3EC International NB 2265 3EC International NB 2265 3EC International NB 2265

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2023-MDR/QS-036

CIMPAX A/S

Address of the registered seat: Lille Pilevang 4, 3550 Slangerup, Denmark
Address of the subsidiary: CIMPAX CZ, Brněnská 469/41b, 682 01 Vyškov, Czech Republic
Contract Manufacturer: DINA-HITEX, Ždánská 987, 685 01 Bučovice, Czech Republic
SRN No.: DK-MF-00010490

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:

Smoke Evacuation Pencil and Accessories
Type/Variants, see 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 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**

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 Technical Documentation Assessment Report No. MDR183_2023 from 27.10.2023, MD Clinical Evaluation Report No. MDR183_2023 from 31.10.2023 and MD Audit Report No. MDR183_2023 from 27.10.2023. Information on all examinations and tests performed is stated in the abovementioned reports 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: **0**
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

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-036

issued for the company

CIMPAX A/S

Address of the registered seat: Lille Pilevang 4, 3550 Slangerup, Denmark
Address of the subsidiary: CIMPAX CZ, Brněnská 469/41b, 682 01 Vyškov, Czech Republic
Contract Manufacturer: DINA-HITEX, Ždánská 987, 685 01 Bučovice, Czech Republic

List of medical devices covered by the EU Quality Management System Certificate:

Type No.	Trade Name	Other Trade Names
Smoke Evacuation Pencil	CIMPAX® C-VAC TORNADO	-
	CIMPAX® C-VAC Xtract	-
	Smoke Shield™	-
Accessories	CIMPAX® Extender	-
	CIMPAX® Electrodes	-
	Smoke Shield™ Extender	-

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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-036

issued for the company

CIMPAX A/S

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Address of the subsidiary: CIMPAX CZ, Brněnská 469/41b, 682 01 Vyškov, Czech Republic
Contract Manufacturer: DINA-HITEX, Ždánská 987, 685 01 Bučovice, Czech Republic

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

CIMPAX® C-VAC with its accessories is used for cutting and coagulation of tissue structures, removal of smoke and aerosols during any form of surgery where electrosurgical pencils are used during the surgical procedure.

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

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-036

issued for the company

CIMPAX A/S

Address of the registered seat: Lille Pilevang 4, 3550 Slangerup, Denmark
Address of the subsidiary: CIMPAX CZ, Brněnská 469/41b, 682 01 Vyškov, Czech Republic
Contract Manufacturer: DINA-HITEX, Ždánská 987, 685 01 Bučovice, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
0	2023-MDR/QS-036	10.11.2023	MDR183_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

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