

DECLARATIE

Prin prezenta, compania Ortofix SRL, declara ca termenul de garantie/valabilitate a bunurilor la momentul livrării va fi nu mai mic de 12 luni.

Bolocan Roman
director Ortofix SRL

17.04.2019



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 11 0673 QS/NB

The quality system of manufacturer

Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):


Orthopaedic Implants, Spinal Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2016-08-09
Valid until: 2021-08-08
First Issued: 2011-08-09
Revision: b

Date: 2016-08-09




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:

Samay Surgical
Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India


Product(s):

Name:	Plates
Trade name(s):	Samay
Model(s):	see table bellow
Class:	IIb
GMDN:	61573

- 3.5 mm Small Compression (DCP) Plates
- 4.5 mm Narrow Compression (DCP) Plates
- 4.5 mm Broad Compression (DCP) Plates
- 3.5 mm Small Compression (LC-DCP) Plates
- 4.5 mm Narrow Compression (LC-DCP) Plates
- 4.5 mm Broad Compression (LC-DCP) Plates
- 2.7 mm Dynamic Compression Plates
- 3.5 mm One Third Tubular Plates
- 4.5 mm Semi Tubular Plates
- 3.5 mm Small T Plates, Right Angled
- 3.5 mm Small T Plates, Oblique Angled
- 3.5 mm Reconstruction Plates, Straight Round Hole
- 3.5 mm Reconstruction Plates, Straight D.C Hole
- 3.5 mm Reconstruction Plates, Curved
- 4.5 mm Reconstruction Plates, Straight Round Hole
- 4.5 mm Reconstruction Plates, Straight D.C Hole
- 4.5 mm Reconstruction Plates, Curved
- 3.5 mm 'Y' Reconstruction Plates
- 4.5 mm 'T' Plates
- 4.5 mm T-Buttress Plates

Date: 2016-08-09




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**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

4.5 mm L-Buttress Plates for Right Leg
4.5 mm L-Buttress Plates for Left Leg
3.5 mm Cloverleaf Plates
4.5 mm Condylar Buttress (C.B.P) Plates for Right Leg
4.5 mm Condylar Buttress (C.B.P) Plates for Right Leg
4.5 mm Lateral Tibia Buttress Plates for Right Leg
4.5 mm Lateral Tibia Buttress Plates for Left Leg
3.5 mm Hook Plates
DHS Barrel Plate Round Hole 120° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 125° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 130° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 135° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 140° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 145° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 120° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 125° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 130° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 135° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 140° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 145° (Barrel Length 25MM & 38mm)
95° DCS Barrel Plate Round Hole
95° DCS Barrel Plate Round Hole
DHS Lag Screw
DHS Compression Screw
Condylar Angled Blade plate 95° (Round Hole) 50mm blade
Condylar Angled Blade plate 95° (Round Hole) 55mm blade

Date: 2016-08-09



Paul Voj
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Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:

