

List of models of Medical Device to Certificate:

10185-2017-CE-CZS-NA-PS Rev. 6.0



Manufacturer:

MEDIN, a.s.
Vlachovická 619
592 31 Nové Město na Moravě, Czech Republic

Product group:

Sterile and non-sterile medical devices

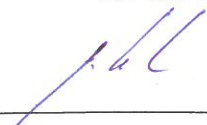
Date of certificate issue:

05. 05. 2021

The Certificate referred to above covers the following devices:

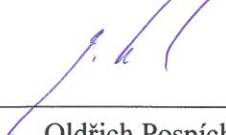
Product description	Product name	Class	Model name	Submodel name
Reusable Surgical Medical Devices	Rotary devices for surgery	IIa	Rotary devices for surgery	Drill (models as listed in M-ZP-01-01 R06) Drill DLC (models as listed in M-ZP-01-03 R04) Cutter (models as listed in M-ZP-01-02 R03)
			File	K-Reamer (models as listed in M-ZP-02-01 R04) Navigator EVO (models as listed in M-ZP-02-01 R04) Unicone (models as listed in M-ZP-02-01 R04)
Dental Medical Devices	Endodony instruments	IIa	Spreader	Gutta Condensor (models as listed in M-ZP-02-03 R02)
			Paste Carrier	Paste Carrier (models as listed in M-ZP-02-04 R02)
			Barbed Broach sterile	Barbed Broach sterile (models as listed in M-ZP-02-02 R05)
	Endodony sterile instruments		Dental burs	Carbide bur (models as listed in M-ZP-03-01 R05)
	Dental burs		Diamond burs	Diamond bur (models as listed in M-ZP-03-02 R02)
Non-Active Implantable Medical Devices - Nails	Intramedullary nails	IIb	Femoral nails and accessories	Reconstruction short nail (models as listed in M-ZP-04-09 R03) Reconstruction nail (models as listed in M-ZP-04-01 R04) Femoral intramedullary nail (models as listed in M-ZP-04-02 R03) Retrograde femoral nail (models as listed in M-ZP-04-03 R03) Femoral lateral nail (models as listed in M-ZP-04-04 R05)

20. 11. 2022


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Regulatory Affairs Manager

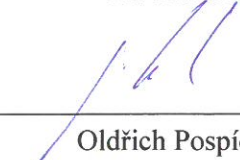
Product description	Product name	Class	Model name	Submodel name
			Tibial nails and accessories	Tibial nail (models as listed in M-ZP-05-01 R03) Proximal tibial nail (models as listed in M-ZP-05-05 R03) Tibiototalcalcaneal retrograde nail (models as listed in M-ZP-05-02 R04)
			Humeral nails and accessories	Humeral nail (models as listed in M-ZP-06-01 R04) Universal humeral nail (models as listed in M-ZP-06-05 R04)
			Calcaneal nails and accessories	C-Nail (models as listed in M-ZP-07-01 R05)
			Elastic nails	Elastic nail (models as listed in M-ZP-08-01 R04)
Non-Active Implantable Medical Devices - Wires	Wires		Wires	K-wire (models as listed in M-ZP-08-02 R04)
Non-Active Implantable Medical Devices - Plates	Plates		Straight plates and accessories	Autocompression plate (models as listed in M-ZP-10-01 R03) Straight plate (models as listed in M-ZP-10-02 R03) Reconstruction plate (models as listed in M-ZP-10-03 R03) Tubular plate (models as listed in M-ZP-10-05 R04) Limited contact plate (models as listed in M-ZP-10-06 R03) Reconstruction plate angularly stable (models as listed in M-ZP-10-04 R03)
			Pelvic plates and accessories	OMEGA pelvic plate (models as listed in M-ZP-11-01 R06) Straight pelvic plate (models as listed in M-ZP-11-02 R03) Curved pelvic plate (models as listed in M-ZP-11-02 R02)
			Hip plates and accessories	Hip plate (models as listed in M-ZP-04-08 R06)
			Femoral plates and accessories	Proximal femoral plate (models as listed in M-ZP-04-05 R03) Distal femoral plate (models as listed in M-ZP-04-06 R07) Straight plate angularly stable (models as listed in M-ZP-04-07 R03)

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Product description	Product name	Class	Model name	Submodel name
			Tibial plates and accessories	Proximal tibial plate (models as listed in M-ZP-05-03 R05) Medial distal tibial plate (models as listed in M-ZP-05-04 R04)
			Fibular plates and accessories	Distal fibular plate (models as listed in M-ZP-12-01 R03) Distal fibular plate II (models as listed in M-ZP-12-02 R01)
			Humeral plates and accessories	Proximal humeral plate (models as listed in M-ZP-06-02 R04) Distal humeral plate (models as listed in M-ZP-06-03 R03)
			Radial plates and accessories	Radial distal volar plate (models as listed in M-ZP-13-01 R06)
			Rib plates and accessories	Rib plate (models as listed in M-ZP-14-01 R05)

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History:

Revision	Description	Issue date
00	First issue of document	18. 12. 2020
01	Change to the Declaration of conformity form (the request of the notified body)	06. 05. 2021
02	New revision of Declaration of conformity (Notified Body changed name) Change of MD name: - merge of Kirchner wire and K-wire MEDIN to K-wire - merge of Short humeral nail and Long humeral nail to Humeral nail	14. 02. 2022
03	Dental medical devices - new revision of Declaration of conformity (Notified Body changed address)	20. 10. 2022
04	Reusable surgical MD, Non-Active Implantable MD - Nails, Wires, Plates - new revision of Declaration of conformity (Notified Body changed address)	20. 11. 2022