



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

## EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

**Non-active osteo- and orthopaedic implants:**

**Rib plate, Hip plate, Pelvic plate, Distal fibular plate, Universal plate, Volar distal radial plate, Proximal humeral plate, Distal humeral plate, Proximal tibial plate, Clavicular plate**

**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: **None**

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. MDR169\_2022 from 15.10.2024 & MDR666\_2024 from 10.09.2025, MD Clinical Evaluation Report No. MDR169\_2022 from 15.10.2024 & MDR666\_2024 from 10.09.2025 and MD Audit Report No. SK-0687/24 from 16.10.2024 & SK-0687/25 from 02.10.2025. 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: **08.10.2025**  
Valid until: **25.10.2029**  
First issue: **25.10.2024**  
Revision: **01**  
History: **see Annex III**

In Bratislava, Slovakia, 08.10.2025



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



# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

### Rib plate

Basic UDI-DI: 85917126020601W8

REF	UDI-DI	MD name; Variant
397129707310	08591712376580	Rib plate; 40 mm
397129707320	08591712376597	Rib plate; 55 mm
397129707330	08591712376603	Rib plate; 75 mm
397129707340	08591712376610	Rib plate; 95 mm
397129707350	08591712376627	Rib plate; 115 mm
397129707360	08591712376634	Rib plate; 135 mm
397129707370	08591712376641	Rib plate; 155 mm

### Rib plate sterile

Basic UDI-DI: 85917126020601SPX

REF	UDI-DI	MD name; Variant
397129707310S	08591712376658	Rib plate sterile; 40 mm
397129707320S	08591712376665	Rib plate sterile; 55 mm
397129707330S	08591712376672	Rib plate sterile; 75 mm
397129707340S	08591712376689	Rib plate sterile; 95 mm
397129707350S	08591712376696	Rib plate sterile; 115 mm
397129707360S	08591712376702	Rib plate sterile; 135 mm
397129707370S	08591712376719	Rib plate sterile; 155 mm



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Director of NB 2265

In Bratislava, Slovakia, 08.10.2025  
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# ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2024-MDR/TD-059/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:

**Hip plate**

Basic UDI-DI: 85917126020401VW

REF	UDI-DI	MD name; Variant
397129082110	08591712395178	Hip plate; 135°, 1,5", 2 holes, 87 mm
397129082270	08591712395185	Hip plate; 135°, 1,5", 3 holes, 107 mm
397129082150	08591712395192	Hip plate; 135°, 1,5", 4 holes, 127 mm
397129082170	08591712395208	Hip plate; 135°, 1,5", 6 holes, 167 mm
397129990208	08591712395215	Hip plate; 135°, 1,5", 8 holes, 207 mm
397129082120	08591712395222	Hip plate; 135°, 1", 2 holes, 80 mm
397129082290	08591712395239	Hip plate; 135°, 1", 3 holes, 100 mm
397129082210	08591712395246	Hip plate; 135°, 1", 4 holes, 120 mm
397129082230	08591712395253	Hip plate; 135°, 1", 6 holes, 160 mm

**Hip plate sterile**

Basic UDI-DI: 85917126020401SPH

REF	UDI-DI	MD name; Variant
397129082110S	08591712395277	Hip plate sterile; 135°, 1,5", 2 holes, 87 mm
397129082270S	08591712395284	Hip plate sterile; 135°, 1,5", 3 holes, 107 mm
397129082150S	08591712395291	Hip plate sterile; 135°, 1,5", 4 holes, 127 mm
397129082170S	08591712395307	Hip plate sterile; 135°, 1,5", 6 holes, 167 mm
397129990208S	08591712395314	Hip plate sterile; 135°, 1,5", 8 holes, 207 mm
397129082120S	08591712395321	Hip plate sterile; 135°, 1", 2 holes, 80 mm
397129082290S	08591712395338	Hip plate sterile; 135°, 1", 3 holes, 100 mm
397129082210S	08591712395345	Hip plate sterile; 135°, 1", 4 holes, 120 mm
397129082230S	08591712395352	Hip plate sterile; 135°, 1", 6 holes, 160 mm



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## ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

**Pelvic plate**

**Basic UDI-DI: 85917126020302VT**

REF	UDI-DI	MD name; Variant
397129704160	08591712392573	Pelvic plate; OMEGA, basic, left
397129704170	08591712392580	Pelvic plate; OMEGA, basic, right
397129704190	08591712392597	Pelvic plate; OMEGA, ILIAC, left
397129704200	08591712392603	Pelvic plate; OMEGA, ILIAC, right
397129704220	08591712392610	Pelvic plate; OMEGA, LONG, left
397129704230	08591712392627	Pelvic plate; OMEGA, LONG, right
397129704250	08591712392634	Pelvic plate; OMEGA, MAXI, left
397129704260	08591712392641	Pelvic plate; OMEGA, MAXI, right
397129715240	08591712392658	Pelvic plate; OMEGA, basic shaped, left
397129715250	08591712392665	Pelvic plate; OMEGA, basic shaped, right
397129715260	08591712392672	Pelvic plate; OMEGA, ILIAC shaped, left
397129715270	08591712392689	Pelvic plate; OMEGA, ILIAC shaped, right
397129715420	08591712392696	Pelvic plate; OMEGA, LONG shaped, left
397129715430	08591712392702	Pelvic plate; OMEGA, LONG shaped, right
397129715440	08591712392719	Pelvic plate; OMEGA, MAXI shaped, left
397129715450	08591712392726	Pelvic plate; OMEGA, MAXI shaped, right
397129789300	08591712392849	Pelvic plate; straight, 58 mm
397129789320	08591712392856	Pelvic plate; straight, 106 mm
397129789340	08591712392863	Pelvic plate; straight, 154 mm