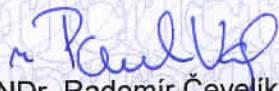
Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Condylar Angled Blade plate 95° (Round Hole) 60mm blade
Condylar Angled Blade plate 95° (Round Hole) 65mm blade
Condylar Angled Blade plate 95° (Round Hole) 70mm blade
Condylar Angled Blade plate 95° (Round Hole) 75mm blade
Condylar Angled Blade plate 95° (Round Hole) 80mm blade
Condylar Angled Blade plate 95° (Round Hole) 85mm blade
Condylar Angled Blade plate 95° (Round Hole) 90mm blade
Condylar Angled Blade plate 130° (Round Hole) 50mm blade
Condylar Angled Blade plate 130° (Round Hole) 55mm blade
Condylar Angled Blade plate 130° (Round Hole) 60mm blade
Condylar Angled Blade plate 130° (Round Hole) 65mm blade
Condylar Angled Blade plate 130° (Round Hole) 70mm blade
Condylar Angled Blade plate 130° (Round Hole) 75mm blade
Condylar Angled Blade plate 130° (Round Hole) 80mm blade
Condylar Angled Blade plate 130° (Round Hole) 85mm blade
Condylar Angled Blade plate 130° (Round Hole) 90mm blade
Condylar Angled Blade plate 95° (D.C Hole) 50mm blade
Condylar Angled Blade plate 95° (D.C Hole) 55mm blade
Condylar Angled Blade plate 95° (D.C Hole) 60mm blade
Condylar Angled Blade plate 95° (D.C Hole) 65mm blade
Condylar Angled Blade plate 95° (D.C Hole) 70mm blade
Condylar Angled Blade plate 95° (D.C Hole) 75mm blade
Condylar Angled Blade plate 95° (D.C Hole) 80mm blade
Condylar Angled Blade plate 95° (D.C Hole) 85mm blade
Condylar Angled Blade plate 95° (D.C Hole) 90mm blade
Condylar Angled Blade plate 130° (D.C Hole) 50mm blade

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**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Condylar Angled Blade plate 130° (D.C Hole) 55mm blade
Condylar Angled Blade plate 130° (D.C Hole) 60mm blade
Condylar Angled Blade plate 130° (D.C Hole) 65mm blade
Condylar Angled Blade plate 130° (D.C Hole) 70mm blade
Condylar Angled Blade plate 130° (D.C Hole) 75mm blade
Condylar Angled Blade plate 130° (D.C Hole) 80mm blade

Condylar Angled Blade plate 130° (D.C Hole) 85mm blade

Condylar Angled Blade plate 130° (D.C Hole) 90mm blade

COBRA PLATE

ELLIS PLATE

Mini Plates 1.5 mm with gap

Mini Plates 2.0 mm with gap

Mini Plates 2.5 mm with gap

Mini Plates 1.5 mm without gap

Mini Plates 2.0 mm without gap

Mini Plates 2.5 mm without gap

90° L Shape Plate (Small)

90° L Shape Plate (Big)

L Shape Plate (Extra Big)

120° L Shape Plate (Small)

120° L Shape Plate (Big)

T Shape Plate


I Shape Plate

Y Shape Plate (Small)

Y Shape Plate (Big)

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Double Y Shape Plate
X Shape Plate
Orbita Plate
Nose Plate H Shape
Nose Plate Y Shape
Z Shape Plate
H Shape Plate
Curved Plate
150° Angular Plate
CHIN PLATE
Mini Burr Hole Plate
3D Plate 2.0 mm
Le Fort 'I' Plate
Wire Mesh per Hole
Straight Reconstruction Plates
T.M.J. Condylar Plate(Left)
T.M.J. Condylar Plate(Right)
T.M.J. Condylar with Recon. Plate (Left)
T.M.J. Condylar with Recon. Plate (Right)
Angled for Mandible Reconstruction Plate(Left)
Angled for Mandible Reconstruction Plate(Right)
Double Angle for Mandible Recon. Plate
Full Mandible Reconstruction Plate
Distal Femur Plate Left Leg
Distal Femur Plate Right Leg
DHS Trochanteric plate

Date: 2016-08-09



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(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Proximal Femur Plate Left
Proximal Femur Plate Right
Proximal Humorous Plate


Name:	Screws
Trade name(s):	Samay
Model(s):	see bellow
Class:	IIb
GMDN:	56642

a) Bone Screws

- 2.7 mm Cortex Screw
- 2.7 mm Cortex Screw Self Tapping
- 3.5 mm Cortex Screw (Pitch 1.25)
- 3.5 mm Cortex Screw Self Tapping (Pitch 1.25)
- 3.5 mm Cortex Screw (Pitch 1.75)
- 3.5 mm Cortex Screw Self Tapping (Pitch 1.75)
- 3.5 mm Cancellous Screw
- 4.5 mm Cortex Screw (Pitch 1.75)
- 4.5 mm Cortex Screw Self Tapping (Pitch 1.75)
- 4.5 mm Malleolar Screw

