



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

## EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-028/A

**MEDIN, a.s.**

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

This EU Technical Documentation Assessment 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 technical documentation of the medical device:

**Reconstruction nail**

**For models / variants, see Annex I**

**Intended purpose: see Annex II**

**MD class IIb, Rule 8**

**Basic UDI-DI: see Annex I**

(detailed list is stated in the annex(es) if applicable)

**meets the requirements of technical documentation assessment according to the Chapter II 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: **None**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed technical documentation assessment of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned medical device is stated in the Technical Documentation Assessment Report No. MDR055\_2022/A from 20.1.2025, Clinical Evaluation Report No. MDR055\_2022/A from 20.1.2025 and 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 Technical Documentation Assessment Certificate** applies only to the abovementioned medical device. For the placing on the market of the MDs / AXVIs which this certificate covers, the EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **27.1.2025**  
Valid until: **31.8.2028**  
First issue: **31.8.2023**  
Revision: **1**  
History: **see Annex III**



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

In Bratislava, Slovakia, 27.1.2025



# ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No.2023-MDR/TD-028/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 Technical Documentation Assessment Certificate:

Reconstruction nail  
Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129771310	08591712366260	Reconstruction nail; short, 11×200 mm, 125°, cannulated
397129771320	08591712366277	Reconstruction nail; short, 11×200 mm, 130°, cannulated
397129771330	08591712366284	Reconstruction nail; short, 11×200 mm, 135°, cannulated
397129771350	08591712366291	Reconstruction nail; short, 13×200 mm, 125°, cannulated
397129771360	08591712366307	Reconstruction nail; short, 13×200 mm, 130°, cannulated
397129771370	08591712366314	Reconstruction nail; short, 13×200 mm, 135°, cannulated
397129772910	08591712366321	Reconstruction nail; short, 11×225 mm, 125°
397129772920	08591712366338	Reconstruction nail; short, 11×225 mm, 130°
397129772930	08591712366345	Reconstruction nail; short, 11×225 mm, 135°
397129772950	08591712366352	Reconstruction nail; short, 13×225 mm, 125°
397129772960	08591712366369	Reconstruction nail; short, 13×225 mm, 130°
397129772970	08591712366376	Reconstruction nail; short, 13×225 mm, 135°

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Katarina Tomin Srdošová, PhD.  
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**MEDIN, a.s.**

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

### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

#### Reconstruction nail

Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129787740	08591712366383	Reconstruction nail; short, 9×200 mm, 125°, cannulated
397129787750	08591712366390	Reconstruction nail; short, 9×200 mm, 130°, cannulated
397129787760	08591712366406	Reconstruction nail; short, 9×200 mm, 135°, cannulated
397129787790	08591712366413	Reconstruction nail; short, 9×225 mm, 130°
397129787800	08591712366420	Reconstruction nail; short, 9×225 mm, 135°
397129787990	08591712366437	Reconstruction nail; short, 9×225 mm, 125°
397129771313	08591712366727	Reconstruction nail; Ti, short, 11×200 mm, 125°, cannulated
397129771323	08591712366734	Reconstruction nail; Ti, short, 11×200 mm, 130°, cannulated
397129771333	08591712366741	Reconstruction nail; Ti, short, 11×200 mm, 135°, cannulated
397129771353	08591712366758	Reconstruction nail; Ti, short, 13×200 mm, 125°, cannulated
397129771363	08591712366765	Reconstruction nail; Ti, short, 13×200 mm, 130°, cannulated
397129771373	08591712366772	Reconstruction nail; Ti, short, 13×200 mm, 135°, cannulated

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**Katarina Tomin Srdošová, PhD.**  
Director of NB 2285



## ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No.2023-MDR/TD-028/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 Technical Documentation Assessment Certificate:

