



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-058/A

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic
SRN No.: CZ-MF-000012371

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:

Elastic nail

For models / variants, see Annex I

Intended purpose: see Annex II

MD class IIb, Rule 8

(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. MDR163_2022/A from 23.06.2025, MD Clinical Evaluation Report No. MDR163_2022 from 14.10.2024 and MD Audit Report No. SK-0687/24 from 16.10.2024. 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. For placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate 2024-MDR/TD-058/A issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **23.06.2025**
Valid until: **25.10.2029**
First issue: **25.10.2024**
Revision: **01**
History: **see Annex III**




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

In Bratislava, Slovakia, 23.06.2025



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-058/A

issued for the company

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

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

Elastic nail

Catalogue No.	UDI-DI	Trade Name
397129775313	08591712369346	Elastic nail; 2.0x400 mm
397129775323	08591712369353	Elastic nail; 2.5x400 mm
397129775333	08591712369360	Elastic nail; 3.0x450 mm
397129775343	08591712369377	Elastic nail; 3.5x450 mm
397129775363	08591712369391	Elastic nail; 4.0x500 mm

Elastic nail sterile

Catalogue No.	UDI-DI	Trade Name
397129775313S	08591712369407	Elastic nail sterile; 2.0x400 mm
397129775323S	08591712369414	Elastic nail sterile; 2.5x400 mm
397129775333S	08591712369421	Elastic nail sterile; 3.0x450 mm
397129775343S	08591712369438	Elastic nail sterile; 3.5x450 mm
397129775363S	08591712369452	Elastic nail sterile; 4.0x500 mm

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Katarina Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 23.06.2025
Valid until 25.10.2029



**ANNEX II TO EU QUALITY MANAGEMENT SYSTEM
CERTIFICATE No. 2024-MDR/QS-058/A**

issued for the company

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

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

The elastic nail is intended for osteosynthesis of long-bone fractures in paediatric patients.

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-058/A

issued for the company

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2024-MDR/QS-058	25.10.2024	MDR163_2022	Initially granted certificate
01	2024-MDR/QS-058/A	23.06.2025	MDR163_2022/A	Change of trade name to Elastic nail and Elastic nail sterile

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