

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

**Sanatmetal Orthopaedic & Traumatologic
Equipment Manufacturer Ltd.**

Headquarters: **Eger, Faiskola út 5., H-3300, Hungary**

Site: **Sanatmetal CIS**
249030 Russia, Kaluga region, Obninsk, Kievskoe shosse, 92.

Scope:

**Sterile and non-sterile traumatology, orthopaedic, spinal, dental and
bone regeneration implants, including associated instruments.**

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

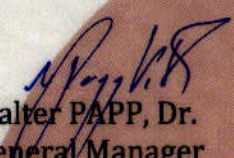
ID number of the related audit report: 181-CE-190109

Issue: 2

Issued: 30 January 2020

First issued: 13 September 2019

Start date of certified status: 13 September 2019


Valter PAPP, Dr.
General Manager

Expires:

25 May 2024



The certificate covers the following devices:

| Description of the device | Type | Intended use | Model | Risk class |
|---------------------------------|------------------------------|-------------------------------------|---|------------|
| screws and screw systems | AO screws and washers | screws and washers for traumatology | <ul style="list-style-type: none"> - Cortical bone screw - Corticalis bone screw - TX - Cancellous bone screw - Malleolar bone screw - Washer - Double-holed washer - Spiked washer - Double-holed spiked washer - Washer for fastening wires - Stud for tendon-suture - Washer for ligament - Plate for fixing ligament - Protector sheath for hand-surgery | II.b |
| | Compression screws | screw for traumatology | <ul style="list-style-type: none"> - Compression screw - A-spire screw | |
| | Interference screws | screw for traumatology | Interference screws Tensofix | |
| | Pelvic screw system | screw for traumatology | <ul style="list-style-type: none"> - Pelvic screw - Washer - Nut | |

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General Manager

The certificate covers the following devices:

| Description of the device | Type | Intended use | Model | Risk class |
|---------------------------|--|------------------------|---|------------|
| screws and screw systems | Femoral neck screw system | screw for traumatology | <ul style="list-style-type: none"> - Femoral neck screw - Added plate for femoral neck screwing - Dynamic barrel - DCD fixed angle plate for femoral neck screwing - Straight plate - Supporting plate for the femoral neck - Compression screw for femoral neck | II.b |
| | Dynamic trochanteric screw system | screw for traumatology | <ul style="list-style-type: none"> - Self-tapping CHS lag screw - Appendage plate - AS - Trochanteric support plate - Compression screw - TL Trochanteric plate - Appendage plate - Appendage plate small | |
| | Anchor screw | screw for traumatology | Anchor screw | |

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General Manager



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| screws and screw systems | Hand & Foot screw system | screw for traumatology | <ul style="list-style-type: none"> - LTF-screw - PEDI-screw - Self-drilling foot screw – H - Tenodesis screw | II.b |
| | Angle stabilized screws | screw for traumatology | <ul style="list-style-type: none"> - Vortex screw - AS screw - Vortex connection screw - Closing screw | |
| | Locking bone screws | screw for traumatology | <ul style="list-style-type: none"> - Locking bone screw - Distal locking screw | |

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General Manager



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| plates and plate systems | traditional plates and plate systems | plate for traumatology | Straight bone plates (AO) - One-third tubular plate – S - One-third tubular plate - Small self-compressing plate - Narrow self-compressing plate - Narrow bone plate - Broad bone plate - Narrow self-compressing plate - Broad self-compressing plate - Self-compressing plate LC - 1/3 Tubular plate – collared - Semi-tubular plate | II.b |

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| Description of the device | Type | Intended use | Model | Risk class |
|---------------------------------|---|-------------------------------|--|-------------|
| plates and plate systems | traditional plates and plate systems | plate for traumatology | Reconstruction plates - Reconstruction plate - Reconstruction plate - AS - Reconstruction plate - curved - Reconstruction plate - curved AS - Cervical reconstruction plate - Y-plate Angled plate - Angled plate self-compressing - Angled plate self-compressing - AS - Plate for Tibial osteotomy with forked blade - Plate for tibia osteotomy Clavicle plates - Clavicle plate - Clavicle plate - curved - Clavicle plate - CH - Clavicle plate - C - Clavicle plate - AS - Clavicle plate - curved - AS | II.b |


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| plates and plate systems | traditional plates and plate systems | plate for traumatology | Proximal humeral plates - Gripper plate - V - Humeral head plate - AS Small T-plates - Oblique small T-plate - Small T-plate Distal femoral plates - Distal femoral plate - AS - Condylar supporting plate femur - AS - Condylar supporting plate femur Distal tibial plates - Tibial distal plate - AS - Distal medial tibia plate - AS - Spoon plate - AS - Cloverleaf plate - AS - Spoon plate - Cloverleaf plate | II.b |