#### Reconstruction nail

Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129772913	08591712366789	Reconstruction nail; Ti, short, 11×225 mm, 125°
397129772923	08591712366796	Reconstruction nail; Ti, short, 11×225 mm, 130°
397129772933	08591712366802	Reconstruction nail; Ti, short, 11×225 mm, 135°
397129772953	08591712366819	Reconstruction nail; Ti, short, 13×225 mm, 125°
397129772963	08591712366826	Reconstruction nail; Ti, short, 13×225 mm, 130°
397129772973	08591712366833	Reconstruction nail; Ti, short, 13×225 mm, 135°
397129787743	08591712366840	Reconstruction nail; Ti, short, 9×200 mm, 125°, cannulated
397129787753	08591712366857	Reconstruction nail; Ti, short, 9×200 mm, 130°, cannulated
397129787763	08591712366864	Reconstruction nail; Ti, short, 9×200 mm, 135°, cannulated
397129787793	08591712366871	Reconstruction nail; Ti, short, 9×225 mm, 130°
397129787803	08591712366888	Reconstruction nail; Ti, short, 9×225 mm, 135°
397129787993	08591712366895	Reconstruction nail; Ti, short, 9×225 mm, 125°

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

### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail**  
Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790031	08591712366444	Reconstruction nail; long, 10×320 mm, 135°, right, cannulated
397129790041	08591712366451	Reconstruction nail; long, 10×320 mm, 135°, left, cannulated
397129790051	08591712366468	Reconstruction nail; long, 10×340 mm, 135°, right, cannulated
397129790061	08591712366475	Reconstruction nail; long, 10×340 mm, 135°, left, cannulated
397129790071	08591712366482	Reconstruction nail; long, 10×360 mm, 135°, right, cannulated
397129790081	08591712366499	Reconstruction nail; long, 10×360 mm, 135°, left, cannulated
397129790091	08591712366505	Reconstruction nail; long, 10×380 mm, 135°, right, cannulated
397129790101	08591712366512	Reconstruction nail; long, 10×380 mm, 135°, left, cannulated
397129790111	08591712366529	Reconstruction nail; long, 10×400 mm, 135°, right, cannulated
397129790121	08591712366536	Reconstruction nail; long, 10×400 mm, 135°, left, cannulated
397129790131	08591712366543	Reconstruction nail; long, 10×420 mm, 135°, right, cannulated
397129790141	08591712366550	Reconstruction nail; long, 10×420 mm, 135°, left, cannulated

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#### Reconstruction nail

Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790151	08591712366567	Reconstruction nail; long, 10×440 mm, 135°, right, cannulated
397129790161	08591712366574	Reconstruction nail; long, 10×440 mm, 135°, left, cannulated
397129790251	08591712366581	Reconstruction nail; long, 11×320 mm, 135°, right, cannulated
397129790261	08591712366598	Reconstruction nail; long, 11×320 mm, 135°, left, cannulated
397129790271	08591712366604	Reconstruction nail; long, 11×340 mm, 135°, right, cannulated
397129790281	08591712366611	Reconstruction nail; long, 11×340 mm, 135°, left, cannulated
397129790291	08591712366628	Reconstruction nail; long, 11×360 mm, 135°, right, cannulated
397129790301	08591712366635	Reconstruction nail; long, 11×360 mm, 135°, left, cannulated
397129790311	08591712366642	Reconstruction nail; long, 11×380 mm, 135°, right, cannulated
397129790321	08591712366659	Reconstruction nail; long, 11×380 mm, 135°, left, cannulated
397129790331	08591712366666	Reconstruction nail; long, 11×400 mm, 135°, right, cannulated
397129790341	08591712366673	Reconstruction nail; long, 11×400 mm, 135°, left, cannulated

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**Reconstruction nail**  
Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790351	08591712366680	Reconstruction nail; long, 11×420 mm, 135°, right, cannulated
397129790361	08591712366697	Reconstruction nail; long, 11×420 mm, 135°, left, cannulated
397129790371	08591712366703	Reconstruction nail; long, 11×440 mm, 135°, right, cannulated
397129790381	08591712366710	Reconstruction nail; long, 11×440 mm, 135°, left, cannulated
397129790491	08591712399497	Reconstruction nail; long, 12×320 mm, 135°, right, cannulated
397129790501	08591712399510	Reconstruction nail; long, 12×320 mm, 135°, left, cannulated
397129790511	08591712399534	Reconstruction nail; long, 12×340 mm, 135°, right, cannulated
397129790521	08591712399558	Reconstruction nail; long, 12×340 mm, 135°, left, cannulated
397129790531	08591712399572	Reconstruction nail; long, 12×360 mm, 135°, right, cannulated
397129790541	08591712399596	Reconstruction nail; long, 12×360 mm, 135°, left, cannulated
397129790551	08591712399619	Reconstruction nail; long, 12×380 mm, 135°, right, cannulated
397129790561	08591712399633	Reconstruction nail; long, 12×380 mm, 135°, left, cannulated

