

## 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>	<b>Surgical drapes</b>
<u>Basic UDI-DI:</u>	8591527000100ISPB
<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-044.

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 manager

**ANNEX I**

Category	Group number	Content
Surgical drapes	01	Cardiovascular drapes
		Drapes for General surgery
		Drapes for Mini-Invasive surgery and Laparoscopic performances
		Drapes for Multi-organ surgery
		Drapes for Plastic surgery
		Drapes for Vascular Interventional Radiology
		ENT drapes
		EsySuit drapes
		Gynaecology drapes
		Incision drapes
		Neurosurgery drapes
		Ophthalmology drapes
		Orthopaedics drapes
		Other drapes
		Stomatology drapes
		Thoracic drapes
Urology drapes		
Vascular drapes		

**Intended purpose:**

Surgical drapes are used to create a sterile barrier between the surgical site and non-sterile areas. They prevent microorganisms from passing through to the surgical site and the transfer of microorganisms from the surgical site to the environment. They help to prevent the spread of infection and ensure patient and medical professional safety during surgical procedures.