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## ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

#### Pelvic plate

Basic UDI-DI: 85917126020302VT

REF	UDI-DI	MD name; Variant
397129789360	08591712392870	Pelvic plate; straight, 202 mm
397129710410	08591712392887	Pelvic plate; straight, plus
397129711410	08591712392962	Pelvic plate; curved, R88, 5 holes
397129789400	08591712392894	Pelvic plate; curved, R88, 9 holes
397129789410	08591712392900	Pelvic plate; curved, R88, 13 holes
397129789430	08591712392917	Pelvic plate; curved, R88, 17 holes
397129711320	08591712392924	Pelvic plate; curved, R108, 5 holes
397129711350	08591712392931	Pelvic plate; curved, R108, 9 holes
397129711360	08591712392948	Pelvic plate; curved, R108, 13 holes
397129711380	08591712392955	Pelvic plate; curved, R108, 17 holes
397129710430	08591712392979	Pelvic plate; curved, plus

#### Pelvic plate sterile

Basic UDI-DI: 85917126020302SPD

REF	UDI-DI	MD name; Variant
397129715240S	08591712392733	Pelvic plate sterile; OMEGA, basic shaped, left
397129715250S	08591712392740	Pelvic plate sterile; OMEGA, basic shaped, right
397129715260S	08591712392757	Pelvic plate sterile; OMEGA, ILIAC shaped, left
397129715270S	08591712392764	Pelvic plate sterile; OMEGA, ILIAC shaped, right



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

**Pelvic plate sterile**

**Basic UDI-DI: 85917126020302SPD**

REF	UDI-DI	MD name; Variant
397129715420S	08591712392771	Pelvic plate sterile; OMEGA, LONG shaped, left
397129715430S	08591712392788	Pelvic plate sterile; OMEGA, LONG shaped, right
397129715440S	08591712392795	Pelvic plate sterile; OMEGA, MAXI shaped, left
397129715450S	08591712392801	Pelvic plate sterile; OMEGA, MAXI shaped, right
397129789300S	08591712392986	Pelvic plate sterile; straight, 58 mm
397129789320S	08591712392993	Pelvic plate sterile; straight, 106 mm
397129789340S	08591712393006	Pelvic plate sterile; straight, 154 mm
397129789360S	08591712393013	Pelvic plate sterile; straight, 202 mm
397129710410S	08591712393020	Pelvic plate sterile; straight, plus
397129711320S	08591712393068	Pelvic plate sterile; curved, R108, 5 holes
397129789400S	08591712393037	Pelvic plate sterile; curved, R88, 9 holes
397129789410S	08591712393044	Pelvic plate sterile; curved, R88, 13 holes
397129789430S	08591712393051	Pelvic plate sterile; curved, R88, 17 holes
397129711410S	08591712393105	Pelvic plate sterile; curved, R88, 5 holes
397129711350S	08591712393075	Pelvic plate sterile; curved, R108, 9 holes
397129711360S	08591712393082	Pelvic plate sterile; curved, R108, 13 holes
397129711380S	08591712393099	Pelvic plate sterile; curved, R108, 17 holes
397129710430S	08591712393112	Pelvic plate sterile; curved, plus



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

### Distal fibular plate

Basic UDI-DI: 85917126020902WR

REF	UDI-DI	MD name; Variant
397129703723	08591712397486	Distal fibular plate; Ti, 3 holes, 80 mm, left
397129703733	08591712397493	Distal fibular plate; Ti, 4 holes, 92 mm, left
397129703743	08591712397509	Distal fibular plate; Ti, 5 holes, 104 mm, left
397129703753	08591712397516	Distal fibular plate; Ti, 6 holes, 116 mm, left
397129703763	08591712397523	Distal fibular plate; Ti, 7 holes, 128 mm, left
397129709633	08591712397530	Distal fibular plate; Ti, 3 holes, 80 mm, right
397129709643	08591712397547	Distal fibular plate; Ti, 4 holes, 92 mm, right
397129709653	08591712397554	Distal fibular plate; Ti, 5 holes, 104 mm, right
397129709663	08591712397561	Distal fibular plate; Ti, 6 holes, 116 mm, right
397129709673	08591712397578	Distal fibular plate; Ti, 7 holes, 128 mm, right

### Distal fibular plate sterile

Basic UDI-DI: 85917126020902SQP

REF	UDI-DI	MD name; Variant
397129703723S	08591712397585	Distal fibular plate sterile; Ti, 3 holes, 80 mm, left
397129703733S	08591712397592	Distal fibular plate sterile; Ti, 4 holes, 92 mm, left
397129703743S	08591712397608	Distal fibular plate sterile; Ti, 5 holes, 104 mm, left
397129703753S	08591712397615	Distal fibular plate sterile; Ti, 6 holes, 116 m, left
397129703763S	08591712397622	Distal fibular plate sterile; Ti, 7 holes, 128 mm, left
397129709633S	08591712397639	Distal fibular plate sterile; Ti, 3 holes, 80 mm, right
397129709643S	08591712397646	Distal fibular plate sterile; Ti, 4 holes, 92 mm, right
397129709653S	08591712397653	Distal fibular plate sterile; Ti, 5 holes, 104 mm, right
397129709663S	08591712397660	Distal fibular plate sterile; Ti, 6 holes, 116 mm, right
397129709673S	08591712397677	Distal fibular plate sterile; Ti, 7 holes, 128 mm, right



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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 Quality Management System Certificate:

