

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

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Date: 11. 10. 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):

### ORTHOPAEDICS PROCEDURE PACK

(8591527006000HPORT5L)

### 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

Group	Model
Absorbent underpads	Absorbent underpads
Absorbent towels	Towels
Applicators	Application sponges
	Cotton wool buds
Bipolar forceps	Bipolar forceps
Tip cleaners	Tip cleaners
	Connecting tube
	Redon drain
Drainage systems	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
Ti di la	Dinafix
Fixation elements	OP tape
Needles	Needles
Cannulas	Cannulas
	Arthroscopic pouch
Pouches	Special pouch
	Universal pouch with one, two or three chambers
Catheters	Catheters
Sharp safety boxes	Sharp safety boxes
	Forceps
	Knives handles
	Knives
	Scalpels
Stainless steel instruments	Needle holders
	Clamps
	Scissors
	Cannulas
	Hooks and Retractors
	Osteotomes
	Roungers
	Bone cutting
	Chisels
	Dilators
	Drills
	Elevators
	Saws
	Screw drivers



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Skin markers         Skin markers           Holloware         Beakers           Plasters         Plasters           Mayo covers         Cable covers           Cable covers         Carm covers           Probe covers         Camera covers           Other covers         Camera covers           Light handle covers         Non-absorbable surgical sutures with atraumatic needle, without needle           Aprons         Aprons           Sleeve covers         Shoe covers           Shoe covers         Surgical face masks           Caps         Cardiovascular drapes           Surgical gowns         Surgical gowns with reinforcement           Surgical gowns with reinforcement         Cardiovascular drapes           Other drapes         Other drapes           Incision films         EsySuit drapes           Forceps         Clamps           Scissors         Kochers           Needle holders         Skowing razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Scampics and blades         Scalpels and blades           Syringes         Syringes           Products for anaesthesiology         Gueed airways		Cutters
Hollowware  Plasters  Plasters  Plasters  Plasters  Povice covers  Device covers  Light handle covers  Light handle covers  Light handle covers  Don-absorbable surgical sutures  Non-absorbable surgical sutures with atraumatic needle, without needle needle  Isolation gowns  Aprons  Sleeve covers  Shoe covers  Surgical face masks  Caps  Surgical gowns  Surgical gowns  Surgical gowns  Surgical gowns  Surgical gowns  Surgical gowns with reinforcement  Cardiovascular drapes  Drapes for general surgery  Drapes for general surgery  Drapes for mini-invasive surgery and laparoscopic performances  Othopaedics drapes  Other drapes  Incision films  EsySuit drapes  Proceps  Clamps  Scissors  Kochers  Needle holders  Shaving razors  Nonmagnetic, magnetic  Solutions and gels  Lubricating gel  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Intubation stylet  Intubation stylet	Skin markers	Skin markers
Plasters         Plasters           Device covers         Cable covers           Carm covers         C-arm covers           Probe covers         Carmer a covers           Other covers         Carner a covers           Non-absorbable surgical sutures         Non-absorbable surgical sutures with atraumatic needle, without needle           Non-absorbable surgical sutures         Non-absorbable surgical sutures with atraumatic needle, without needle           Protective clothes         Sleeve covers           Shoe covers         Surgical face masks           Caps         Surgical face masks           Caps         Surgical gowns           Surgical gowns         Surgical gowns           Surgical gowns with reinforcement         Cardiovascular drapes           Drapes for general surgery         Drapes for general surgery           Drapes for general surgery         Drapes for general surgery           Drapes for general surgery         Drapes for mini-invasive surgery and laparoscopic performances           Orthopactics drapes         Orthopactics drapes           Clamps         Escissors           Kochers         Kochers           Needle holders         Shaving razors           Instrument pads         Nommagnetic, magnetic           Solutions and gels         Lubri	Hollowware	Beakers
