

EU Declaration of Conformity

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| <u>Manufacturer:</u> | DINA – HITEX, spol. s r.o. Ždánská 987 Bučovice, 685 01 Czech Republic |
| <u>SRN:</u> | CZ-MF-000000312 |
| <u>Product identification:</u> | Absorbent towels |
| <u>Basic UDI-DI:</u> | 8591527000700ISR |
| <u>Classification:</u> | I sterile (Class 1, rule 1) |
| <u>Notified Body:</u> | 3EC International a.s. Hraničná 18 821 05 Bratislava |
| <u>NB Identification number:</u> | 2265 |
| <u>Conformity assessment route:</u> | Chosen conformity assessment process as per Annex IX conformity assessment based on a quality management system and on assessment of technical documentation. |

This declaration of conformity is issued under the sole responsibility of DINA-HITEX spol. s r.o. We hereby declare that the medical device(s) specified above meet the relevant provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the EU Quality management system certificate issued by 3EC International a.s., certificate No. 2023-MDR/QS-053.

This EU declaration of conformity applies to the products listed in Annex I.

A handwritten signature in blue ink, appearing to read 'Pavel Hrabovský'.

Ing. Pavel Hrabovský
Managing director

A handwritten signature in blue ink, appearing to read 'Jiří Novotný'.

Ing. Jiří Novotný
Regulatory affairs

ANNEX I

| Category | Group number | Content |
|------------------|--------------|------------------|
| Absorbent towels | 06 | Absorbent towels |

Intended purpose:

Absorbent towels are intended to be used for the absorption of liquids, during medical procedures. Their use prevents patients and medical professionals from disease, contamination, microorganisms, body fluids, and particulate matter; therefore they maintain sterility of the operation area.