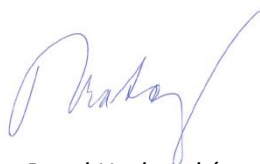


EU Declaration of Conformity

| | |
|-------------------------------------|---|
| <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> | Device covers |
| <u>Basic UDI-DI:</u> | 8591527000300ISPZ |
| <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-050.

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 |
|---------------|--------------|---------------|
| Device covers | 03 | Camera covers |
| | | C-arm covers |
| | | Cord covers |
| | | Mayo covers |
| | | Other covers |
| | | Probe covers |

Intended purpose:

Device covers are intended to cover and isolate various types of devices and equipment and prevent mechanical and microbiological contamination. They prevent patients a medical professional's form disease, contamination, microorganisms, body fluids and particulate matter, therefore they maintain sterility of the operation area.