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**Basic UDI-DI: 85917126010101V4**

Catalogue No.	UDI-DI	Variant
397129790571	08591712399657	Reconstruction nail; long, 12×400 mm, 135°, right, cannulated
397129790581	08591712399671	Reconstruction nail; long, 12×400 mm, 135°, left, cannulated
397129790591	08591712399695	Reconstruction nail; long, 12×420 mm, 135°, right, cannulated
397129790601	08591712399718	Reconstruction nail; long, 12×420 mm, 135°, left, cannulated
397129790611	08591712400889	Reconstruction nail; long, 12×440 mm, 135°, right, cannulated
397129790621	08591712400896	Reconstruction nail; long, 12×440 mm, 135°, left, cannulated
397129790033	08591712366901	Reconstruction nail; Ti, long, 10×320 mm, 135°, right, cannulated
397129790043	08591712366918	Reconstruction nail; Ti, long, 10×320 mm, 135°, left, cannulated
397129790053	08591712366925	Reconstruction nail; Ti, long, 10×340 mm, 135°, right, cannulated
397129790063	08591712366932	Reconstruction nail; Ti, long, 10×340 mm, 135°, left, cannulated
397129790073	08591712366949	Reconstruction nail; Ti, long, 10×360 mm, 135°, right, cannulated
397129790083	08591712366956	Reconstruction nail; Ti, long, 10×360 mm, 135°, left, cannulated

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**Reconstruction nail**  
Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790093	08591712366963	Reconstruction nail; Ti, long, 10×380 mm, 135°, right, cannulated
397129790103	08591712366970	Reconstruction nail; Ti, long, 10×380 mm, 135°, left, cannulated
397129790113	08591712366987	Reconstruction nail; Ti, long, 10×400 mm, 135°, right, cannulated
397129790123	08591712366994	Reconstruction nail; Ti, long, 10×400 mm, 135°, left, cannulated
397129790133	08591712367007	Reconstruction nail; Ti, long, 10×420 mm, 135°, right, cannulated
397129790143	08591712367014	Reconstruction nail; Ti, long, 10×420 mm, 135°, left, cannulated
397129790153	08591712367021	Reconstruction nail; Ti, long, 10×440 mm, 135°, right, cannulated
397129790163	08591712367038	Reconstruction nail; Ti, long, 10×440 mm, 135°, left, cannulated
397129790253	08591712367045	Reconstruction nail; Ti, long, 11×320 mm, 135°, right, cannulated
397129790263	08591712367052	Reconstruction nail; Ti, long, 11×320 mm, 135°, left, cannulated
397129790273	08591712367069	Reconstruction nail; Ti, long, 11×340 mm, 135°, right, cannulated
397129790283	08591712367076	Reconstruction nail; Ti, long, 11×340 mm, 135°, left, cannulated

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## List of medical devices covered by the EU Technical Documentation Assessment Certificate:

### Reconstruction nail

Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790293	08591712367083	Reconstruction nail; Ti, long, 11×360 mm, 135°, right, cannulated
397129790303	08591712367090	Reconstruction nail; Ti, long, 11×360 mm, 135°, left, cannulated
397129790313	08591712367106	Reconstruction nail; Ti, long, 11×380 mm, 135°, right, cannulated
397129790323	08591712367113	Reconstruction nail; Ti, long, 11×380 mm, 135°, left, cannulated
397129790333	08591712367120	Reconstruction nail; Ti, long, 11×400 mm, 135°, right, cannulated
397129790343	08591712367137	Reconstruction nail; Ti, long, 11×400 mm, 135°, left, cannulated
397129790353	08591712367144	Reconstruction nail; Ti, long, 11×420 mm, 135°, right, cannulated
397129790363	08591712367151	Reconstruction nail; Ti, long, 11×420 mm, 135°, left, cannulated
397129790373	08591712367168	Reconstruction nail; Ti, long, 11×440 mm, 135°, right, cannulated
397129790383	08591712367175	Reconstruction nail; Ti, long, 11×440 mm, 135°, left, cannulated
397129790493	08591712399503	Reconstruction nail; Ti, long, 12×320 mm, 135°, right, cannulated
397129790503	08591712399527	Reconstruction nail; Ti, long, 12×320 mm, 135°, left, cannulated