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(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**


4.0 mm Cancellous Screw Short Threaded
4.0 mm Cancellous Screw Fully Threaded
6.5 mm Cancellous Screw 16.0 mm Threaded
6.5 mm Cancellous Screw 32.0 mm Threaded
6.5 mm Cancellous Screw Fully Threaded
4.0 mm Cannulated Cancellous Screw Short Threaded
4.0 mm Cannulated Cancellous Screw Fully Threaded
6.5 mm Cannulated Cancellous Screw 16.0 mm Threaded
6.5 mm Cannulated Cancellous Screw 32.0 mm Threaded
6.5 mm Cannulated Cancellous Screw Fully Threaded
7.0 mm Cannulated Cancellous Screw 16.0 mm Threaded
7.0 mm Cannulated Cancellous Screw 32.0 mm Threaded
7.0 mm Cannulated Cancellous Screw Fully Threaded
1.5 mm Cortex Screw
2.0 mm Cortex Screw
2.5 mm Cortex Screw
1.5 mm Cortex Screw Self Tapping
2.0 mm Cortex Screw Self Tapping
2.5 mm Cortex Screw Self Tapping
7.0 mm WASHER
13.0 mm WASHER

b) Locking Screws

2.7 mm Locking Screw
3.5 mm Locking Screw
5.0 mm Locking Screw

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(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

- 4.0 mm Locking Screw
- 6.5 mm Cancellous locking Screw 16 mm Threaded
- 6.5 mm Cancellous locking Screw 32 mm Threaded
- 6.5 mm Cancellous locking Screw Fully Threaded
- 3.5 mm Cancellous Locking Screw (Full Thread)
- 5.0 mm Cancellous Locking Screw (Full Thread)
- 7.3 mm C.C Locking Screw (Full Thread)
- 2.4 mm Locking Screw
- Spacer
- 3.5 mm Small Locking Plates
- 4.5 mm Narrow Locking Plates
- 4.5 mm Broad Locking Plates
- 3.5 mm Small T Locking Plates, Right Angled
- 3.5 mm Small T Locking Plates, Oblique Angled Right
- 3.5 mm Small T Locking Plates, Oblique Angled Left
- 3.5 mm Small T Locking Plates, Oblique Angled Right
- 3.5 mm Reconstruction Locking Plates, Straight Round Hole
- 3.5 mm Reconstruction Locking Plates, Straight D.C Hole
- 4.5 mm Reconstruction Locking Plates, Straight Round Hole
- 4.5 mm Reconstruction Locking Plates, Straight D.C Hole
- 4.5 mm 'T' Locking Plates
- 4.5 mm T-Buttress Locking Plates
- 4.5 mm L-Buttress Locking Plates for Right Leg
- 4.5 mm L-Buttress Locking Plates for Left Leg
- 4.5 mm Condylar Buttress (C.B.P) Locking Plates for Right Leg

Date: 2016-08-09



Radomir Čevelík
RNDr. Radomír Čevelík
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**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

4.5 mm Condylar Buttress (C.B.P) Locking Plates for Left Leg
4.5 mm Lateral Tibia Buttress Locking Plates for Right Leg 5.0mm
4.5 mm Lateral Tibia Buttress Locking Plates for Left Leg 5.0mm
4.5 mm Lateral Tibia Buttress Locking Plates for Right Leg 6.5mm
4.5 mm Lateral Tibia Buttress Locking Plates for Left Leg 6.5mm
DHS Barrel Locking Plate 120°
DHS Barrel Locking Plate 125°
DHS Barrel Locking Plate 130°
DHS Barrel Locking Plate 135°
DHS Barrel Locking Plate 140°
DHS Barrel Locking Plate 145°
Distal Femur Locking Plate Right Leg 5.0mm
Distal Femur Locking Plate Left Leg 5.0mm
Distal Femur Locking Plate Right Leg 6.5mm
Distal Femur Locking Plate Left Leg 6.5mm
Distal Tibia LCP Plates 3.5mm Right
Distal Tibia LCP Plates 3.5mm Left
Proximal Humorous Locking Plate
Philos Locking Plate Short
Philos Locking Plate
Distal Medial Tibia LCP Plates 3.5mm Right Without tab
Distal Medial Tibia LCP Plates 3.5mm Left Without tab
Anterolateral Distal Tibia Lcp Plate Right
Anterolateral Distal Tibia Lcp Plate Left

