

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>	Fixation elements
<u>Basic UDI-DI:</u>	8591527000500ISQP
<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-052.

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
Fixation elements	05	Dinafix
		OP tape

Intended purpose:

Fixation elements are intended to be used by medical professionals during surgical procedures to ensure a sterile barrier in the operation area by fixing cables, tubes and other medical devices. Their use prevents patients and medical professionals from disease, contamination, microorganisms, body fluids, and particulate matter; therefore they maintain sterility in the operation area.