

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>Basic UDI-DI and product identifications:</u>	8591527000100INSNE - Surgical drapes 8591527000200INSNT - Surgical gowns 8591527000300INSP8 - Device covers 8591527000400INSPM - Pouches (rule 2) 8591527000500INSQ2 - Fixation elements 8591527000600INSQF - Absorbent towels 8591527000700INSQU - Caps 8591527000710INSR7 - Colonoscopy shorts 8591527000730INSRV - Isolation gowns 8591527000740INSS8 - Medics 8591527000720INSRJ - Patient underpads 8591527000750INSSK - Sleeve covers 8591527000800INSR9 - Umbilical cord tape
<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 to the Regulation MDR 2017/745: Class I non-sterile: EC conformity declaration according to annexes II and III of the Regulation MDR 2017/745 for medical devices.

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 3EC International a.s., certificate No. M-0545/23.

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



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Managing director



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Regulatory affairs

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		
Gowns	02	Surgical gowns
		Surgical gowns with reinforcement
Covers	03	Camera covers
		C-arm covers
		Cord covers
		Mayo covers
		Other covers
		Probe covers
Pouches	04	Arthroscopic pouches
		Caesartomy pouches
		Gynaecological pouches
		Neurosurgery pouches
		Special pouches
Fixation elements	05	OP tape
		Dinafix
Absorbent towels	06	Absorbent towels
Caps	07	Caps
Colonoscopy shorts	08	Colonoscopy shorts
Isolation gowns	09	Isolation gowns
Medics	10	Medics
Patient underpads	11	Patient underpads
Sleeve covers	12	Sleeve covers
Umbilical cord tape	13	Umbilical cord tape

Intended purposes:

01 - 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. The product must be sterilized before use.

02 - Surgical gowns are intended to be worn by medical professionals during surgery in order to provide a barrier between patients and medical professionals. They prevent patients and medical professionals from disease, contamination, microorganisms, body fluids, and particulate matter; therefore they maintain sterility of the operation area. The product must be sterilized before use.

03 - 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. The product must be sterilized before use.

04 - Pouches are intended to collect fluids from the surgery area. Due to that they prevent patients and medical professionals from disease, contamination, microorganisms, body fluids, and particulate matter; therefore they maintain sterility of the operation area. The product must be sterilized before use.

05 - 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. The product must be sterilized before use.

06 - 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. The product must be sterilized before use.

07 – Caps are used as disposable headcover for medical staff. They help to prevent the spread of infection and ensure patient and medical professional safety during surgical procedures.

08 – Colonoscopy shorts: Disposable colonoscopy shorts are used during a colonoscopy examination to ensure patient comfort, hygiene and privacy. They help to prevent the spread of infection and ensure patient and medical professional safety during surgical procedures.

09 – Patient underpad: Disposable pad under the patient used during the examination or intervention. It serves to ensure a clean environment and prevents the transmission of contamination. It is equipped with 8 handles which enable easy manipulation.

10 – Isolation gowns are designed to provide a protective barrier between the wearer and potential sources of contamination. They help to prevent the spread of infection and microorganisms.

11 – Medics: Disposable medical scrubs are intended for healthcare professionals to provide them with comfortable, hygienic, and easily identifiable clothing. They help to prevent the spread of infection and ensure patient and medical professional safety.

12 – Sleeve covers serve as additional protection for the health care professional. They help to prevent the spread of infection and ensure patient and medical professional safety. The sleeve cover is meant to be put on a sleeve of a gown.

13 – Umbilical cord tape is used for holding the umbilical cord safely and securely after the birth of a newborn. They help to prevent bleeding in the newborn. The product must be sterilized before use.