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| plates and plate systems | traditional plates and plate systems | plate for traumatology | Gripper plates -Gripper plate -Gripper plate - AS Chest and rib plates - Kálmán T-chest plate - Chest plate - Rib securing plate - Chest stabilizing plate | II.b |
| plates and plate systems | Vortex plates and plate systems | plate for traumatology | Vortex olecranon plate Vortex proximal humeral plate Vortex distal humeral plates - DL, -M, -EDL, -SM Vortex distal radius plates - V+, -D, -V Vortex clavicle plates -HK, -H, -MA | |


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| plates and plate systems | Vortex plates and plate systems | plate for traumatology | Vortex Hand & Foot plates - 1,5 XS straight plate - 1,5 XS T-plate - 1,5 XS parallel plate - 1,5 XS Y-plate - 1,5 XS L-plate - 2,0 XS straight plate - 2,0 XS T-plate - 2,0 XS parallel plate - 2,0 XS Y-plate - 2,0 XS L-plate - Spider plate - X-plate - Arthrodesis plate - bent, straight - Mini T-plate - Mini L-plate Vortex pelvic plates - Vortex reconstruction plates - L, O, J, curved - Vortex symphysis plate | II.b |

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|---------------------------------|--|------------------------|--|------------|
| plates and plate systems | Vortex plates and plate systems | plate for traumatology | Vortex diaphysis plates - Vortex straight plate - Vortex curved plate - Vortex attachment plate - CN- Vortex straight plate Vortex proximal tibia plates - Vortex proximal tibia plates - LAT, -L, -M, -LAT-L - CN - Proximal tibia plates - M-AS, -LAT-AS | II.b |

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| Description of the device | Type | Intended use | Model | Risk class |
|--|---|-------------------------------|--|-------------|
| <p>plates and plate systems</p> | <p>Vortex plates and plate systems</p> | <p>plate for traumatology</p> | <p>Vortex distal tibia plates - Vortex distal tibia plates -M, -AL - Vortex distal fibula plate - CN - Distal tibia plate-M - CN - Vortex distal fibula plate - CN - Vortex gripper plate</p> <p>Vortex distal femur plates - Vortex distal femur plate - CN - Distal femoral plate-AS</p> <p>Vortex calcaneal plate Vortex proximal femoral plate</p> | <p>II.b</p> |


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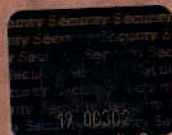

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|---------------------------|------------------------|------------------------|---|------------|
| wires | Cerclage system | wires for traumatology | <ul style="list-style-type: none"> - Securing block - Closing component - Fixing screw - Strand wire - Cerclage wire with loop - Cerclage wire coil | II.b |
| | Wires | | <p>Sirtalis cerclage system</p> <ul style="list-style-type: none"> - Threaded band support - Spiked band support - Cerclage band - Compressional fastening wire with collar - Collar - Sleeve - Kirschner boring wire - Threaded kirschner wire - Kirschner wire with double tip - Bored Kirschner wire - Threaded shoulder fixation wire | |

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The certificate covers the following devices:

| Description of the device | Type | Intended use | Model | Risk class |
|-------------------------------|-----------------------------------|------------------------|---|------------|
| nails and nail systems | Trochanter nailing systems | intramedullary nailing | Fi-nail system - Fi-nail - Trochanter Screw - Closing Cap Fi nail system Strong - Fi-nail - Trochanter Screw - Trochanter spiral - Supporting screw | II.b |
| | Humerus nailing systems | | - AR humerus nail - Humerus nail - HWDA - End-cap - Conical end-cap | |

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The certificate covers the following devices:

| Description of the device | Type | Intended use | Model | Risk class |
|---------------------------|---|---|--|------------|
| nails and nail systems | Retrograde femur nailing system | intramedullary nailing | <ul style="list-style-type: none"> - Retrograde femoral nail - Nut – RETRO - Locking bone screw – RETRO - Closing cap | II.b |
| | Ankle arthrodesis nailing system | ankle athrodesis with intramedullary nail | <ul style="list-style-type: none"> - Ankle arthrodesis nail - End-cap | |
| | SpectruM nailing systems | intramedullary nailing | <p>SpectruM trochanter nail system</p> <ul style="list-style-type: none"> - Fi-nail - Trochanter Screw - Trochanter spiral - Closing Cap <p>SpectruM humerus nail system</p> <ul style="list-style-type: none"> - Humerus nail – HWX – Rigid - Humerus nail – HWX – Flex | |

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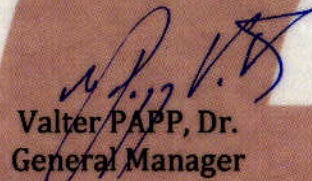