Plasters         Plasters           Ayo covers         Cable covers           Carm covers         Carm covers           Probe covers         Camera covers           Other covers         Other covers           Light handle covers         Light handle covers           Non-absorbable surgical sutures with atraumatic needle, without needle         Isolation gowns           Aprons         Sleeve covers           Shoe covers         Surgical face masks           Caps         Surgical gowns           Surgical gowns         Surgical gowns with reinforcement           Cardiovascular drapes         Drapes for general surgery           Drapes for general surgery         Drapes for general surgery and laparoscopic performances           Other drapes         Incision films           EsySuit drapes         Clamps           Forceps         Clamps           Clamps         Scissors           Kochers         Kochers           Needle holders         Shaving razors           Instrument pads         Nommagnetic, magnetic           Solutions and gels         Lubricating gel           Examination gloves         Surgical gloves           Scalpels and blades         Syringes           Intubation stylet <td>Trays</td>		Trays
Device covers         Cable covers           Came covers         Came covers           Probe covers         Camera covers           Other covers         Other covers           Light handle covers         Light handle covers           Non-absorbable surgical sutures         Non-absorbable surgical sutures with atraumatic needle, without needle needle           Aprons         Sleeve covers           Shoe covers         Silece covers           Surgical face masks         Caps           Surgical gowns         Surgical gowns with reinforcement           Cardiovascular drapes         Drapes for general surgery           Drapes for mini-invasive surgery and laparoscopic performances         Orthor drapes           Orthor drapes         Incision films           Esysuit drapes         Forceps           Clamps         Scissors           Kochers         Needle holders           Shaving razors         Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Gloves         Surgical gloves           Scalpels and blades         Scripces           Syringes         Intubation stylet		Bowls
Device covers         Cable covers           C-arm covers           Probe covers           Camera covers           Other covers           Light handle covers           Non-absorbable surgical sutures           Non-absorbable surgical sutures           Isolation gowns           Aprons           Sleeve covers           Shoe covers           Surgical face masks           Caps           Surgical gowns           Surgical gowns           Surgical gowns with reinforcement           Cardiovascular drapes           Drapes for general surgery           Drapes for mini-invasive surgery and laparoscopic performances           Orthopaedics drapes           Other drapes           Incision films           EsySuit drapes           Porceps           Clamps           Scissors           Kochers           Noedle holders           Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Examination gloves           Scalpels and blades         Scalpels and blades           Syringes         Intubation stylet  <	Plasters	Plasters
Device covers         C-arm covers           Probe covers         Camera covers           Other covers         Other covers           Light handle covers         Non-absorbable surgical sutures with atraumatic needle, without needle           Non-absorbable surgical sutures         Non-absorbable surgical sutures with atraumatic needle, without needle           Aprons         Sleeve covers           Shoe covers         Shoe covers           Surgical face masks         Caps           Surgical gowns         Surgical gowns with reinforcement           Cardiovascular drapes         Drapes for general surgery           Drapes for general surgery         Drapes for mini-invasive surgery and laparoscopic performances           Orthopaedics drapes         Other drapes           Incision films         EsySuit drapes           Forceps         Clamps           Clamps         Scissors           Kochers         Needle holders           Shaving razors         Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Gloves         Surgical gloves           Scalpels and blades         Scalpels and blades           Syringes         Intubation stylet		Mayo covers
Probe covers	Device covers	Cable covers
Probe covers           Camera covers           Other covers           Light handle covers           Non-absorbable surgical sutures           Non-absorbable surgical sutures with atraumatic needle, without needle           needle           Isolation gowns           Aprons           Sleeve covers           Surgical face masks           Caps           Surgical gowns           Surgical gowns           Surgical gowns with reinforcement           Cardiovascular drapes           Drapes for general surgery           Drapes for mini-invasive surgery and laparoscopic performances           Other drapes           Incision films           EsySuit drapes           Clamps           Clamps           Scissors           Kochers           Needle holders           Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Examination gloves           Scalpels and blades         Scalpels and blades           Syringes         Myringes           Products for anaesthesiology         Intubation