

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

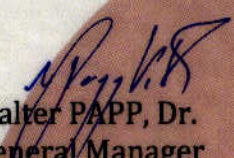
Issued: 30 January 2020

First issued: 13 September 2019

Start date of certified status: 13 September 2019

Expires:

25 May 2024


Valter PAPP, Dr.
General Manager

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	- 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	- Compression screw - A-spire screw	
	Interference screws	screw for traumatology	Interference screws Tensofix	
	Pelvic screw system	screw for traumatology	- Pelvic screw - Washer - Nut	

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Valter PAPP, Dr.
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	- 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	- 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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Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
screws and screw systems	Hand & Foot screw system	screw for traumatology	- LTF-screw - PEDI-screw - Self-drilling foot screw – H - Tenodesis screw	II.b
	Angle stabilized screws	screw for traumatology	- Vortex screw - AS screw - Vortex connection screw - Closing screw	
	Locking bone screws	screw for traumatology	- Locking bone screw - Distal locking screw	

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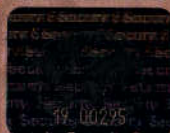

Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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 Valter PAPP, Dr.
 General Manager



The certificate covers the following devices:

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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Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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Valter PAPP, Dr.
General Manager

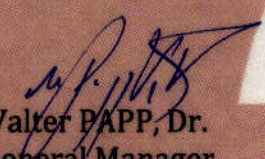


The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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 Valter PAPP, Dr.
 General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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Valter FAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
plates and plate systems	Vortex plates and plate systems	plate for traumatology	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 Vortex distal femur plates - Vortex distal femur plate - CN - Distal femoral plate-AS Vortex calcaneal plate Vortex proximal femoral plate	II.b

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Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
wires	Cerclage system	wires for traumatology	- Securing block - Closing component - Fixing screw - Strand wire - Cerclage wire with loop - Cerclage wire coil	II.b
	Wires		Sirtalis cerclage system - 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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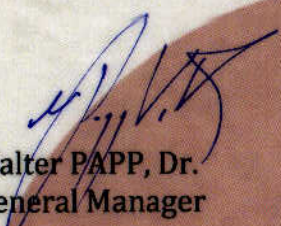

Valter PAPP, Dr.
General Manager

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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 Valter PAPP, Dr.
 General Manager



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	- Retrograde femoral nail - Nut – RETRO - Locking bone screw – RETRO - Closing cap	II.b
	Ankle arthrodesis nailing system	ankle athrodesis with intramedullary nail	- Ankle arthrodesis nail - End-cap	
	SpectruM nailing systems	intramedullary nailing	SpectruM trochanter nail system - Fi-nail - Trochanter Screw - Trochanter spiral - Closing Cap SpectruM humerus nail system - Humerus nail – HWX – Rigid - Humerus nail – HWX – Flex	

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Valter PAPP, Dr.
General Manager

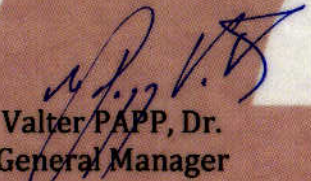


The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
nails and nail systems	SpectruM nailing systems	intramedullary nailing	SpectruM retrograde femur system - SpectruM Retrograde Femur Nail - Closing cap - SRF - Locking bone screw - SRF - Washer - SRF - Nut - SRF SpectruM tibia nail system - Tibia nail - TWX - End-cap - Tibia nail - TWXE - S SpectruM femur nail system - Femoral Nail - FWDA - Femoral Nail - FWDA - S - Conical end-cap SpectruM femur 2 nail system - SpectruM Femur 2 Nail - End-cap - SpectruM Femur 2	II.b

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Issued: 30 January 2020


Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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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 Valter PAPP, Dr.
 General Manager



The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
pins	intramedullary pins	pins for traumatology	- Sanat P.I.N. - Closing component-P.I.N. - Bundle pin.	II.b
external fixateur	fixateur externe systems	for orthopaedics and traumatology	- Schanz screw - Schanz screw self-drilling - Schanz screw with conical thread - Fixateur pin with centre thread - Steinmann pin - Fixateur - Aluminium rod - Plastic cover SanatFIX - Clamp - Insert - Screw - Rod - Fixateur rod - Rod - C - Bented rod Bone lengthener system - Bone lengthener - Bone lengthener accessory - Femoral nail for lengthening - Tibia nail for lengthening	

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Issued: 30 January 2020



[Signature]
Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
dental implants	one-piece dental implant sytems	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 sytems		- 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	

Issue: 2

Issued: 30 January 2020

Valter PAPP, Dr.
General Manager

Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
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	

Issue: 2

Issued: 30 January 2020


Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
surgical instruments	dental drills	surgical instruments	- Drills - Cutters - Initial twist drill - Nest drill - Tap drills - Round trepan - ABH drill - ABH sleeve - Drivers	II.a

Issue: 2
Issued: 30 January 2020


Valter PAPP, Dr.
General Manager

EC DESIGN-EXAMINATION CERTIFICATE**Directive 93/42/EEC on Medical devices, Annex II (4)**

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the requirements of the directive.