### Universal plate

Basic UDI-DI: 85917126020105VP

REF	UDI-DI	MD name; Variant
397129781090	08591712397684	Universal plate; tubular, 1/3, 4 holes, 49 mm
397129781100	08591712397691	Universal plate; tubular, 1/3, 5 holes, 61 mm
397129781110	08591712397707	Universal plate; tubular, 1/3, 6 holes, 73 mm
397129781120	08591712397714	Universal plate; tubular, 1/3, 7 holes, 85 mm
397129781130	08591712397721	Universal plate; tubular, 1/3, 8 holes, 97 mm
397129781140	08591712397738	Universal plate; tubular, 1/3, 10 holes, 121 mm
397129785020	08591712403347	Universal plate; straight, 9 holes, 169 mm
397129785025	08591712403354	Universal plate; straight, 10 holes, 186 mm
397129785030	08591712403361	Universal plate; straight, 11 holes, 203 mm
397129785035	08591712403378	Universal plate; straight, 12 holes, 220 mm
397129785040	08591712403385	Universal plate; straight, 13 holes, 237 mm
397129785045	08591712403392	Universal plate; straight, 14 holes, 254 mm
397129785050	08591712403408	Universal plate; straight, 15 holes, 271 mm
397129785055	08591712403415	Universal plate; straight, 16 holes, 288 mm
397129785060	08591712403422	Universal plate; straight, 17 holes, 305 mm
397129785355	08591712403439	Universal plate; straight, 18 holes, 322 mm
397129785360	08591712403446	Universal plate; straight, 19 holes, 339 mm
397129785365	08591712403453	Universal plate; straight, 20 holes, 356 mm
397129717780	08591712402470	Universal plate; reconstruction, 3.5 COMBI, 4 holes, 56 mm
397129717790	08591712402487	Universal plate; reconstruction, 3.5 COMBI, 5 holes, 70 mm
397129717800	08591712402494	Universal plate; reconstruction, 3.5 COMBI, 6 holes, 84 mm
397129717810	08591712402500	Universal plate; reconstruction, 3.5 COMBI, 7 holes, 98 mm



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# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/A

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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 Quality Management System Certificate:

### Universal plate

Basic UDI-DI: 85917126020105VP

REF	UDI-DI	MD name; Variant
397129717820	08591712402517	Universal plate; reconstruction, 3.5 COMBI, 8 holes, 112 mm
397129717830	08591712402524	Universal plate; reconstruction, 3.5 COMBI, 9 holes, 126 mm
397129717840	08591712402531	Universal plate; reconstruction, 3.5 COMBI, 10 holes, 140 mm
397129717850	08591712402548	Universal plate; reconstruction, 3.5 COMBI, 11 holes, 154 mm
397129717860	08591712402555	Universal plate; reconstruction, 3.5 COMBI, 12 holes, 168 mm
397129717870	08591712402562	Universal plate; reconstruction, 3.5 COMBI, 13 holes, 182 mm
397129717900	08591712402579	Universal plate; straight, 3.5 COMBI, 4 holes, 59 mm
397129717910	08591712402586	Universal plate; straight, 3.5 COMBI, 5 holes, 72 mm
397129717920	08591712402593	Universal plate; straight, 3.5 COMBI, 6 holes, 85 mm
397129717930	08591712402609	Universal plate; straight, 3.5 COMBI, 7 holes, 98 mm
397129717940	08591712402616	Universal plate; straight, 3.5 COMBI, 8 holes, 111 mm
397129717950	08591712402623	Universal plate; straight, 3.5 COMBI, 9 holes, 124 mm
397129717960	08591712402630	Universal plate; straight, 3.5 COMBI, 10 holes, 137 mm
397129717970	08591712402647	Universal plate; straight, 3.5 COMBI, 11 holes, 150 mm
397129717980	08591712402654	Universal plate; straight, 3.5 COMBI, 12 holes, 163 mm
397129717990	08591712402661	Universal plate; straight, 3.5 COMBI, 13 holes, 176 mm

### Universal plate sterile

Basic UDI-DI: 85917126020105SP8

REF	UDI-DI	MD name; Variant
397129781090S	08591712397745	Universal plate sterile; tubular, 1/3, 4 holes, 49 mm
397129781100S	08591712397752	Universal plate sterile; tubular, 1/3, 5 holes, 61 mm
397129781110S	08591712397769	Universal plate sterile; tubular, 1/3, 6 holes, 73 mm



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# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/A

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

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

### Universal plate sterile

Basic UDI-DI: 85917126020105SP8

REF	UDI-DI	MD name; Variant
397129781120S	08591712397776	Universal plate sterile; tubular, 1/3, 7 holes, 85 mm
397129781130S	08591712397783	Universal plate sterile; tubular, 1/3, 8 holes, 97 mm
397129781140S	08591712397790	Universal plate sterile; tubular, 1/3, 10 holes, 121 mm
397129785020S	08591712403460	Universal plate sterile; straight, 9 holes, 169 mm
397129785025S	08591712403477	Universal plate sterile; straight, 10 holes, 186 mm
397129785030S	08591712403484	Universal plate sterile; straight, 11 holes, 203 mm
397129785035S	08591712403491	Universal plate sterile; straight, 12 holes, 220 mm
397129785040S	08591712403507	Universal plate sterile; straight, 13 holes, 237 mm
397129785045S	08591712403514	Universal plate sterile; straight, 14 holes, 254 mm
397129785050S	08591712403521	Universal plate sterile; straight, 15 holes, 271 mm
397129785055S	08591712403538	Universal plate sterile; straight, 16 holes, 288 mm
397129785060S	08591712403545	Universal plate sterile; straight, 17 holes, 305 mm
397129785355S	08591712403552	Universal plate sterile; straight, 18 holes, 322 mm
397129785360S	08591712403569	Universal plate sterile; straight, 19 holes, 339 mm
397129785365S	08591712403576	Universal plate sterile; straight, 20 holes, 356 mm
397129717780S	08591712402678	Universal plate sterile; reconstruction, 3.5 COMBI, 4 holes, 56 mm
397129717790S	08591712402685	Universal plate sterile; reconstruction, 3.5 COMBI, 5 holes, 70 mm
397129717800S	08591712402692	Universal plate sterile; reconstruction, 3.5 COMBI, 6 holes, 84 mm
397129717810S	08591712402708	Universal plate sterile; reconstruction, 3.5 COMBI, 7 holes, 98 mm
397129717820S	08591712402715	Universal plate sterile; reconstruction, 3.5 COMBI, 8 holes, 112 mm
397129717830S	08591712402722	Universal plate sterile; reconstruction, 3.5 COMBI, 9 holes, 126 mm
397129717840S	08591712402739	Universal plate sterile; reconstruction, 3.5 COMBI, 10 holes, 140 mm
397129717850S	08591712402746	Universal plate sterile; reconstruction, 3.5 COMBI, 11 holes, 154 mm
397129717860S	08591712402753	Universal plate sterile; reconstruction, 3.5 COMBI, 12 holes, 168 mm



