

## EC 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>	Disposable medical devices for infection control and prevention.
<u>Basic UDI-DI and name of the Devices:</u>	8591527000100INSNE - Drapes 8591527000200INSNT - Gowns 8591527000300INSP8 - Covers 8591527000400INSPM - Pouches 8591527000500INSQ2 - Fixation elements 8591527000600INSQF - Protective devices 8591527000700INSQU - Absorbent towel 8591527000800INSR9 - Incision films
<u>Classification:</u>	I non-sterile, rule 1
<u>Conformity assessment route:</u>	DINA-HITEX, spol. s r.o. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745:  Class I non-sterile: EC conformity declaration according to annex I of the Regulation MDR 2017/745 for medical devices.
<u>Harmonized standards:</u>	EN ISO 10993-1:2009; EN ISO 14971:2019; EN 13795-1:2019; EN ISO 15223-1:2016; EN 14683:2019+AC

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 provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV, certificate No.: 243575-2017-AQ-CZE-NA-PS rev.4.0

All supporting documentation is retained at the premises of the manufacturer.



Ing. Pavel Hrabovský  
Managing director



Ing. Jiří Novotný  
Regulatory affairs

## Annex 1

Category	Group number	Content
Drapes	01	Simple surgical drapes
		Drapes with adhesive edge
		Drapes with aperture
		Drapes with adhesive aperture
		Drapes with adhesive aperture and incision film
		Drapes with elastic cuffs
		Drapes EsySuit
Gowns	02	Surgical gowns
		Surgical gowns with reinforcement
Covers	03	Armaterium table covers
		Mayo covers
		Device covers
		Cable covers
		C-arm covers
		Probe covers
		Camera covers
		FAKO covers
		Arm board covers
		Special covers
		Extremity covers
Pouches	04	Universal pouch with one two or three chambers
		Arthroscopic pouch
		Caesarotomy pouch
		Neurosurgery pouch
		Gynecological pouch
		Special pouch
Fixation elements	05	OP tape
		Dinafix
Protective devices	06	Isolation gowns
		Sleeve covers
		Caps
		Medics/scrubs
		Colonoscopy shorts
		Handling sheet
Surgical face masks		
Absorbent towels	07	
Incision films	08	

## Annex 2 – Intended use

### 01 Drapes

Surgical drapes are fundamental elements of the barrier system HITEX. The barrier system serves to isolate non-sterile surfaces near the operating area (patient body, surgical table, instrument table, instruments, etc.). They absorb fluids coming out of the operation area.

### 02 Gowns

Surgical gowns are designed to protect the patient and the surgeon from infection.

### 03 Covers

Mayo covers serve as isolation of the instrumentation table. Extremity covers serve to isolate the legs or hands of the patient during surgery. Device covers isolate the equipment, cables, and other devices from the operation area.

### 04 Pouches

Pouches are used to drain away from the fluid from the operated area during surgery. These bags are equipped with a plastic brace to form the collection pocket and to catch maximum fluid quantity.

### 05 Fixation Elements

Fixation elements are intended for the fixation of protective covers, collection pouches, or cables during surgical procedures for the creation of a sterile barrier.

### 06 Protective devices

Non-sterile protective devices are intended for the protection of the user and patient. They serve as the first layer of protection against contamination. This group of product is meant to cover the user and offer an additional layer of protection.

### 07 Absorbent towels

The towel is designed to absorb liquids that can be a source of contamination. The towel is used to dry intact patient skin.

### 08 Incision films

The self-adhesive foil used for fixing onto the whole operating field and designed to cover the entire surgical field in order to avoid the possibility of surgical wound contamination by infections coming from its immediate surroundings.