stylet		C-arm 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         Shoe covers           Surgical face masks         Caps           Surgical gowns         Surgical gowns           Surgical gowns with reinforcement         Cardiovascular drapes           Drapes for general surgery         Drapes for mini-invasive surgery and laparoscopic performances           Other drapes         Incision films           EsySuit drapes         EsySuit drapes           Plastic instruments         Forceps           Clamps         Scissors           Kochers         Needle holders           Shaving razors         Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Gloves         Surgical gloves           Scalpels and blades         Scalpels and blades           Syringes         Intubation stylet		Probe covers
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Non-absorbable surgical sutures         Non-absorbable surgical sutures with atraumatic needle, without needle solution gowns           Aprons         Sleeve covers           Shoe covers         Shoe covers           Surgical face masks         Caps           Surgical gowns         Surgical gowns           Surgical gowns with reinforcement         Cardiovascular drapes           Drapes for general surgery         Drapes for mini-invasive surgery and laparoscopic performances           Orthopaedics drapes         Other drapes           Incision films         EsySuit drapes           Forceps         Clamps           Scissors         Kochers           Needle holders         Shaving razors           Instrument pads         Nonmagnetic, magnetic           Solutions and gels         Lubricating gel           Gloves         Surgical gloves           Scalpels and blades         Scalpels and blades           Syringes         Intubation stylet		Other covers
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Protective clothes    Aprons     Sleeve covers     Shoe covers     Surgical face masks     Caps     Surgical gowns     Surgical gowns     Surgical gowns with reinforcement     Cardiovascular drapes     Drapes for general surgery     Drapes for mini-invasive surgery and laparoscopic performances     Orthopaedics drapes     Other drapes     Incision films     EsySuit drapes     Forceps     Clamps     Scissors     Kochers     Needle holders     Shaving razors     Instrument pads     Solutions and gels     Lubricating gel     Examination gloves     Scalpels and blades     Syringes     Products for anaesthesiology     Instudent pages     Intubation stylet     Intubation stylet	Non-absorbable surgical sutures	
Protective clothes    Sileeve covers     Shoe covers     Surgical face masks     Caps     Surgical gowns     Surgical gowns     Surgical gowns     Surgical gowns with reinforcement     Cardiovascular drapes     Drapes for general surgery     Drapes for mini-invasive surgery and laparoscopic performances     Other drapes     Other drapes     Incision films     EsySuit drapes     Forceps     Clamps     Scissors     Clamps     Scissors     Kochers     Needle holders     Shaving razors     Instrument pads     Solutions and gels     Lubricating gel     Examination gloves     Scalpels and blades     Scalpels and blades     Syringes     Products for anaesthesiology     Intubation stylet     Intubation		Isolation gowns
Protective clothes    Shoe covers     Surgical face masks     Caps     Surgical gowns     Surgical gowns     Surgical gowns with reinforcement     Cardiovascular drapes     Drapes for general surgery     Drapes for mini-invasive surgery and laparoscopic performances     Other drapes     Incision films     EsySuit drapes     Incision films     EsySuit drapes     Forceps     Clamps     Scissors     Kochers     Needle holders     Shaving razors     Instrument pads     Solutions and gels     Lubricating gel     Examination gloves     Scalpels and blades     Scalpels and blades     Syringes     Products for anaesthesiology     Intubation stylet     Intubati		Aprons
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Caps       Surgical gowns       Surgical gowns       Surgical gowns with reinforcement       Cardiovascular drapes       Drapes for general surgery       Drapes for mini-invasive surgery and laparoscopic performances       Orthopaedics drapes       Other drapes       Incision films       EsySuit drapes       Forceps       Clamps       Scissors       Kochers       Needle holders       Shaving razors       Instrument pads     Nonmagnetic, magnetic       Solutions and gels     Lubricating gel       Examination gloves       Surgical gloves       Scalpels and blades     Scalpels and blades       Syringes     Syringes       Intubation stylet	Protective ciotiles	Shoe covers