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## ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

**Universal plate sterile**

**Basic UDI-DI: 85917126020105SP8**

REF	UDI-DI	MD name; Variant
397129717870S	08591712402760	Universal plate sterile; reconstruction, 3.5 COMBI, 13 holes, 182 mm
397129717900S	08591712402777	Universal plate sterile; straight, 3.5 COMBI, 4 holes, 59 mm
397129717910S	08591712402784	Universal plate sterile; straight, 3.5 COMBI, 5 holes, 72 mm
397129717920S	08591712402791	Universal plate sterile; straight, 3.5 COMBI, 6 holes, 85 mm
397129717930S	08591712402807	Universal plate sterile; straight, 3.5 COMBI, 7 holes, 98 mm
397129717940S	08591712402814	Universal plate sterile; straight, 3.5 COMBI, 8 holes, 111 mm
397129717950S	08591712402821	Universal plate sterile; straight, 3.5 COMBI, 9 holes, 124 mm
397129717960S	08591712402838	Universal plate sterile; straight, 3.5 COMBI, 10 holes, 137 mm
397129717970S	08591712402845	Universal plate sterile; straight, 3.5 COMBI, 11 holes, 150 mm
397129717980S	08591712402852	Universal plate sterile; straight, 3.5 COMBI, 12 holes, 163 mm
397129717990S	08591712402869	Universal plate sterile; straight, 3.5 COMBI, 13 holes, 176 mm



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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 Quality Management System Certificate:

**Volar distal radial plate**

**Basic UDI-DI: 85917126021001VH**

REF	UDI-DI	MD name; Variant
397129717503	08591712399206	Volar distal radial plate; VI., Ti, 6x1 hole, 55 mm, left
397129717513	08591712399213	Volar distal radial plate; VI., Ti, 6x2 holes, 63 mm, left
397129717543	08591712399220	Volar distal radial plate; VI., Ti, 6x6 holes, 95 mm, left
397129717573	08591712399237	Volar distal radial plate; VI., Ti, 7x1 hole, 55 mm, left
397129717583	08591712399244	Volar distal radial plate; VI., Ti, 7x2 holes, 63 mm, left
397129717613	08591712399251	Volar distal radial plate; VI., Ti, 7x6 holes, 95 mm, left
397129717643	08591712399268	Volar distal radial plate; VI., Ti, 6x1 hole, 55 mm, right
397129717653	08591712399275	Volar distal radial plate; VI., Ti, 6x2 holes, 63 mm, right
397129717683	08591712399282	Volar distal radial plate; VI., Ti, 6x6 holes, 95 mm, right
397129717713	08591712399299	Volar distal radial plate; VI., Ti, 7x1 hole, 55 mm, right
397129717723	08591712399305	Volar distal radial plate; VI., Ti, 7x2 holes, 63 mm, right
397129717753	08591712399312	Volar distal radial plate; VI., Ti, 7x6 holes, 95 mm, right

**Volar distal radial plate sterile**

**Basic UDI-DI: 85917126021001SNY**

REF	UDI-DI	MD name; Variant
397129717503S	08591712399329	Volar distal radial plate sterile; VI., Ti, 6x1 hole, 55 mm, left
397129717513S	08591712399336	Volar distal radial plate sterile; VI., Ti, 6x2 holes, 63 mm, left
397129717543S	08591712399343	Volar distal radial plate sterile; VI., Ti, 6x6 holes, 95 mm, left
397129717573S	08591712399350	Volar distal radial plate sterile; VI., Ti, 7x1 hole, 55 mm, left
397129717583S	08591712399367	Volar distal radial plate sterile; VI., Ti, 7x2 holes, 63 mm, left
397129717613S	08591712399374	Volar distal radial plate sterile; VI., Ti, 7x6 holes, 95 mm, left
397129717643S	08591712399381	Volar distal radial plate sterile; VI., Ti, 6x1 hole, 55 mm, right
397129717653S	08591712399398	Volar distal radial plate sterile; VI., Ti, 6x2 holes, 63 mm, right
397129717683S	08591712399404	Volar distal radial plate sterile; VI., Ti, 6x6 holes, 95 mm, right
397129717713S	08591712399411	Volar distal radial plate sterile; VI., Ti, 7x1 hole, 55 mm, right
397129717723S	08591712399428	Volar distal radial plate sterile; VI., Ti, 7x2 holes, 63 mm, right
397129717753S	08591712399435	Volar distal radial plate sterile; VI., Ti, 7x6 holes, 95 mm, right



