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

EU QUALITY ASSURANCE CERTIFICATE

No. 2026-MDR/QA-037/A

Lynax s.r.o.
Půlkruhová 158/1, Vokovice, 160 00 Praha, Czech Republic
Manufacturing site: Brodce 24, 257 41 Týnec nad Sázavou, Czech Republic
SRN No.: CZ-MF-000034349

This EU Quality Assurance 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 for the manufacture of medical device:

Dispensing unit
Variant: Annex I
Intended purpose: Annex II
MD class Im
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Part A of Annex XI 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 Im devices, the audit by the NB 2265 of the quality management system was limited to the aspects relating to the conformity of the MDs with the metrological requirements.

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 for the manufacture of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system for the manufacture of the abovementioned medical device is stated in the MD Audit Report No. MDR018_2026 from 2026-06-12 and Decision on MD / IVD / Conformity Assessment No. MDR018_2026/A from 2026-07-17. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Assurance Certificate** applies only to the quality management system for the manufacture of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **2026-07-17**
Valid until: **2031-06-15**
First issue: **2026-06-15**
Revision: **01**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-07-17

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ANNEX I TO EU QUALITY ASSURANCE CERTIFICATE No. 2026-MDR/QA-037/A

issued for the company

Lynax s.r.o.

Půlkruhová 158/1, Vokovice, 160 00 Praha, Czech Republic
Manufacturing site: Brodce 24, 257 41 Týnec nad Sázavou, Czech Republic

List of medical devices covered by the EU Quality Assurance Certificate:

Basic UDI-DI: 859421637ROZUQ

Medical device name	Variant	UDI-DI
Dispensing unit	Manual Dispensing Unit PT468R4	08594216370047
	Automatic Dispensing Unit PT317R7	08594216370030
	Automatic Dispensing Unit Twin Tracer PT459R5	08594216370023

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-07-17
Valid until 2031-06-15

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ANNEX II TO EU QUALITY ASSURANCE CERTIFICATE No. 2026-MDR/QA-037/A

issued for the company

Lynax s.r.o.

Půlkruhová 158/1, Vokovice, 160 00 Praha, Czech Republic
Manufacturing site: Brodce 24, 257 41 Týnec nad Sázavou, Czech Republic

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

The dispensing unit is a medical device intended for measuring doses of radioactive solution with a predetermined radioactivity value.

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-07-17
Valid until 2031-06-15

ANNEX III TO EU QUALITY ASSURANCE CERTIFICATE No. 2026-MDR/QA-037/A

issued for the company

Lynax s.r.o.

Půlkruhová 158/1, Vokovice, 160 00 Praha, Czech Republic
Manufacturing site: Brodce 24, 257 41 Týnec nad Sázavou, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2026-MDR/QA-037	2026-06-15	MDR018_2026	Initially issued certificate
01	2026-MDR/QA-037/A	2026-07-17	MDR018_2026/A	Certificate amended due to change of manufacturer's business name from LYNAX s.r.o. to Lynax s.r.o.

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-07-17
Valid until 2031-06-15

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