

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

IČO: **36794619**
IČ DPH/VAT No: **SK2022402822**

EU DECLARATION OF CONFORMITY

(no. EC 04-2024)

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 INSULIN SYRINGE FOR SINGLE USE

Brand name: CHIRANA® / HARMOFINE® / SELFINJECT

versions: various sizes and types

Intended use for: Insulin syringe for single use is intended for administration of liquids and drugs into the body

Indikácia: Insulin syringe is intended for subcutaneous injection of the prescribed insulin dose to diabetic patients. Specifically 1 ml; 0,5 ml or 0,3 ml, that is 100, 50 or 30 units of U-100 insulin, or 1 ml of 40 units of U-40 Insulin.

classified as Class: *Ia* 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 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 320-0404-01, EN ISO 8537:2016, EN ISO 7886-1:2018, 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.

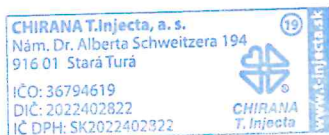
- are certified by the Notified Body 3EC International a.s., identification number 2265


Product: STERILE INSULIN SYRINGE FOR SINGLE USE – CHIRANA / HARMOFINE / SELFINJECT

It was issued Certificate no. 2022-MDR/QS-026/A Rev.01 dated of 14.07.2023, 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 02.02.2024





Rastislav Broska, PhD.
Quality Manager

Product: STERILE INSULIN SYRINGE FOR SINGLE USE – CHIRANA / HARMOFINE / SELFINJECT

Versions:

Insulin syringe: 0,3ml/0,5ml/1ml/2ml – needle 26G/27G/28G/29G/30G/31G/32G/33G - U40/U100
1 ml Luer - U100

Product variants – CHIRANA:

Product REF code	Product model	Basic UDI-DI (GMN)
CHINS0127	1ml 27G x 1/2"U100	858601504INSULIN04W7
CHINS4129	1ml 29G x 1/2"U40	
CHINS01298	1ml 29G x 5/16"U100	
CHINS0129	1ml 29G x 1/2"U100	
CHINS0130	1ml 30G x 1/2"U100	
CHINS01308	1ml 30G x 5/16"U100	
CHINS01316	1ml 31G x 4/16"U100	
CHINS01318	1ml 31G x 5/16"U100	
CHINS01	1 ml Luer – U100	
CHINS41	1ml Luer – U40	
CHINS00529	0,5ml 29G x 1/2"U100	
CHINS00530	0,5ml 30G x 1/2"U100	
CHINS005308	0,5ml 30G x 5/16"U100	
CHINS005318	0,5ml 31G x 5/16"U100	
CHINS005316	0,5ml 31G x 4/16"U100	
CHINS00329	0,3ml 29G x 1/2"U100	
CHINS00330	0,3ml 30G x 1/2"U100	
CHINS003308	0,3ml 30G x 5/16"U100	
CHINS003318	0,3ml 31G x 5/16"U100	
CHINS003316	0,3ml 31G x 4/16"U100	
CHINS0127PB	1ml 27G x 1/2"U100	
CHINS4129PB	1ml 29G x 1/2"U40	
CHINS01298PB	1ml 29G x 5/16"U100	
CHINS0129PB	1ml 29G x 1/2"U100	
CHINS0130PB	1ml 30G x 1/2"U100	
CHINS01308PB	1ml 30G x 5/16"U100	
CHINS01316PB	1ml 31G x 4/16"U100	
CHINS01318PB	1ml 31G x 5/16"U100	
CHINS00529PB	0,5ml 29G x 1/2"U100	
CHINS00530PB	0,5ml 30G x 1/2"U100	
CHINS005308PB	0,5ml 30G x 5/16"U100	
CHINS005318PB	0,5ml 31G x 5/16"U100	
CHINS005316PB	0,5ml 31G x 4/16"U100	
CHINS00329PB	0,3ml 29G x 1/2"U100	
CHINS00330PB	0,3ml 30G x 1/2"U100	
CHINS003318PB	0,3ml 31G x 5/16"U100	
CHINS003316PB	0,3ml 31G x 4/16"U100	

Product: STERILE INSULIN SYRINGE FOR SINGLE USE – CHIRANA / HARMOFINE / SELFINJECT

Product variants – HARMOFINE:

Product REF code	Product model	Basic UDI-DI (GMN)
HFINS0127	1ml 27G x 1/2"U100	858601504INSULIN04W7
HFINS4129	1ml 29G x 1/2"U40	
HFINS01298	1ml 29G x 5/16"U100	
HFINS0129	1ml 29G x 1/2"U100	
HFINS0130	1ml 30G x 1/2"U100	
HFINS01308	1ml 30G x 5/16"U100	
HFINS01316	1ml 31G x 4/16"U100	
HFINS01318	1ml 31G x 5/16"U100	
HFINS01	1 ml Luer – U100	
HFINS41	1ml Luer – U40	
HFINS00529	0,5ml 29G x 1/2"U100	
HFINS00530	0,5ml 30G x 1/2"U100	
HFINS005308	0,5ml 30G x 5/16"U100	
HFINS005318	0,5ml 31G x 5/16"U100	
HFINS005316	0,5ml 31G x 4/16"U100	
HFINS00329	0,3ml 29G x 1/2"U100	
HFINS00330	0,3ml 30G x 1/2"U100	
HFINS003308	0,3ml 30G x 5/16"U100	
HFINS003318	0,3ml 31G x 5/16"U100	
HFINS003316	0,3ml 31G x 4/16"U100	
HFINS0127PB	1ml 27G x 1/2"U100	
HFINS4129PB	1ml 29G x 1/2"U40	
HFINS01298PB	1ml 29G x 5/16"U100	
HFINS0129PB	1ml 29G x 1/2"U100	
HFINS0130PB	1ml 30G x 1/2"U100	
HFINS01308PB	1ml 30G x 5/16"U100	
HFINS01316PB	1ml 31G x 4/16"U100	
HFINS01318PB	1ml 31G x 5/16"U100	
HFINS00529PB	0,5ml 29G x 1/2"U100	
HFINS00530PB	0,5ml 30G x 1/2"U100	
HFINS005308PB	0,5ml 30G x 5/16"U100	
HFINS005318PB	0,5ml 31G x 5/16"U100	
HFINS005316PB	0,5ml 31G x 4/16"U100	
HFINS00329PB	0,3ml 29G x 1/2"U100	
HFINS00330PB	0,3ml 30G x 1/2"U100	
HFINS003318PB	0,3ml 31G x 5/16"U100	
HFINS003316PB	0,3ml 31G x 4/16"U100	

Product: STERILE INSULIN SYRINGE FOR SINGLE USE – CHIRANA / HARMOFINE / SELFINJECT

Product variants – SELFINJECT:

Product REF code	Product model	Basic UDI-DI (GMN)
AP03-19-00	1ml 27G x 1/2"U100	858601504INSULIN04W7
AP03-20-00	1ml 29G x 1/2"U100	
AP03-21-00	1ml 30G x 1/2"U100	
AP03-22-00	1ml 29G x 1/2"U40	
AP03-19-00/S10	1ml 27G x 1/2"U100	
AP03-20-00/S10	1ml 29G x 1/2"U100	
AP03-21-00/S10	1ml 30G x 1/2"U100	
AP03-22-00/S10	1ml 29G x 1/2"U40	

