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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2024-MDR/QS-011

CHEIRÓN a.s.

Seat: Kukulova 24, Břevnov, 169 00 Praha 6, Czech Republic
Manufacturing site: Republikánská 1102/45, 312 00 Plzeň - Lobzy, Czech Republic
SRN No.: CZ-MF-000027014

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:

Electric suction device
Trade name: Electric suction device Victoria
Models: Lipos, Portable, Thorax, Versa, Economy (see Annex I)
Intended purpose: Annex II
MD class IIa
(detailed list is stated in the annex(es) if applicable)

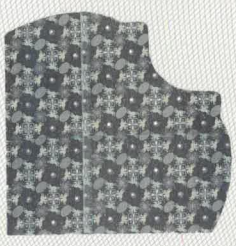
meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

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. MDR145_2022 from 10.03.2024, MD Clinical Evaluation Report No. MDR145_2022 from 10.03.2024 and MD Audit Report No. MDR145_2022 from 16.03.2024. 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: **20.3.2024**
Valid until: **20.3.2029**
First issue: **20.3.2024**
Revision: **00**
History: **Annex III**

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

In Bratislava, Slovakia, 20.3.2024

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-011

issued for the company

CHEIRÓN a.s.

Seat: Kukulova 24, Břevnov, 169 00 Praha 6, Czech Republic

Manufacturing site: Republikánská 1102/45, 312 00 Plzeň - Lobzy, Czech Republic

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

MD name	Models
Electric suction device Victoria	Lipos, Portable, Thorax, Versa, Economy

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 20.3.2024
Valid until 20.3.2029

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-011

issued for the company

CHEIRÓN a.s.

Seat: Kukulova 24, Břevnov, 169 00 Praha 6, Czech Republic

Manufacturing site: Republikánská 1102/45, 312 00 Plzeň - Lobzy, Czech Republic

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

The medical device is intended for suction by creating a negative pressure in accordance with the stated purpose of use of the connected medical device that comes into contact with the patient.

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 20.3.2024
Valid until 20.3.2029

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-011

issued for the company

CHEIRÓN a.s.

Seat: Kukulova 24, Břevnov, 169 00 Praha 6, Czech Republic

Manufacturing site: Republikánská 1102/45, 312 00 Plzeň - Lobzy, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2024-MDR/QS-011	20.3.2024	MDR145_2022	Initially granted certification

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 20.3.2024
Valid until 20.3.2029