



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-052

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 medical device:

Fixation elements
(for detailed list refer to Annex I)

Intended purpose: Annex II
MD class Is

meets the requirements on quality management system according to the Chapter I and III of 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: **N/A**

For class Is devices, the audit by the NB2265 of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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 medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device 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 medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **10.11.2023**
Valid until: **10.11.2028**
First issue: **10.11.2023**
Revision: **00**
History: **Annex III**

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-052

issued for the company

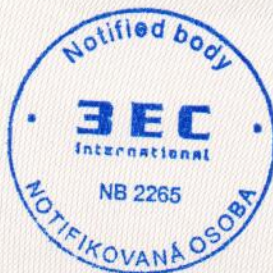
DINA-HITEX spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic
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List of medical devices covered by the EU Quality Management System Certificate:

MD Name	Model / variant	Basic UDI-DI
Fixation elements	DinaFix	8591527000500ISQP
	OP tape	8591527000500ISQP

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In Bratislava, Slovakia, 10.11.2023
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Director of NB2265



ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-052

issued for the company

DINA-HITEX spol. s r.o.

Head Office: Ždánská 987, 685 01 Bučovice, Czech Republic
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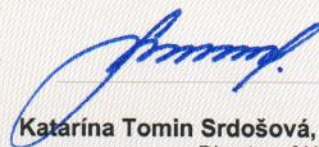
Intended purpose of medical devices covered by the EU Quality Management System Certificate:

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 of the operation area.

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In Bratislava, Slovakia, 10.11.2023
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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-052

issued for the company

DINA-HITEX spol. s r.o.

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

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
0	2023-MDR/QS-052	10.11.2023	MDR194_2023	Initially granted certification

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In Bratislava, Slovakia, 10.11.2023
Valid until 10.11.2028

Katarina Tomin Srdošová, PhD.
Director of NB2265