Product:

CHIRANA T. Injecta
We supply values for life

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 07-2024)

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 FILTER FOR SINGLE USE

Brand name: ***SYRIFILT / STERIFILT BASIC / STERI5 / STERIFILT FAST / STERIFILT +***

Versions: *cotton filter / plastic filter*

intended use for: filtering of impurities during suction of solution into syringe

classified as Class: Is *according to classification set out in Annex VIII, Rule 2 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 technical specification TPF 320-0508-02, 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 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 (7a) 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*

Product:

STERILE FILTER FOR SINGLE USE – SYRIFILT / STERIFILT BASIC / STERI5 / STERIFILT FAST / STERIFILT +

It was issued Certificate no. 2022/MDR/QS-024/A Rev.01 dated of 11.09.2023, 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

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

Rastislav Broska, PhD.
Quality Manager

Product variants:

Product REF code	***Product model***	***Basic UDI-DI (GMN)***
10500	*SYRIFILT*	*858601504FILTER073J*
AP02-001-00/CH	*STERIFILT BASIC*	
AP02-003-00/CH	*STERI5*	
AP02-005-00/CH	*STERIFILT FAST*	
AP02-006-00/CH	*STERIFILT +*	