

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

General product group:

Sterile and non-sterile medical devices

Date of certificate issue:

05. 05. 2021

The Certificate referred to above covers the following devices:

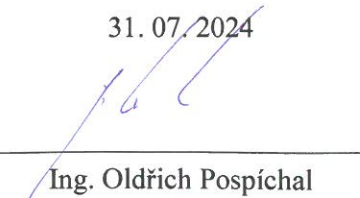
| Product group description | Product group name | Class | Generic device group | Medical device name |
|--|-------------------------------|-------|-------------------------------|--|
| Reusable Surgical Medical Devices | Rotary devices for surgery | IIa | Rotary devices for surgery | Drill (models as 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 | Endodency 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) |
| | Endodency 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) |

31. 07. 2024


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Regulatory Affairs Manager

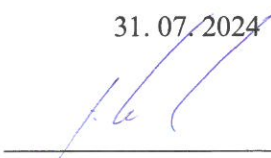
| Product group description | Product group name | Class | Generic device group | Medical device name |
|--|--------------------|-------|---------------------------------|--|
| | | | Tibial nails and accessories | Tibial nail (models as listed in M-ZP-05-01 R04) Proximal tibial nail (models as listed 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 R03) |
| | | | 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 group description | Product group name | Class | Generic device group | Medical device name |
|---------------------------|--------------------|-------|--------------------------------|---|
| | | | Tibial plates and accessories | Lateral proximal tibial plate (models as listed in M-ZP-05-03 R05) Medial distal tibial plate (models as listed in M-ZP-05-04 R05) |
| | | | 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 |
| 05 | Formal modification of the table - column names Issue of language mutation: CZ | 31. 07. 2024 |