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The certificate covers the following devices:

| Description of the device | Type | Intended use | Model | Risk class |
|---------------------------|--------------------------|------------------------|---|------------|
| nails and nail systems | SpectruM nailing systems | intramedullary nailing | <p>SpectruM retrograde femur system</p> <ul style="list-style-type: none"> - SpectruM Retrograde Femur Nail - Closing cap - SRF - Locking bone screw - SRF - Washer - SRF - Nut - SRF <p>SpectruM tibia nail system</p> <ul style="list-style-type: none"> - Tibia nail - TWX - End-cap - Tibia nail - TWXE - S <p>SpectruM femur nail system</p> <ul style="list-style-type: none"> - Femoral Nail - FWDA - Femoral Nail - FWDA - S - Conical end-cap <p>SpectruM femur 2 nail system</p> <ul style="list-style-type: none"> - SpectruM Femur 2 Nail - End-cap - SpectruM Femur 2 | II.b |

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|-------------------------------|------------------------------|--------------------------|--|------------|
| nails and nail systems | MAGIC nailing systems | intramedullary nailing | MAGIC humerus nail system - MAGIC Humerus nail - Proximal locking screw - End-cap MAGIC Trochanter nail system - MAGIC Trochanter nail - MAGIC Trochanter screw - MAGIC Trochanter spiral - MAGIC Trochanter anti-rotation screw | II.b |
| staples | bone staples | staples for traumatology | - Compression staple - Varisation staple - Bone staple | |

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| pins | intramedullary pins | pins for traumatology | <ul style="list-style-type: none"> - Sanat P.I.N. - Closing component-P.I.N. - Bundle pin. | |
| external fixateur | fixateur externe systems | for orthopaedics and traumatology | <ul style="list-style-type: none"> - Schanz screw - Schanz screw self-drilling - Schanz screw with conical thread - Fixateur pin with centre thread - Steinmann pin - Fixateur - Aluminium rod - Plastic cover <p>SanatFIX</p> <ul style="list-style-type: none"> - Clamp - Insert - Screw - Rod - Fixateur rod - Rod - C - Bented rod <p>Bone lengthener system</p> <ul style="list-style-type: none"> - Bone lengthener - Bone lengthener accessory - Femoral nail for lengthening - Tibia nail for lengthening | II.b |

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The certificate covers the following devices:

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|---------------------------|---|----------------------------|---|-------------|
| dental implants | one-piece dental implant systems | dental implantation | Solo implant system - SOLO-D ballhead implant - SOLO ballhead implant - SOLO-D conical head implant - SOLO conical head implant - Metal housing | II.b |
| | two-piece dental implant systems | | - Helix implant system - Helix-D implant system - Nexus implant system - Nexus-D implant system - Protinus implant system BoneTact - Protinus implant system SLA Abutments, screws, end-caps, accessories | |

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| membrane system | titane membrane system | anchorage of dental autograft | <ul style="list-style-type: none"> - Titanium membrane - 1 wall augmentation - Titanium membrane - 2 wall augmentation - Titanium membrane - 3 wall augmentation - Titanium membrane - universal - Membrane abutment - Healing abutment - Fixation screw - Cover screw - Tenting screw | II.b |
| prosthesis | radial head prosthesis | radial head prosthesis | Radial head prosthesis | |
| cage | cervical interbody fusion cage system | cervical interbody fusion | CFF cage system <ul style="list-style-type: none"> - CFF screw - Ti - CFF screw - P - CFF cage Castle cage | |
| | thoracolumbar interbody fusion cage system TLIF | thoracolumbar interbody fusion | <ul style="list-style-type: none"> - Intervertebral spacer dorsal - P - Respace cage | |
| | thoracolumbar interbody fusion cage system OLIF | thoracolumbar interbody fusion | <ul style="list-style-type: none"> - Emerald cage | |

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| cervical plate | cervical plate system | cervical interbody fusion | - Whirlock plate - Whirlock screw - Self drilling - Whirlock screw - Self tapping | II.b |
| pedicle screw | thoracolumbar pedicle screw fixation system | spinal surgery | TLT pedicle screw fixation system (Rigid / FLEX / PEEK) | |
| surgical instruments | drills, reamers | surgical instruments | - Drills - Spiral drills - Stepped drills - Fraises - Sinkers - Reamers - Cylindrical reamer - Intramedullary reamers - Adaptors - Tap drills - Acetabular drill - Acetabular reamer handle - Patella drill | II.a |
| | drivers | | - Quick-connecting screwdrivers - Torque screwdrivers | |

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|-----------------------------|----------------------|-----------------------------|--|------------|
| surgical instruments | dental drills | surgical instruments | <ul style="list-style-type: none"> - Drills - Cutters - Initial twist drill - Nest drill - Tap drills - Round trepan - ABH drill - ABH sleeve - Drivers | II.a |

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