Name of the manufacturer:

**Sanatmetal Ortopédiai és Traumatológiai
Eszközöket Gyártó Kft.**Headquarters: **3300 Eger, Faiskola út 5.**Manufacturing plant: **Sanatmetal CIS
249030 Russia, Kaluga region, Obninsk, Kievskoe shosse, 92**

Scope:

Ceramic ball head

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
ceramic ball head	ceramic ball head	ceramic head to hip prosthesis	see product list	III.*
	ceramic ball head with adaptor			

This certificate is valid only with the annexes and the system certificate No. **144969-19-11-06**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 181-G3-190109

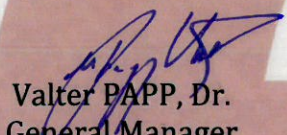
Issue: 1

Issued: 6 November 2019

First issued: 6 November 2019

Start date of certified status: 6 November 2019

Expires:

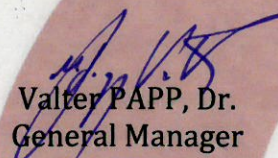
25 May 2024
Valter PAPP, Dr.
General Manager

The certificate covers the following devices:

Tételkód / Code	Megnevezés	Description	Méret / Size
412200280	Kerámia fej	Ceramic head	28/M (0)
412200283	Kerámia fej	Ceramic head	28/L (+3.5)
412200320	Kerámia fej	Ceramic head	32/M (0)
412200323	Kerámia fej	Ceramic head	32/L (+3.5)
412200327	Kerámia fej	Ceramic head	32/XL (+7)
412200360	Kerámia fej	Ceramic head	36/M (0)
412200363	Kerámia fej	Ceramic head	36/L (+3.5)
412200367	Kerámia fej	Ceramic head	36/XL (+7)
412200400	Kerámia fej	Ceramic head	40/M (0)
412200403	Kerámia fej	Ceramic head	40/L (+3.5)
412200407	Kerámia fej	Ceramic head	40/XL (+7)
412203280	Kerámia fej	Ceramic head	28/S (-3.5)
412203320	Kerámia fej	Ceramic head	32/S (-3.5)
412203360	Kerámia fej	Ceramic head	36/S (-3.5)
412203400	Kerámia fej	Ceramic head	40/S (-3.5)
412220000	Fém adapter	Metal adaptor	M (0)
412220004	Fém adapter	Metal adaptor	L (+4)
412220007	Fém adapter	Metal adaptor	XL (+7)
412220013	Fém adapter	Metal adaptor	S (-3)
412220028	Kerámia fej adapterhez	Ceramic head for adaptor	28 mm
412220032	Kerámia fej adapterhez	Ceramic head for adaptor	32 mm
412220036	Kerámia fej adapterhez	Ceramic head for adaptor	36 mm
412220040	Kerámia fej adapterhez	Ceramic head for adaptor	40 mm

Issue: 1

Issued: 6 November 2019


Václav PAPP, Dr.
General Manager



Certificate number: 144887-19-05-29

Name of certified organisation:

**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:

Design, development, manufacture and distribution of sterile and non-sterile traumatology, orthopaedic, spinal, dental and bone regeneration implants, including associated instruments.

CE Certiso Ltd. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

**MSZ EN ISO 13485:2016
(ISO 13485:2016)**

Headquarters: no exclusion

Site: with exclusion of Design and development (7.3)

Issue: 1

Issued: 29 May 2019

First issued: 29 May 2019

Start date of certified status: 29 May 2019


Valter PAPP, dr
General Manager

Expires:

27 February 2022





Certificate

We hereby certify that

**Sanatmetal Ortopédiai és Traumatológiai
Eszközöket Gyártó Kft.**

Headquarters: 3300 Eger, Faiskola út 5.

in the following fields

**design, manufacture and distribution of both sterile and non sterile
implants for orthopaedic and trauma, instruments**

has introduced and applied an Environmental Management System
which satisfies the requirements of **ISO 14001:2015**



Expiry Date:	16 04 2023
Registration Number:	01-19123/20-13876
Certified since:	18 04 2017
Date of Issue:	Budapest, 17 04 2020

Certificate is valid only with successful surveillance audits.
Validity of Certificate may be confirmed by scanning QR code.



Nagyibay Tamás

In the name of certification body

CERTOP
Termék- és Rendszertanúsító Kft.
H-1149 Budapest, Magyarádi út 32.
H-6720 Szeged, Arany J. u. 7.
www.certop.hu