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### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail**  
Basic UDI-DI: 85917126010101V4

Catalogue No.	UDI-DI	Variant
397129790513	08591712399541	Reconstruction nail; Ti, long, 12×340 mm, 135°, right, cannulated
397129790523	08591712399565	Reconstruction nail; Ti, long, 12×340 mm, 135°, left, cannulated
397129790533	08591712399589	Reconstruction nail; Ti, long, 12×360 mm, 135°, right, cannulated
397129790543	08591712399602	Reconstruction nail; Ti, long, 12×360 mm, 135°, left, cannulated
397129790553	08591712399626	Reconstruction nail; Ti, long, 12×380 mm, 135°, right, cannulated
397129790563	08591712399640	Reconstruction nail; Ti, long, 12×380 mm, 135°, left, cannulated
397129790573	08591712399664	Reconstruction nail; Ti, long, 12×400 mm, 135°, right, cannulated
397129790583	08591712399688	Reconstruction nail; Ti, long, 12×400 mm, 135°, left, cannulated
397129790593	08591712399701	Reconstruction nail; Ti, long, 12×420 mm, 135°, right, cannulated
397129790603	08591712399725	Reconstruction nail; Ti, long, 12×420 mm, 135°, left, cannulated
397129790613	08591712399732	Reconstruction nail; Ti, long, 12×440 mm, 135°, right, cannulated
397129790623	08591712399749	Reconstruction nail; Ti, long, 12×440 mm, 135°, left, cannulated

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

## List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Reconstruction nail sterile  
Basic UDI-DI: 85917126010101SNF

Catalogue No.	UDI-DI	Variant
397129771310S	08591712367182	Reconstruction nail sterile; short, 11×200 mm, 125°, cannulated
397129771320S	08591712367199	Reconstruction nail sterile; short, 11×200 mm, 130°, cannulated
397129771330S	08591712367205	Reconstruction nail sterile; short, 11×200 mm, 135°, cannulated
397129771350S	08591712367212	Reconstruction nail sterile; short, 13×200 mm, 125°, cannulated
397129771360S	08591712367229	Reconstruction nail sterile; short, 13×200 mm, 130°, cannulated
397129771370S	08591712367236	Reconstruction nail sterile; short, 13×200 mm, 135°, cannulated
397129772910S	08591712367243	Reconstruction nail sterile; short, 11×225 mm, 125°
397129772920S	08591712367250	Reconstruction nail sterile; short, 11×225 mm, 130°
397129772930S	08591712367267	Reconstruction nail sterile; short, 11×225 mm, 135°
397129772950S	08591712367274	Reconstruction nail sterile; short, 13×225 mm, 125°
397129772960S	08591712367281	Reconstruction nail sterile; short, 13×225 mm, 130°
397129772970S	08591712367298	Reconstruction nail sterile; short, 13×225 mm, 135°

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**Reconstruction nail sterile**  
**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129787740S	08591712367304	Reconstruction nail sterile; short, 9×200 mm, 125°, cannulated
397129787750S	08591712367311	Reconstruction nail sterile; short, 9×200 mm, 130°, cannulated
397129787760S	08591712367328	Reconstruction nail sterile; short, 9×200 mm, 135°, cannulated
397129787790S	08591712367335	Reconstruction nail sterile; short, 9×225 mm, 130°
397129787800S	08591712367342	Reconstruction nail sterile; short, 9×225 mm, 135°
397129787990S	08591712367359	Reconstruction nail sterile; short, 9×225 mm, 125°
397129771313S	08591712367649	Reconstruction nail sterile; Ti, short, 11×200 mm, 125°, cannulated
397129771323S	08591712367656	Reconstruction nail sterile; Ti, short, 11×200 mm, 130°, cannulated
397129771333S	08591712367663	Reconstruction nail sterile; Ti, short, 11×200 mm, 135°, cannulated
397129771353S	08591712367670	Reconstruction nail sterile; Ti, short, 13×200 mm, 125°, cannulated
397129771363S	08591712367687	Reconstruction nail sterile; Ti, short, 13×200 mm, 130°, cannulated
397129771373S	08591712367694	Reconstruction nail sterile; Ti, short, 13×200 mm, 135°, cannulated

