfine / HARMOFINE® / DIABFINE /  
cleanFINE / cleanFINE penta**

versions: various sizes (29G, 30G, 31G, 32G, 33G)

intended purpose: delivery of insulin in conjunction with injection pens

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 310-1016-02, EN ISO 7864:2016, EN ISO 11608-1:2015, EN ISO 11608-2:2012, EN ISO 9626:2016, 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 and Product conformity verification set out in Annex XI.
- 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 Kibecková  
Regulatory Affairs Manager



## EU DECLARATION OF CONFORMITY

Product:

INSULIN PEN NEEDLE FOR SINGLE USE – MEDOJECTfine / HARMOFINE® /  
DIABFINE / cleanFINE / cleanFINE penta

### Product variants - MEDOJECTfine:

Product REF code	Product model	Basic UDI-DI (GMN)
CHPN2910	29G x 10 mm	858601504PENNEEDLE112Y
CHPN29127	29G x 12,7 mm	
CHPN3006	30G x 6 mm	
CHPN3008	30G x 8 mm	
CHPN3104	31G x 4 mm	
CHPN3105	31G x 5 mm	
CHPN3106	31G x 6 mm	
CHPN3108	31G x 8 mm	
CHPN3204	32G x 4 mm	
CHPN3205	32G x 5 mm	
CHPN3206	32G x 6 mm	
CHPN3208	32G x 8 mm	
CHPN3304	33G x 4 mm	

### Product variants - HARMOFINE:

Product REF code	Product model	Basic UDI-DI (GMN)
HFPN2910	29G x 10 mm	858601504PENNEEDLE112Y
HFPN29127	29G x 12,7 mm	
HFPN3006	30G x 6 mm	
HFPN3008	30G x 8 mm	
HFPN3104	31G x 4 mm	
HFPN3105	31G x 5 mm	
HFPN3106	31G x 6 mm	
HFPN3108	31G x 8 mm	
HFPN3204	32G x 4 mm	
HFPN3205	32G x 5 mm	
HFPN3206	32G x 6 mm	
HFPN3304	33G x 4 mm	

### Product variants - DIABFINE:

Product REF code	Product model	Basic UDI-DI (GMN)
DBF531	31G x 5 mm	858601504PENNEEDLE112Y
DBF831	31G x 8 mm	
DBF432	32G x 4 mm	

### Product variants - cleanFINE:

Product REF code	Product model	Basic UDI-DI (GMN)
A067040TREN-TR01X	31G x 4 mm	858601504PENNEEDLE112Y
A067050TREN-TR01X	31G x 5 mm	
A067060TREN-TR01X	31G x 6 mm	
A067080TREN-TR01X	31G x 8 mm	

### Product variants – cleanFINE penta:

Product REF code	Product model	Basic UDI-DI (GMN)
A068040DEEN-XX00X	31G x 4 mm	858601504PENNEEDLE112Y
A068060DEEN-XX00X	31G x 6 mm	
A068080DEEN-XX00X	31G x 8 mm	