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(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Proximal Femoral LCP Plate 5.0 mm Right
Proximal Femoral LCP Plate 5.0 mm Left
Proximal Tibia LCP Plate 3.5mm Right
Proximal Tibia LCP Plate 3.5mm Left
Proximal Tibia LCP Plate 4.5mm Right
Proximal Tibia LCP Plate 4.5mm Left
Proximal Medial Tibia LCP Plate 3.5mm Right
Proximal Medial Tibia LCP Plate 3.5mm Left
Proximal Medial Tibia LCP Plate 4.5mm Right
Proximal Medial Tibia LCP Plate 4.5mm Left
Metaphyseal LCP Plates 3.5/5.0 mm
Metaphyseal LCP Plates 3.5/5.0 mm for distal medial tibia Right
Metaphyseal LCP Plates 3.5/5.0 mm for distal medial tibia Left
Calcaneal LCP plate 3.5 mm Right
Calcaneal LCP plate 3.5 mm Left
Calcaneal LCP plate 3.5 mm Right
Calcaneal LCP plate 3.5 mm Left
Clavicle Hook LCP Plates 3.5mm Right Hook depth 12mm
Clavicle Hook LCP Plates 3.5mm Right Hook depth 15mm
Clavicle Hook LCP Plates 3.5mm Right Hook depth 18mm
Clavicle Hook LCP Plates 3.5mm Right Hook depth 12mm
Clavicle Hook LCP Plates 3.5mm Right Hook depth 15mm
Clavicle Hook LCP Plates 3.5mm Right Hook depth 18mm
Superior Anterior Clavicle LCP Plate Right
Superior Anterior Clavicle LCP Plate Left

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Superior Anterior Clavicle LCP Plate Left With Lateral extension Right
Superior Anterior Clavicle LCP Plate Left With Lateral extension Left
Distal Humeral LCP Plate, Dorsolateral - without Lateral Support - 2.7 / 3.5 mm
Right
Distal Humeral LCP Plate, Dorsolateral - without Lateral Support - 2.7 / 3.5 mm
Left
Distal Humeral LCP Plate, Dorsolateral - with Lateral Support - 2.7 / 3.5 mm Right
Distal Humeral LCP Plate, Dorsolateral - with Lateral Support - 2.7 / 3.5 mm Left
Distal Medial Humeral LCP Plate 2.7 / 3.5 mm Right
Distal Medial Humeral LCP Plate 2.7 / 3.5 mm Left
Metaphyseal LCP Plates 3.5mm for distal, medial humerus
Fibula Locking Plate 3.5mm
One Third Tubular Locking Plate 3.5 mm
Ankle Hook Locking Plate 3.5 mm
Side winder Locking Plate 3.5 mm Right
Side winder Locking Plate 3.5 mm Left
V.A. Proximal Tibia Locking Plate 3.5 mm Right
V.A. Proximal Tibia Locking Plate 3.5 mm Left
Olecranon Locking Plate, 3.5 mm - Right
Olecranon Locking Plate, 3.5 mm - Left
Cervical LCP Plate
Tomifix Mid High T LCP Plate
2.4mm Distal Radius Plare LCP Straight
2.4mm L Distal Radius Plate Lcp Left Angled Shaft (Head 2 Hole)
2.4mm L Distal Radius Plate Lcp Right Angled Shaft (Head 2 Hole)