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

### Proximal humeral plate

Basic UDI-DI: 85917126021101VN

REF	UDI-DI	MD name; Variant
397129783500	08591712402883	Proximal humeral plate; 2 holes, 97 mm
397129783520	08591712402890	Proximal humeral plate; 4 holes, 127 mm
397129783540	08591712402906	Proximal humeral plate; 6 holes, 157 mm
397129783560	08591712402913	Proximal humeral plate; 8 holes, 187 mm
397129783503	08591712395369	Proximal humeral plate; Ti, 2 holes, 97 mm
397129783523	08591712395376	Proximal humeral plate; Ti, 4 holes, 127 mm
397129783543	08591712395383	Proximal humeral plate; Ti, 6 holes, 157 mm
397129783563	08591712395390	Proximal humeral plate; Ti, 8 holes, 187 mm

### Proximal humeral plate sterile

Basic UDI-DI: 85917126021101SP7

REF	UDI-DI	MD name; Variant
397129783500S	08591712402920	Proximal humeral plate sterile; 2 holes, 97 mm
397129783520S	08591712402937	Proximal humeral plate sterile; 4 holes, 127 mm
397129783540S	08591712402944	Proximal humeral plate sterile; 6 holes, 157 mm
397129783560S	08591712402951	Proximal humeral plate sterile; 8 holes, 187 mm
397129783503S	08591712395406	Proximal humeral plate sterile; Ti, 2 holes, 97 mm
397129783523S	08591712395413	Proximal humeral plate sterile; Ti, 4 holes, 127 mm
397129783543S	08591712395420	Proximal humeral plate sterile; Ti, 6 holes, 157 mm
397129783563S	08591712395437	Proximal humeral plate sterile; Ti, 8 holes, 187 mm



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

**Distal humeral plate**

**Basic UDI-DI: 85917126021102VQ**

REF	UDI-DI	MD name; Variant
397129700223	08591712393235	Distal humeral plate; Ti, extraarticular, 2 holes, 92 mm, right
397129700243	08591712393259	Distal humeral plate; Ti, extraarticular, 4 holes, 116 mm, right
397129700263	08591712393273	Distal humeral plate; Ti, extraarticular, 6 holes, 140 mm, right
397129700283	08591712402975	Distal humeral plate; Ti, extraarticular, 8 holes, 164 mm, right
397129700323	08591712393211	Distal humeral plate; Ti, extraarticular, 12 holes, 212, right
397129700373	08591712393228	Distal humeral plate; Ti, extraarticular, 2 holes, 92, left
397129700393	08591712393242	Distal humeral plate; Ti, extraarticular, 4 holes, 116, left
397129700413	08591712393266	Distal humeral plate; Ti, extraarticular, 6 holes, 140, left
397129700433	08591712402982	Distal humeral plate; Ti, extraarticular, 8 holes, 164 mm, left
397129700473	08591712393204	Distal humeral plate; Ti, extraarticular, 12 holes, 212 mm, left
397129787873	08591712393303	Distal humeral plate; Ti, medial, 2 holes, 89 mm, left
397129787893	08591712393327	Distal humeral plate; Ti, medial, 4 holes, 113 mm, left
397129787913	08591712393341	Distal humeral plate; Ti, medial, 6 holes, 137 mm, left
397129787933	08591712402999	Distal humeral plate; Ti, medial, 8 holes, 161 mm, left
397129787973	08591712393280	Distal humeral plate; Ti, medial, 12 holes, 209 mm, left
397129788023	08591712393310	Distal humeral plate; Ti, medial, 2 holes, 89 mm, right
397129788043	08591712393334	Distal humeral plate; Ti, medial, 4 holes, 113 mm, right
397129788063	08591712393358	Distal humeral plate; Ti, medial, 6 holes, 137 mm, right
397129788083	08591712403002	Distal humeral plate; Ti, medial, 8 holes, 161 mm, right
397129788123	08591712393297	Distal humeral plate; Ti, medial, 12 holes, 209 mm, right
397129788173	08591712393143	Distal humeral plate; Ti, dorsolateral, 2 holes, 92 mm, left
397129788193	08591712393167	Distal humeral plate; Ti, dorsolateral, 4 holes, 116 mm, left
397129788213	08591712393181	Distal humeral plate; Ti, dorsolateral, 6 holes, 140 mm, left



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

#### Distal humeral plate

Basic UDI-DI: 85917126021102VQ

REF	UDI-DI	MD name; Variant
397129788233	08591712403019	Distal humeral plate; Ti, dorsolateral, 8 holes, 164 mm, left
397129788273	08591712393136	Distal humeral plate; Ti, dorsolateral, 12 holes, 212 mm, left
397129788323	08591712393150	Distal humeral plate; Ti, dorsolateral, 2 holes, 92 mm, right
397129788343	08591712393174	Distal humeral plate; Ti, dorsolateral, 4 holes, 116 mm, right
397129788363	08591712393198	Distal humeral plate; Ti, dorsolateral, 6 holes, 140 mm, right
397129788383	08591712403026	Distal humeral plate; Ti, dorsolateral, 8 holes, 164 mm, right
397129788423	08591712393129	Distal humeral plate; Ti, dorsolateral, 12 holes, 212 mm, right

#### Distal humeral plate sterile

Basic UDI-DI: 85917126021102SPA

REF	UDI-DI	MD name; Variant
397129700223S	08591712393471	Distal humeral plate sterile; Ti, extraarticular, 2 holes, 92 mm, right
397129700243S	08591712393495	Distal humeral plate sterile; Ti, extraarticular, 4 holes, 116 mm, right
397129700263S	08591712393518	Distal humeral plate sterile; Ti, extraarticular, 6 holes, 140 mm, right
397129700283S	08591712403033	Distal humeral plate sterile; Ti, extraarticular, 8 holes, 164 mm, right
397129700323S	08591712393457	Distal humeral plate sterile; Ti, extraarticular, 12 holes, 212 mm, right
397129700373S	08591712393464	Distal humeral plate sterile; Ti, extraarticular, 2 holes, 92 mm, left
397129700393S	08591712393488	Distal humeral plate sterile; Ti, extraarticular, 4 holes, 116 mm, left
397129700413S	08591712393501	Distal humeral plate sterile; Ti, extraarticular, 6 holes, 140 mm, left
397129700433S	08591712403040	Distal humeral plate sterile; Ti, extraarticular, 8 holes, 164 mm, left
397129700473S	08591712393440	Distal humeral plate sterile; Ti, extraarticular, 12 holes, 212 mm, left
397129787873S	08591712393549	Distal humeral plate sterile; Ti, medial, 2 holes, 89 mm, left