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**List of medical devices covered by the EU Technical Documentation Assessment Certificate:**

**Reconstruction nail sterile**  
**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129772913S	08591712367700	Reconstruction nail sterile; Ti, short, 11×225 mm, 125°
397129772923S	08591712367717	Reconstruction nail sterile; Ti, short, 11×225 mm, 130°
397129772933S	08591712367724	Reconstruction nail sterile; Ti, short, 11×225 mm, 135°
397129772953S	08591712367731	Reconstruction nail sterile; Ti, short, 13×225 mm, 125°
397129772963S	08591712367748	Reconstruction nail sterile; Ti, short, 13×225 mm, 130°
397129772973S	08591712367755	Reconstruction nail sterile; Ti, short, 13×225 mm, 135°
397129787743S	08591712367762	Reconstruction nail sterile; Ti, short, 9×200 mm, 125°, cannulated
397129787753S	08591712367779	Reconstruction nail sterile; Ti, short, 9×200 mm, 130°, cannulated
397129787763S	08591712367786	Reconstruction nail sterile; Ti, short, 9×200 mm, 135°, cannulated
397129787793S	08591712367793	Reconstruction nail sterile; Ti, short, 9×225 mm, 130°
397129787803S	08591712367809	Reconstruction nail sterile; Ti, short, 9×225 mm, 135°
397129787993S	08591712367816	Reconstruction nail sterile; Ti, short, 9×225 mm, 125°

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## ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No.2023-MDR/TD-028/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 Technical Documentation Assessment Certificate:

**Reconstruction nail sterile**

**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129790031S	08591712367366	Reconstruction nail sterile; long, 10×320 mm, 135°, right, cannulated
397129790041S	08591712367373	Reconstruction nail sterile; long, 10×320 mm, 135°, left, cannulated
397129790051S	08591712367380	Reconstruction nail sterile; long, 10×340 mm, 135°, right, cannulated
397129790061S	08591712367397	Reconstruction nail sterile; long, 10×340 mm, 135°, left, cannulated
397129790071S	08591712367403	Reconstruction nail sterile; long, 10×360 mm, 135°, right, cannulated
397129790081S	08591712367410	Reconstruction nail sterile; long, 10×360 mm, 135°, left, cannulated
397129790091S	08591712367427	Reconstruction nail sterile; long, 10×380 mm, 135°, right, cannulated
397129790101S	08591712367434	Reconstruction nail sterile; long, 10×380 mm, 135°, left, cannulated
397129790111S	08591712367441	Reconstruction nail sterile; long, 10×400 mm, 135°, right, cannulated
397129790121S	08591712367458	Reconstruction nail sterile; long, 10×400 mm, 135°, left, cannulated
397129790131S	08591712367465	Reconstruction nail sterile; long, 10×420 mm, 135°, right, cannulated
397129790141S	08591712367472	Reconstruction nail sterile; long, 10×420 mm, 135°, left, cannulated

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### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail sterile**

**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129790151S	08591712367489	Reconstruction nail sterile; long, 10×440 mm, 135°, right, cannulated
397129790161S	08591712367496	Reconstruction nail sterile; long, 10×440 mm, 135°, left, cannulated
397129790251S	08591712367502	Reconstruction nail sterile; long, 11×320 mm, 135°, right, cannulated
397129790261S	08591712367519	Reconstruction nail sterile; long, 11×320 mm, 135°, left, cannulated
397129790271S	08591712367526	Reconstruction nail sterile; long, 11×340 mm, 135°, right, cannulated
397129790281S	08591712367533	Reconstruction nail sterile; long, 11×340 mm, 135°, left, cannulated
397129790291S	08591712367540	Reconstruction nail sterile; long, 11×360 mm, 135°, right, cannulated
397129790301S	08591712367557	Reconstruction nail sterile; long, 11×360 mm, 135°, left, cannulated
397129790311S	08591712367564	Reconstruction nail sterile; long, 11×380 mm, 135°, right, cannulated
397129790321S	08591712367571	Reconstruction nail sterile; long, 11×380 mm, 135°, left, cannulated
397129790331S	08591712367588	Reconstruction nail sterile; long, 11×400 mm, 135°, right, cannulated
397129790341S	08591712367595	Reconstruction nail sterile; long, 11×400 mm, 135°, left, cannulated

