3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2023-MDR/QS-054

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic
SRN No.: CZ-MF-000000312

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of system / procedure pack:

Hitex procedure pack
for detailed list refer to Annex I
Intended purpose: See Annex II
MD class IIb
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **certified pack composition**

For procedure packs, the audit by the NB2265 of the quality management system was limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned procedure pack and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned procedure pack is stated in the MD Audit Report No. SK-0740/23 from 19.10.2023. Information on all examinations and tests performed is stated in the abovementioned report and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned system / procedure pack. The certificate validity is conditional upon fulfilment of relevant legal requirements by the natural / legal person combining the system / procedure pack.

Valid from: **10.11.2023**
Valid until: **10.11.2028**
First issue: **10.11.2023**
Revision: **0**
History: **See Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 10.11.2023

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-054

issued for the company

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic

Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic

List of procedure packs covered by the EU Quality Management System Certificate:

Type No.	Trade Name	Other Trade Names
Hitex pack	Vascular procedure pack	N/A
	Gynaecologic procedure pack	
	Thoracic procedure pack	
	Cardiovascular procedure pack	
	Neurosurgical procedure pack	
	Ophthalmologic procedure pack	
	ENT procedure pack	
	Orthopaedic procedure pack	
	Other procedure pack	
	Vascular interventional radiology procedure pack	
	Procedure pack for mini-invasive surgery and laparoscopic performances	
	Procedure pack for multi-organ surgery	
	Procedure pack for plastic surgery	
	Procedure pack for general surgery	
	Stomatological procedure pack	
	Urological procedure pack	

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-054

issued for the company

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic

Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic

Intended purpose of procedure packs covered by the EU Quality Management System Certificate:

Vascular procedure pack
Vascular procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within vascular surgery.

Gynaecologic procedure pack
Gynaecologic procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within gynaecology.

Thoracic procedure pack
Thoracic procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within thoracic surgery.

Cardiovascular procedure pack
Cardiovascular procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within cardiovascular surgery.

Neurosurgical procedure pack
Neurosurgical procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within cardiovascular surgery.

Notified body · EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028

Katarína Tomin Srdošová, PhD.
Director of NB2265

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-054

issued for the company

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic

Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic

Intended purpose of procedure packs covered by the EU Quality Management System Certificate:

Ophthalmologic procedure pack
Ophthalmologic procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within ophthalmic surgery.

ENT procedure pack
ENT procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within ENT surgery.

Orthopaedic procedure pack
Orthopaedic procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within orthopaedics.

Other procedure pack
This procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures.

Vascular interventional radiology procedure pack
Vascular interventional radiology procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps to minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within vascular interventional radiology.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-054

issued for the company

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic

Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic

Intended purpose of procedure packs covered by the EU Quality Management System Certificate:

Procedure pack for mini-invasive surgery and laparoscopic performances
Procedure pack for mini-invasive and laparoscopic performances provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps minimize the risk of transmitting microorganisms into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within mini-invasive surgery and laparoscopy.

Procedure pack for multi-organ surgery
Procedure pack for multi-organ surgery provides a sterile and comprehensive pack of products necessary for the tissue extraction. It protects the patients and medical professionals; it helps to minimize the risk of transmission of microorganisms to the surgical wound as well as the extracted tissues.

Procedure pack for plastic surgery
Procedure pack for plastic surgery provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of microbial transmission into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within plastic surgery.

Procedure pack for general surgery
Procedure pack for general surgery provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals; it helps to minimize the risk of microbial transmission into the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within general surgery.

Stomatological procedure pack
Stomatological procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedures. It protects the patients and medical professionals and helps to minimize the risk of microbial transmission to the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within Stomatology.

Urological procedure pack
Urological procedure pack provides a sterile and comprehensive pack of products necessary for the specific surgical procedure. It protects the patients and medical professionals; it helps to minimize the risk of microbial transmission to the surgical site, thereby reducing the risk of postoperative complications. It is designed to save time and increase efficiency through its layout. It is used in procedures for the modification of anatomical structures within urology.

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028

Katarína Tomin Srdošová, PhD.
Director of NB2265

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-054

issued for the company

DINA-HITEX, spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic

Manufacturing site I: Ždánská 987, 685 01 Bučovice, Czech Republic
Manufacturing site II: Nad Tratí 427, 684 01 Hodějice, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
0	2023-MDR/QS-054	10.11.2023	MDR196_2023	Initially granted certification

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028