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Surgical gowns  Surgical gowns with reinforcement  Cardiovascular drapes  Drapes for general surgery  Drapes for mini-invasive surgery and laparoscopic performances  Orthopaedics drapes  Other drapes  Incision films  EsySuit drapes  Forceps  Clamps  Scissors  Kochers  Needle holders  Shaving razors  Instrument pads  Nonmagnetic, magnetic  Solutions and gels  Lubricating gel  Examination gloves  Scalpels and blades  Syringes  Products for anaesthesiology  Surgical glows with reinforcement  Cardiovascular drapes  Drapes for general surgery  Drapes for mini-invasive surgery and laparoscopic performances  Orthopaedics drapes  Other drapes  Incision films  EsySuit drapes  Forceps  Clamps  Scissors  Kochers  Needle holders  Shaving razors  Shaving razors  Shaving razors  Shaving agnetic  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Intubation stylet		Caps
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EsySuit drapes  Forceps  Clamps  Scissors  Kochers  Needle holders  Shaving razors  Instrument pads  Nonmagnetic, magnetic  Solutions and gels  Lubricating gel  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Products for anaesthesiology  EsySuit drapes  Forceps  Lumps  Lamps  Examination  EsySuit drapes  Forceps  Lamps  Louricating  Examination  Solutions  Surgical gloves  Surgical gloves  Surgical gloves  Surgical gloves  Surgical gloves  Intubation stylet		Other drapes
Plastic instruments  Forceps Clamps Scissors Kochers Needle holders Shaving razors Instrument pads Nonmagnetic, magnetic Solutions and gels Lubricating gel Examination gloves Surgical gloves Scalpels and blades Syringes Syringes Products for anaesthesiology  Forceps  Limps Scissors Kochers Needle holders Shaving razors Instrument pads Syringes Instrument pads Syringes Intubation stylet		Incision films
Plastic instruments  Clamps Scissors Kochers Needle holders Shaving razors  Instrument pads Nonmagnetic, magnetic Solutions and gels Lubricating gel Examination gloves Surgical gloves Scalpels and blades Syringes Syringes Products for anaesthesiology  Clamps Scissors Kochers Needle holders Shaving razors  Instrument pads Shaving razors Shaving razors  Nonmagnetic, magnetic Shaving gel Examination gloves Surgical gloves Surgical gloves Intubation stylet		EsySuit drapes
Plastic instruments  Clamps Scissors Kochers Needle holders Shaving razors  Instrument pads Nonmagnetic, magnetic Solutions and gels Lubricating gel Examination gloves Surgical gloves Scalpels and blades Syringes Syringes Products for anaesthesiology  Clamps Scissors Kochers Needle holders Shaving razors  Instrument pads Shaving razors Shaving razors  Nonmagnetic, magnetic Shaving gel Examination gloves Surgical gloves Surgical gloves Intubation stylet	Plastic instruments	Forceps
Plastic instruments  Kochers  Needle holders  Shaving razors  Instrument pads  Nonmagnetic, magnetic  Lubricating gel  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Products for anaesthesiology  Kochers  Needle holders  Shaving razors  Lubricating gel  Examination gloves  Surgical gloves  Surgical gloves  Scalpels and blades  Syringes  Intubation stylet		
Kochers Needle holders Shaving razors  Instrument pads Nonmagnetic, magnetic Solutions and gels Lubricating gel Examination gloves Surgical gloves Scalpels and blades Syringes Syringes Products for anaesthesiology  Kochers Needle holders Shaving razors  Nonmagnetic Examination Solutions and gels Lubricating gel Examination gloves Surgical gloves Surgical gloves Intubation stylet		Scissors
Instrument pads Nonmagnetic, magnetic  Solutions and gels Lubricating gel  Gloves Examination gloves Surgical gloves Scalpels and blades Scalpels and blades Syringes Syringes  Products for anaesthesiology  Intubation stylet		Kochers
Instrument pads  Solutions and gels  Lubricating gel  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Products for anaesthesiology  Nonmagnetic, magnetic  Examination gel  Examination gloves  Surgical gloves  Surgical gloves  Intubation stylet		Needle holders
Solutions and gels  Lubricating gel  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Syringes  Products for anaesthesiology  Lubricating gel  Examination gloves  Surgical gloves  Surgical gloves  Intubation stylet		Shaving razors
Gloves  Examination gloves  Surgical gloves  Scalpels and blades  Syringes  Syringes  Products for anaesthesiology  Examination gloves  Surgical gloves  Intubation stylet	Instrument pads	Nonmagnetic, magnetic
Scalpels and blades Scalpels and blades Syringes Syringes Intubation stylet	Solutions and gels	Lubricating gel
Scalpels and blades Scalpels and blades Syringes Syringes Intubation stylet		
Scalpels and blades Syringes Syringes Products for anaesthesiology Intubation stylet		Surgical gloves
Syringes Syringes Products for anaesthesiology Intubation stylet	Scalpels and blades	
Products for anaesthesiology Intubation stylet		-
Products for anaesthesiology		
		Guedel airways



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	Endotracheal tubes
Products for aspiration	Suction sets
	Connectors
Infusion therapy products	Transfer set
	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