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### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail sterile**

**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129790351S	08591712367601	Reconstruction nail sterile; long, 11×420 mm, 135°, right, cannulated
397129790361S	08591712367618	Reconstruction nail sterile; long, 11×420 mm, 135°, left, cannulated
397129790371S	08591712367625	Reconstruction nail sterile; long, 11×440 mm, 135°, right, cannulated
397129790381S	08591712367632	Reconstruction nail sterile; long, 11×440 mm, 135°, left, cannulated
397129790491S	08591712399756	Reconstruction nail sterile; long, 12×320 mm, 135°, right, cannulated
397129790501S	08591712399770	Reconstruction nail sterile; long, 12×320 mm, 135°, left, cannulated
397129790511S	08591712399794	Reconstruction nail sterile; long, 12×340 mm, 135°, right, cannulated
397129790521S	08591712399817	Reconstruction nail sterile; long, 12×340 mm, 135°, left, cannulated
397129790531S	08591712399831	Reconstruction nail sterile; long, 12×360 mm, 135°, right, cannulated
397129790541S	08591712399855	Reconstruction nail sterile; long, 12×360 mm, 135°, left, cannulated
397129790551S	08591712399879	Reconstruction nail sterile; long, 12×380 mm, 135°, right, cannulated
397129790561S	08591712399893	Reconstruction nail sterile; long, 12×380 mm, 135°, left, cannulated

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### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Reconstruction nail sterile  
Basic UDI-DI: 85917126010101SNF

Catalogue No.	UDI-DI	Variant
397129790571S	08591712399916	Reconstruction nail sterile; long, 12×400 mm, 135°, right, cannulated
397129790581S	08591712399930	Reconstruction nail sterile; long, 12×400 mm, 135°, left, cannulated
397129790591S	08591712399954	Reconstruction nail sterile; long, 12×420 mm, 135°, right, cannulated
397129790601S	08591712399978	Reconstruction nail sterile; long, 12×420 mm, 135°, left, cannulated
397129790611S	08591712400902	Reconstruction nail sterile; long, 12×440 mm, 135°, right, cannulated
397129790621S	08591712400919	Reconstruction nail sterile; long, 12×440 mm, 135°, left, cannulated
397129790033S	08591712367823	Reconstruction nail sterile; Ti, long, 10×320 mm, 135°, right, cannulated
397129790043S	08591712367830	Reconstruction nail sterile; Ti, long, 10×320 mm, 135°, left, cannulated
397129790053S	08591712367847	Reconstruction nail sterile; Ti, long, 10×340 mm, 135°, right, cannulated
397129790063S	08591712367854	Reconstruction nail sterile; Ti, long, 10×340 mm, 135°, left, cannulated
397129790073S	08591712367861	Reconstruction nail sterile; Ti, long, 10×360 mm, 135°, right, cannulated
397129790083S	08591712367878	Reconstruction nail sterile; Ti, long, 10×360 mm, 135°, left, cannulated

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**List of medical devices covered by the EU Technical Documentation Assessment Certificate:**

**Reconstruction nail sterile**

**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129790093S	08591712367885	Reconstruction nail sterile; Ti, long, 10×380 mm, 135°, right, cannulated
397129790103S	08591712367892	Reconstruction nail sterile; Ti, long, 10×380 mm, 135°, left, cannulated
397129790113S	08591712367908	Reconstruction nail sterile; Ti, long, 10×400 mm, 135°, right, cannulated
397129790123S	08591712367915	Reconstruction nail sterile; Ti, long, 10×400 mm, 135°, left, cannulated
397129790133S	08591712367922	Reconstruction nail sterile; Ti, long, 10×420 mm, 135°, right, cannulated
397129790143S	08591712367939	Reconstruction nail sterile; Ti, long, 10×420 mm, 135°, left, cannulated
397129790153S	08591712367946	Reconstruction nail sterile; Ti, long, 10×440 mm, 135°, right, cannulated
397129790163S	08591712367953	Reconstruction nail sterile; Ti, long, 10×440 mm, 135°, left, cannulated
397129790253S	08591712367960	Reconstruction nail sterile; Ti, long, 11×320 mm, 135°, right, cannulated
397129790263S	08591712367977	Reconstruction nail sterile; Ti, long, 11×320 mm, 135°, left, cannulated
397129790273S	08591712367984	Reconstruction nail sterile; Ti, long, 11×340 mm, 135°, right, cannulated
397129790283S	08591712367991	Reconstruction nail sterile; Ti, long, 11×340 mm, 135°, left, cannulated

