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

EU DECLARATION OF CONFORMITY

(no. EC 25.2-2022)

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: SINGLE USE MEDICAL DEVICES

declare in our own responsibility, that the product:

BOUFFANT CAP FOR SINGLE USE

versions:	*non-woven airy textile, size 53cm (21") / 61cm (24")*
intended purpose:	*protection of environment against contamination*
classified as Class: I	*according to classification set out in Annex VIII, Rule 1 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 310-0814-02, EN ISO 13688:2013, EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, 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 products*

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

CHIRANA T.Injecta, a. s.
Nám. Dr. Alberta Schweitzera 194
916 01 Stará Turá
IČO: 36794619
DIČ: 2022402822
IČ DPH: SK2022402822
CHIRANA T. Injecta
www.t-injecta.sk

in Stará Turá, date 01.10.2022

PaedDr. Zdenka Klbečková
Regulatory Affairs Manager

Product:
BOUFFANT CAP FOR SINGLE USE

Product variants:

Product REF code	***Product model***	***Basic UDI-DI (GMN)***
CHC01	*blue - 21" (53cm)*	*858601504BOUFFANTCAP255N*
CHC02	*blue - 24" (61cm)*	
CHC03	*green - 21" (53cm)*	
CHC04	*green - 24" (61cm)*	