

DINA-HITEX spol. s r.o., Ždánská 987, 685 01 Bučovice, Czech Republic

Tel +420 517 380 215, Fax +420 517 380 831, e-mail info@dina-hitex.com, www.dina-hitex.com

Date: 10. 11. 2023 Valid until: 10.11.2028 Revision: 1

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):

CARDIOVASCULAR PROCEDURE PACK

(8591527006000HPCARZW)

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.



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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

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Annex I: Device bearing the CE marking

Absorbent underpads Absorbent towels Towels Applicators Applicators Cotton wool buds Bipolar forceps Tip cleaners Contrast Controller handset Drainage systems Drainage systems Electrosurgical pencils Filtration systems Fixation elements Cannulas Cannulas Cannulas Cannulas Cannulas Catheters Sharp safety boxes Sharp safety boxes Sharp safety boxes Stainless steel instruments Stainless steel instruments Flasters Hollowware Hollowware Flasters Plasters Pagina Application sponges Cotton wool buds Bipolar forceps Rectonton buds Repleacion sponges Contents agents Recton buds Pleaners Poetes application sponges Cotton wool buds Bipolar forceps Rectonton buds Repleacion sponges Contents agents Repleacion sponges Contents agents Repleacion sponges Cotton wool buds Bipolar forceps Recton on buds Bipolar forceps Recton buds Recton precise dosing of contrast agents Recton buds Placteners Plasters Pla	Group	Model
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		C-arm covers



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	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
	Isolation gowns
	Aprons
Destruction destruction	Sleeve covers
Protective clothes	Shoe covers
	Surgical face masks
	Caps
G	Surgical gowns
Surgical gowns	Surgical gowns with reinforcement
	Cardiovascular drapes
	Drapes for general surgery
Surgical drapes	Drapes for mini-invasive surgery and laparoscopic performances
	Other drapes
	Incision films
	Forceps
	Clamps
	Scissors
Plastic instruments	Kochers
	Needle holders
	Shaving razors
Instrument pads	Nonmagnetic, magnetic
Solutions and gels	Lubricating gel
Classic	Examination gloves
Gloves	Surgical gloves
Scalpels and blades	Scalpels and blades
Syringes	Syringes
	Intubation stylet
Products for anaesthesiology	Guedel airways
	Endotracheal tubes
Duodusta for againstica	Suction sets
Products for aspiration	Connectors
	Transfer set
Infusion therapy products	Stoppers
	Extension lines
	Connectors
	Dispensing pin
	Three way stopcocks
	Manifolds, manifolds with holders
	Mainfolds, mainfolds with holders



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	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	