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**Distal humeral plate sterile**

**Basic UDI-DI: 85917126021102SPA**

REF	UDI-DI	MD name; Variant
397129787893S	08591712393563	Distal humeral plate sterile; Ti, medial, 4 holes, 113 mm, left
397129787913S	08591712393587	Distal humeral plate sterile; Ti, medial, 6 holes, 137 mm, left
397129787933S	08591712403057	Distal humeral plate sterile; Ti, medial, 8 holes, 161 mm, left
397129787973S	08591712393525	Distal humeral plate sterile; Ti, medial, 12 holes, 209 mm, left
397129788023S	08591712393556	Distal humeral plate sterile; Ti, medial, 2 holes, 89 mm, right
397129788043S	08591712393570	Distal humeral plate sterile; Ti, medial, 4 holes, 113 mm, right
397129788063S	08591712393594	Distal humeral plate sterile; Ti, medial, 6 holes, 137 mm, right
397129788083S	08591712403064	Distal humeral plate sterile; Ti, medial, 8 holes, 161 mm, right
397129788123S	08591712393532	Distal humeral plate sterile; Ti, medial, 12 holes, 209 mm, right
397129788173S	08591712393389	Distal humeral plate sterile; Ti, dorsolateral, 2 holes, 92 mm, left
397129788193S	08591712393402	Distal humeral plate sterile; Ti, dorsolateral, 4 holes, 116 mm, left
397129788213S	08591712393426	Distal humeral plate sterile; Ti, dorsolateral, 6 holes, 140 mm, left
397129788233S	08591712403071	Distal humeral plate sterile; Ti, dorsolateral, 8 holes, 164 mm, left
397129788273S	08591712393372	Distal humeral plate sterile; Ti, dorsolateral, 12 holes, 212 mm, left
397129788323S	08591712393396	Distal humeral plate sterile; Ti, dorsolateral, 2 holes, 92 mm, right
397129788343S	08591712393419	Distal humeral plate sterile; Ti, dorsolateral, 4 holes, 116 mm, right
397129788363S	08591712393433	Distal humeral plate sterile; Ti, dorsolateral, 6 holes, 140 mm, right
397129788383S	08591712403088	Distal humeral plate sterile; Ti, dorsolateral, 8 holes, 164 mm, right
397129788423S	08591712393365	Distal humeral plate sterile; Ti, dorsolateral, 12 holes, 212 mm, right



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

### Proximal tibial plate

Basic UDI-DI: 85917126020801WJ

REF	UDI-DI	MD name; Variant
397129703863	08591712394669	Proximal tibial plate; Ti, lateral 3.5, 99 mm, 7 holes, left
397129703883	08591712394676	Proximal tibial plate; Ti, lateral 3.5, 129 mm, 9 holes, left
397129703903	08591712394683	Proximal tibial plate; Ti, lateral 3.5, 159 mm, 11 holes, left
397129703923	08591712394690	Proximal tibial plate; Ti, lateral 3.5, 189 mm, 13 holes, left
397129703973	08591712394706	Proximal tibial plate; Ti, lateral 3.5, 264 mm, 18 holes, left
397129704023	08591712394713	Proximal tibial plate; Ti, lateral 3.5, 99 mm, 7 holes, right
397129704043	08591712394720	Proximal tibial plate; Ti, lateral 3.5, 129 mm, 9 holes, right
397129704063	08591712394737	Proximal tibial plate; Ti, lateral 3.5, 159 mm, 11 holes, right
397129704083	08591712394744	Proximal tibial plate; Ti, lateral 3.5, 189 mm, 13 holes, right
397129704133	08591712394751	Proximal tibial plate; Ti, lateral 3.5, 264 mm, 18 holes, right
397129782353	08591712394577	Proximal tibial plate; Ti, lateral 5, 135 mm, 8 holes, right
397129782373	08591712394584	Proximal tibial plate; Ti, lateral 5, 165 mm, 10 holes, right
397129782413	08591712394591	Proximal tibial plate; Ti, lateral 5, 225 mm, 14 holes, right
397129782453	08591712394607	Proximal tibial plate; Ti, lateral 5, 285 mm, 18 holes, right
397129782493	08591712394621	Proximal tibial plate; Ti, lateral 5, 135 mm, 8 holes, left
397129782513	08591712394638	Proximal tibial plate; Ti, lateral 5, 165 mm, 10 holes, left
397129782553	08591712394645	Proximal tibial plate; Ti, lateral 5, 225 mm, 14 holes, left
397129782593	08591712394652	Proximal tibial plate; Ti, lateral 5, 285 mm, 18 holes, left
397129705103	08591712403606	Proximal tibial plate; Ti, posteromedial 3.5, 62 mm, 4 holes
397129705123	08591712403613	Proximal tibial plate; Ti, posteromedial 3.5, 78 mm, 6 holes
397129705143	08591712403620	Proximal tibial plate; Ti, posteromedial 3.5, 94 mm, 8 holes
397129705163	08591712403637	Proximal tibial plate; Ti, posteromedial 3.5, 110 mm, 10 holes



