

STATEMENT

Under requirement of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017, article 22.

Manufacturer: Dina-Hitex spol. s r.o.,
Zdanska 987,
Bucovice 685 01, Czech Republic

Herewith declares that for sterile surgical HITEX-PACKS (Basic UDI-DI):

GYNAECOLOGIC PROCEDURE PACK (8591527006000HPGYN4M)

- 1) Containing:
 - a) Other devices bearing the CE marking, listed in annex I;
 - c) Other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified, listed in annex II;
- 2) Declares:
 - a) Has verified the mutual compatibility of all medical devices listed in annex I and of other products listed in annex II, in accordance with the manufacturer's instructions and has carried out his operations in accordance with these instructions.
 - b) Has packed the procedure pack of medical devices and supplied relevant information to users incorporating relevant instructions from the manufacturers of the devices or other products which have been put together.
 - c) Has ensured the implementation, checking and control of all appropriate activities to assembling, packaging and sterilization process in accordance with relevant internal monitoring, verification and validation for all components in procedure packs.
 - d) The sterilization has been carried out in accordance with the manufacturer's instructions as per validation and verification for the components in procedure packs.
- 3) Has a purpose of placing sterilised procedure pack referred to in this statement and applies procedures set out in annex IX of MDR 2017/745. Dina-Hitex declares that sterilisation has been carried out in accordance with the manufacturer's instructions.

- 4) The procedure pack referred to in paragraph 1 does not bear an additional CE marking, but the name of Dina-Hitex. Procedure pack is accompanied with information as per Section 23 of Annex I of MDR 2017/745. All relevant documents considering procedure pack are kept and stored as per Article 10, paragraph 8 of MDR 2017/745.



Pavel Hrabovský
Managing Director



Jiří Novotný
Regulatory Affairs

Date: 10.11.2023

Valid until: 10.11.2028

Revision: 1

Annex I: Device bearing the CE marking

Group	Model
Absorbent underpads	Absorbent underpads
Absorbent towels	Towels
Applicators	Application sponges
	Cotton wool buds
Bipolar forceps	Bipolar forceps
Tip cleaners	Tip cleaners
Drainage systems	Connecting tube
	Redon drain
	Urine collection bags
	Wound drainage system
Sharp holders	Sharp holders
Electrosurgical pencils	Electrosurgical pencils
Filtration systems	Infusion, injection, paediatric infusion, ventilation, epidural, anesthesiological, dispensing pins with filter, bone filter
Fixation elements	Dinafix
	OP tape
Isothermal foils	Isothermal foils
Needles	Needles
Cannulas	Cannulas
Pouches	Caesartomy pouch
	Gynaecological pouch
	Special pouch
	Universal pouch with one, two or three chambers
Catheters	Catheters
Sharp safety boxes	Sharp safety boxes
Stainless steel instruments	Forceps
	Knives handles
	Knives
	Scalpels
	Needle holders
	Clamps
	Scissors
	Cannulas
Hooks and Retractors	
Stainless steel instruments	Roungers
	Bone cutting
	Chisels
Skin markers	Skin markers
Hollowware	Beakers
	Trays
	Bowls

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Plasters	Plasters
Device covers	Mayo covers
	Cable covers
	C-arm covers
	Probe covers
	Camera covers
	Other covers
Light handle covers	Light handle covers
Non-absorbable surgical sutures	Non-absorbable surgical sutures with atraumatic needle, without needle
Protective clothes	Isolation gowns
	Aprons
	Sleeve covers
	Shoe covers
	Surgical face masks
	Caps
Surgical gowns	Surgical gowns
	Surgical gowns with reinforcement
Surgical drapes	Drapes for general surgery
	Drapes for mini-invasive surgery and laparoscopic performances
	Gynaecology drapes
	Other drapes
	Incision films
Plastic instruments	Forceps
	Clamps
	Scissors
	Kochers
	Needle holders
	Shaving razors
	Umbilical cord Clamps
Instrument pads	Nonmagnetic, magnetic
Obstetric pads	Obstetric pads
Umbilical cord bands	Cotton, elastic
Solutions and gels	Lubricating gel
Gloves	Examination gloves
	Surgical gloves
Scalpels and blades	Scalpels and blades
Syringes	Syringes
Products for anaesthesiology	Intubation stylet
	Guedel airways
	Endotracheal tubes
Products for aspiration	Suction sets
	Connectors
Infusion therapy products	Transfer set

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	Stoppers
	Extension lines
	Connectors
	Dispensing pin
	Three way stopcocks
	Manifolds, manifolds with holders
	I. V Cannulas
	Pressure extension lines
	Infusion sets
Wound care products	Abdominal sponges from nonwoven textile of cotton gauze, size 5-80 cm, variably equipped with tape or x-ray
	Gauze size 7-300 cm, 4-48 ply, in models folded gauze with cellulose wadding, hydrophilic gauze, gauze with pad
	Compresses from nonwoven textile or cotton gauze size 5-80cm, variably equipped with x-ray or cut
	Bandages - hydrophilic, fixation, elastic
	Absorbent drape for fire injuries
	Triangular knitted bandage
	Twisted swabs from nonwoven textile or cotton gauze, size from 9 to 60 cm, variably equipped with x-ray

Annex II: Other products without CE marking

Product
Anti-slip socks
Bowl for liquid waste
Bowl Gallipot
Bowl I – three chamber
Bowl with two chambers
Paper bag for waste
Paper emesis basin
Plastic bowl
Plastic bowl with cover
Square bowl, alumina
Transparent bowl
White bowl
White tray