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## List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail sterile**

**Basic UDI-DI: 85917126010101SNF**

Catalogue No.	UDI-DI	Variant
397129790293S	08591712368004	Reconstruction nail sterile; Ti, long, 11×360 mm, 135°, right, cannulated
397129790303S	08591712368011	Reconstruction nail sterile; Ti, long, 11×360 mm, 135°, left, cannulated
397129790313S	08591712368028	Reconstruction nail sterile; Ti, long, 11×380 mm, 135°, right, cannulated
397129790323S	08591712368035	Reconstruction nail sterile; Ti, long, 11×380 mm, 135°, left, cannulated
397129790333S	08591712368042	Reconstruction nail sterile; Ti, long, 11×400 mm, 135°, right, cannulated
397129790343S	08591712368059	Reconstruction nail sterile; Ti, long, 11×400 mm, 135°, left, cannulated
397129790353S	08591712368066	Reconstruction nail sterile; Ti, long, 11×420 mm, 135°, right, cannulated
397129790363S	08591712368073	Reconstruction nail sterile; Ti, long, 11×420 mm, 135°, left, cannulated
397129790373S	08591712368080	Reconstruction nail sterile; Ti, long, 11×440 mm, 135°, right, cannulated
397129790383S	08591712368097	Reconstruction nail sterile; Ti, long, 11×440 mm, 135°, left, cannulated
397129790493S	08591712399763	Reconstruction nail sterile; Ti, long, 12×320 mm, 135°, right, cannulated
397129790503S	08591712399787	Reconstruction nail sterile; Ti, long, 12×320 mm, 135°, left, cannulated

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**MEDIN, a.s.**

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

### List of medical devices covered by the EU Technical Documentation Assessment Certificate:

**Reconstruction nail sterile**  
Basic UDI-DI: 85917126010101SNF

Catalogue No.	UDI-DI	Variant
397129790513S	08591712399800	Reconstruction nail sterile; Ti, long, 12×340 mm, 135°, right, cannulated
397129790523S	08591712399824	Reconstruction nail sterile; Ti, long, 12×340 mm, 135°, left, cannulated
397129790533S	08591712399848	Reconstruction nail sterile; Ti, long, 12×360 mm, 135°, right, cannulated
397129790543S	08591712399862	Reconstruction nail sterile; Ti, long, 12×360 mm, 135°, left, cannulated
397129790553S	08591712399886	Reconstruction nail sterile; Ti, long, 12×380 mm, 135°, right, cannulated
397129790563S	08591712399909	Reconstruction nail sterile; Ti, long, 12×380 mm, 135°, left, cannulated
397129790573S	08591712399923	Reconstruction nail sterile; Ti, long, 12×400 mm, 135°, right, cannulated
397129790583S	08591712399947	Reconstruction nail sterile; Ti, long, 12×400 mm, 135°, left, cannulated
397129790593S	08591712399961	Reconstruction nail sterile; Ti, long, 12×420 mm, 135°, right, cannulated
397129790603S	08591712399985	Reconstruction nail sterile; Ti, long, 12×420 mm, 135°, left, cannulated
397129790613S	08591712399992	Reconstruction nail sterile; Ti, long, 12×440 mm, 135°, right, cannulated
397129790623S	08591712400001	Reconstruction nail sterile; Ti, long, 12×440 mm, 135°, left, cannulated

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**ANNEX II TO EU TECHNICAL DOCUMENTATION  
ASSESSMENT CERTIFICATE No. 2023-MDR/TD-028/A**

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**MEDIN, a.s.**

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

**Intended purpose of medical devices covered by the EU Technical Documentation  
Assessment Certificate:**

Reconstruction nail is intended for temporary osteosynthesis of femoral fractures.

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Director of NB 2265

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## ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-028/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 Number for Conformity Assessment	Description
0	2023-MDR/QS-028	31.8.2023	MDR055_2022	Initially granted certification
1	2023-MDR/QS-028/A	27.1.2025	MDR055_2022/A	New variants added, names changed, basic UDI-DI split into sterile and non-sterile models.

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