

DECLARATION (no. EN 39-2023)

We, **CHIRANA T. Injecta a.s.**,

Nám. Dr. A. Schweitzera 194
916 01 Stará Turá
Slovakia

manufacturer of:

STERILE SINGLE USE MEDICAL DEVICES

declare, that products listed below:

Sterile Irrigation Syringe for Single Use
Sterile Enteral Syringe for Single Use
Spike for Single Use
Sterile Filter for Single Use
Sterile Blunt Fill Needle for Single Use
Sterile Cup for Single Use
Sterile Hypodermic Syringe for Single Use
Sterile Injection Set for Single Use
Sterile Insulin Syringe with/without Integrated Needle or Side Packed Needle for Single Use
Sterile Tuberculin Syringe with/without Integrated Needle or Side Packed Needle for Single Use
Sterile Perfusion Syringe for Single Use
Infusion Set for Single Use
Transfusion Set for Single Use
Extension Line for Single Use
Mandrin for Single Use
Three Way Stop Cock for Single Use
Stopper for Single Use
Port for Single Use
I.V. Cannula for Single Use
Sterile Hypodermic Needle for Single Use
Sterile Ophthalmic Needle for Single Use
Blood Collection Needle for Single Use
Insulin Pen Needle for Single Use
Scalp Vein Set for Single Use
Sterile Safety Hypodermic Needle for Single Use

EC DECLARATION OF CONFORMITY

Product:

INSULIN PEN NEEDLE – MEDOJECT fine

- meet the requirements of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), don't contain any Substance listed in the latest version of the candidate List of Substance of Very High Concern (SVHC) in a concentration above 0,1% (w/w).
- meet the requirements of Directive 2002/95/EC - Restriction of Hazardous Substances (RoHS) concerning the use restriction of specific hazardous materials found in electrical and electronic products (EEE).
- meet the requirements of RoHS 2 - Directive 2011/65/EU from 8th June 2011 and RoHS 3 - Directive 2015/863/EU amended the RoHS 2 by adding 4 new phthalates (DEHP, BBP, DBP and DIBP) to the list of restricted substances in Annex II.

in Stará Turá, date 17.10.2023



Mgr. Katarína Zemková
Regulatory Specialist