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

EU DECLARATION OF CONFORMITY

(no. EC 26.2-2024)

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: SINGLE USE MEDICAL DEVICES

declare in our own responsibility, that the product:

LATEX EXAMINATION GLOVES FOR SINGLE USE

brand name:	***CHIRASKIN***
versions:	*various sizes and types*
intended purpose:	*protection in infectious situations*
classified as Class: I	*according to classification set out in Annex VIII, Rule 4 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 Regulation (EU) 2017/745, Article 52 (7) relating to the Technical Documentation set out in Annex II and Annex III*
- *with provisions of specification PS 310-0513-05, EN ISO 21420:2020, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 374-1:2016/A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, ISO 374-5:2016, standards selected from the group EN ISO 14644 and EN ISO 10993 and other relevant ISO/EN standards mentioned in product specification and list of standards for product*

Product models are marked with CE.

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

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CHIRANA T. Injecta
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Rastislav Broska, PhD.
Quality Manager

EU DECLARATION OF CONFORMITY

Product:
LATEX EXAMINATION GLOVES FOR SINGLE USE - CHIRASKIN

Types: *powdered / powder free, non-sterile, for single use*

Product variants - CHIRASKIN:

Product REF code	***Product model***	***Basic UDI-DI (GMN)***
CHL01S	*S (powdered)*	*858601504GLOVES267W*
CHLF01S	*S (powder free)*	
CHL01M	*M (powdered)*	
CHLF01M	*M (powder free)*	
CHL01L	*L (powdered)*	
CHLF01L	*L (powder free)*	