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

#### Proximal tibial plate

Basic UDI-DI: 85917126020801WJ

REF	UDI-DI	MD name; Variant
397129718303	08591712403644	Proximal tibial plate; Ti, medial 5, 98 mm, 5 holes
397129718313	08591712403651	Proximal tibial plate; Ti, medial 5, 128 mm, 7 holes
397129718323	08591712403668	Proximal tibial plate; Ti, medial 5, 158 mm, 9 holes
397129718333	08591712403675	Proximal tibial plate; Ti, medial 5, 188 mm, 11 holes

#### Proximal tibial plate sterile

Basic UDI-DI: 85917126020801SQD

REF	UDI-DI	MD name; Variant
397129703863S	08591712394669	Proximal tibial plate sterile; Ti, lateral 3.5, 99 mm, 7 holes, left
397129703883S	08591712394676	Proximal tibial plate sterile; Ti, lateral 3.5, 129 mm, 9 holes, left
397129703903S	08591712394683	Proximal tibial plate sterile; Ti, lateral 3.5, 159 mm, 11 holes, left
397129703923S	08591712394690	Proximal tibial plate sterile; Ti, lateral 3.5, 189 mm, 13 holes, left
397129703973S	08591712394706	Proximal tibial plate sterile; Ti, lateral 3.5, 264 mm, 18 holes, left
397129704023S	08591712394713	Proximal tibial plate sterile; Ti, lateral 3.5, 99 mm, 7 holes, right
397129704043S	08591712394720	Proximal tibial plate sterile; Ti, lateral 3.5, 129 mm, 9 holes, right
397129704063S	08591712394737	Proximal tibial plate sterile; Ti, lateral 3.5, 159 mm, 11 holes, right
397129704083S	08591712394744	Proximal tibial plate sterile; Ti, lateral 3.5, 189 mm, 13 holes, right
397129704133S	08591712394751	Proximal tibial plate sterile; Ti, lateral 3.5, 264 mm, 18 holes, right
397129782353S	08591712394577	Proximal tibial plate sterile; Ti, lateral 5, 135 mm, 8 holes, right
397129782373S	08591712394584	Proximal tibial plate sterile; Ti, lateral 5, 165 mm, 10 holes, right
397129782413S	08591712394591	Proximal tibial plate sterile; Ti, lateral 5, 225 mm, 14 holes, right
397129782453S	08591712394607	Proximal tibial plate sterile; Ti, lateral 5, 285 mm, 18 holes, right



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

#### Proximal tibial plate sterile

Basic UDI-DI: 85917126020801SQD

REF	UDI-DI	MD name; Variant
397129782493S	08591712394621	Proximal tibial plate sterile; Ti, lateral 5, 135 mm, 8 holes, left
397129782513S	08591712394638	Proximal tibial plate sterile; Ti, lateral 5, 165 mm, 10 holes, left
397129782553S	08591712394645	Proximal tibial plate sterile; Ti, lateral 5, 225 mm, 14 holes, left
397129782593S	08591712394652	Proximal tibial plate sterile; Ti, lateral 5, 285 mm, 18 holes, left
397129705103S	08591712403682	Proximal tibial plate sterile; Ti, posteromedial 3.5, 62 mm, 4 holes
397129705123S	08591712403699	Proximal tibial plate sterile; Ti, posteromedial 3.5, 78 mm, 6 holes
397129705143S	08591712403705	Proximal tibial plate sterile; Ti, posteromedial 3.5, 94 mm, 8 holes
397129705163S	08591712403712	Proximal tibial plate sterile; Ti, posteromedial 3.5, 110 mm, 10 holes
397129718303S	08591712403729	Proximal tibial plate sterile; Ti, medial 5, 98 mm, 5 holes
397129718313S	08591712403736	Proximal tibial plate sterile; Ti, medial 5, 128 mm, 7 holes
397129718323S	08591712403743	Proximal tibial plate sterile; Ti, medial 5, 158 mm, 9 holes
397129718333S	08591712403750	Proximal tibial plate sterile; Ti, medial 5, 188 mm, 11 holes

#### Clavicular plate

Basic UDI-DI: 85917126021301VY

REF	UDI-DI	MD name; Variant
397129718410	08591712403774	Clavicular plate; hook, 15×63 mm, 5 holes, left
397129718430	08591712403781	Clavicular plate; hook, 15×80 mm, 7 holes, left
397129718450	08591712403798	Clavicular plate; hook, 15×98 mm, 9 holes, left
397129718470	08591712403804	Clavicular plate; hook, 18×63 mm, 5 holes, left
397129718490	08591712403811	Clavicular plate; hook, 18×80 mm, 7 holes, left
397129718510	08591712403828	Clavicular plate; hook, 18×98 mm, 9 holes, left
397129718530	08591712403835	Clavicular plate; hook, 15×63 mm, 5 holes, right



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

#### Clavicular plate

Basic UDI-DI: 85917126021301VY

REF	UDI-DI	MD name; Variant
397129718550	08591712403842	Clavicular plate; hook, 15×80 mm, 7 holes, right
397129718570	08591712403859	Clavicular plate; hook, 15×98 mm, 9 holes, right
397129718590	08591712403866	Clavicular plate; hook, 18×63 mm, 5 holes, right
397129718610	08591712403873	Clavicular plate; hook, 18×80 mm, 7 holes, right
397129718630	08591712403880	Clavicular plate; hook, 18×98 mm, 9 holes, right
397129718660	08591712403897	Clavicular plate; superior-lateral, 79 mm, 6 holes, left
397129718670	08591712403903	Clavicular plate; superior-lateral, 100 mm, 8 holes, left
397129718690	08591712403910	Clavicular plate; superior-lateral, 79 mm, 6 holes, right
397129718700	08591712403927	Clavicular plate; superior-lateral, 100 mm, 8 holes, right
397129718720	08591712403934	Clavicular plate; anterior-diaphyseal, 82 mm, 6 holes
397129718730	08591712403941	Clavicular plate; anterior-diaphyseal, 104 mm, 8 holes
397129718740	08591712403958	Clavicular plate; anterior-diaphyseal, 119 mm, 11 holes
397129718760	08591712403965	Clavicular plate; superior-diaphyseal, 84 mm, 6 holes, left
397129718770	08591712403972	Clavicular plate; superior-diaphyseal, 104 mm, 8 holes, left
397129718780	08591712403989	Clavicular plate; superior-diaphyseal, 121 mm, 10 holes, left
397129718800	08591712403996	Clavicular plate; superior-diaphyseal, 84 mm, 6 holes, right
397129718810	08591712404009	Clavicular plate; superior-diaphyseal, 104 mm, 8 holes, right
397129718820	08591712404016	Clavicular plate; superior-diaphyseal, 121 mm, 10 holes, right



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

Clavicular plate sterile

Basic UDI-DI: 85917126021301SPM

REF	UDI-DI	MD name; Variant
397129718410S	08591712404023	Clavicular plate sterile; hook, 15×63 mm, 5 holes, left
397129718430S	08591712404030	Clavicular plate sterile; hook, 15×80 mm, 7 holes, left
397129718450S	08591712404047	Clavicular plate sterile; hook, 15×98 mm, 9 holes, left
397129718470S	08591712404054	Clavicular plate sterile; hook, 18×63 mm, 5 holes, left
397129718490S	08591712404061	Clavicular plate sterile; hook, 18×80 mm, 7 holes, left
397129718510S	08591712404078	Clavicular plate sterile; hook, 18×98 mm, 9 holes, left
397129718530S	08591712404085	Clavicular plate sterile; hook, 15×63 mm, 5 holes, right
397129718550S	08591712404092	Clavicular plate sterile; hook, 15×80 mm, 7 holes, right
397129718570S	08591712404108	Clavicular plate sterile; hook, 15×98 mm, 9 holes, right
397129718590S	08591712404115	Clavicular plate sterile; hook, 18×63 mm, 5 holes, right
397129718610S	08591712404122	Clavicular plate sterile; hook, 18×80 mm, 7 holes, right
397129718630S	08591712404139	Clavicular plate sterile; hook, 18×98 mm, 9 holes, right
397129718660S	08591712404146	Clavicular plate sterile; superior-lateral, 79 mm, 6 holes, left
397129718670S	08591712404153	Clavicular plate sterile; superior-lateral, 100 mm, 8 holes, left
397129718690S	08591712404160	Clavicular plate sterile; superior-lateral, 79 mm, 6 holes, right
397129718700S	08591712404177	Clavicular plate sterile; superior-lateral, 100 mm, 8 holes, right
397129718720S	08591712404184	Clavicular plate sterile; anterior-diaphyseal, 82 mm, 6 holes
397129718730S	08591712404191	Clavicular plate sterile; anterior-diaphyseal, 104 mm, 8 holes
397129718740S	08591712404207	Clavicular plate sterile; anterior-diaphyseal, 119 mm, 10 holes
397129718760S	08591712404214	Clavicular plate sterile; superior-diaphyseal, 84 mm, 6 holes, left
397129718770S	08591712404221	Clavicular plate sterile; superior-diaphyseal, 104 mm, 8 holes, left
397129718780S	08591712404238	Clavicular plate sterile; superior-diaphyseal, 121 mm, 10 holes, left
397129718800S	08591712404245	Clavicular plate sterile; superior-diaphyseal, 84 mm, 6 holes, right
397129718810S	08591712404252	Clavicular plate sterile; superior-diaphyseal, 104 mm, 8 holes, right
397129718820S	08591712404269	Clavicular plate sterile; superior-diaphyseal, 121 mm, 10 holes, right



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Director of NB 2265

In Bratislava, Slovakia, 08.10.2025  
Valid until 25.10.2029



## ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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:

#### Rib plate

The rib plate is intended for temporary osteosynthesis of rib fractures.

#### Hip plate

The Hip plate is intended for temporary osteosynthesis of proximal femoral fractures.

#### Pelvic plate

The Pelvic plates are intended for temporary osteosynthesis of pelvic fractures.

#### Distal fibular plate

The Distal fibular plate is intended for temporary osteosynthesis of distal fibular fractures.

#### Universal plate

The Universal plate is intended for temporary osteosynthesis of long bone fractures.

#### Volar distal radial plate

The Volar distal radial plate is intended for temporary osteosynthesis of distal radius fractures.

#### Proximal humeral plate

The Proximal humeral plate is intended for temporary osteosynthesis of proximal humerus fractures.

#### Distal humeral plate

The Distal humeral plate is intended for temporary osteosynthesis of distal humerus fractures.

#### Proximal tibial plate

The Proximal tibial plate is intended for temporary osteosynthesis of proximal tibia fractures.

#### Clavicular plate

The Clavicular plate is intended for temporary osteosynthesis of clavicle fractures or osteotomies.



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## ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-059/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-059	25.10.2024	MDR169_2022 MDR670_2024 MDR671_2024 MDR677_2024	Initially granted certification
01	2024-MDR/QS-059/A	08.10.2025	MDR662_2024 <b>MDR666_2024</b> MDR667_2024 MDR668_2024 MDR675_2024 MDR026_2025	Scope extension of a certification & cancellation of Certificate of EU Technical documentation Assessment Certificate No. 2024-MDR/TD-059 due to issuance in non-compliance with the requirements of Regulation (EU) 2017/745 as amended



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