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- 2.4mm L Distal Radius Plate Lcp Left Angled Shaft (Head 3 Hole)
- 2.4mm L Distal Radius Plate Lcp Right Angled Shaft (Head 3 Hole)
- 2.4mm L Distal Radius Plate Lcp Oblique Left Angled Shaft (Head 3 Hole)
- 2.4mm L Distal Radius Plate Lcp Oblique Right Angled Shaft (Head 3 Hole)
- 2.4mm T Distal Radius Plate Lcp Shaft (Head 3 Hole)
- 2.4MM Distal Radius Plate Lcp Left Angled Shaft (Head 5 Hole)
- 2.4MM Distal Radius Plate Lcp Right Angled Shaft (Head 5 Hole)
- 2.4MM Buttress Plate Lcp Left Angled Shaft (Head 5 Hole)
- 2.4MM Buttress Plate Lcp Right Angled Shaft (Head 5 Hole)
- 2.4 mm Distal Redius Plate Extra Articular LCP Left
- 2.4 mm Distal Redius Plate Extra Articular LCP Right
- 2.4 mm Distal Redius Plate Extra Long LCP
- Two-Columa Distal Radius LCP Plate – Left
- Two-Columa Distal Radius LCP Plate – Right
- Extra Articular Distal Humerus LCP Plate Right
- Extra Articular Distal Humerus LCP Plate Left
- Posterior Medial Proximal Tibia LCP Plate
- 3.5mm Hook LCP Plate

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R. Radomir Čevelík
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Name:	Nails
Trade name(s):	Samay
Model(s):	see table bellow
Class:	IIb
GMDN:	60411

- Inter-Locking Tibia Nail (8.0 mm)
- Inter-Locking Tibia Nail (9.0 mm)
- Inter-Locking Tibia Nail (10.0 mm)
- Inter-Locking Tibia Nail (11.0 mm)
- Inter-Locking Femoral Nail (9.0 mm)
- Inter-Locking Femoral Nail (10.0 mm)
- Inter-Locking Femoral Nail (11.0 mm)
- Inter-Locking Femoral Nail (12.0 mm)
- Inter-Locking Humerus Nail (Solid) (6.0 mm)
- Inter-Locking Humerus Nail (Solid) (7.0 mm)
- Inter-Locking Humerus Nail (Solid) (8.0 mm)
- Inter-Locking Humerus Nail (Cannulated) (6.0 mm)
- Inter-Locking Humerus Nail (Cannulated) (7.0 mm)
- Inter-Locking Humerus Nail (Cannulated) (8.0 mm)
- Proximal Femoral Nail (P.F.N), (Right) (9.0 mm)
- Proximal Femoral Nail (P.F.N), (Right) (10.0 mm)
- Proximal Femoral Nail (P.F.N), (Right) (11.0 mm)
- Proximal Femoral Nail (P.F.N), (Left) (9.0 mm)
- Proximal Femoral Nail (P.F.N), (Left) (10.0 mm)

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Proximal Femoral Nail (P.F.N), (Left) (11.0 mm)
Proximal Femoral Nail (P.F.N), (Shot) 135° 25cm
Proximal Femoral Nail (P.F.N), (Shot) 130° 25cm
Recon Nail 9.0 mm Right
Recon Nail 10.0 mm Right
Recon Nail 11.0 mm Right
Recon Nail 12.0 mm Right
Recon Nail 9.0 mm Left
Recon Nail 10.0 mm Left
Recon Nail 11.0 mm Left
Recon Nail 12.0 mm Left
Recon Nail 22 cm (Short)
Supra Nail 10.0 mm
Supra Nail 11.0 mm
Supra Nail 12.0 mm
Supra Nail 13.0 mm
Inter-Locking Nail For Hyper Tibia (8.0 mm)
Inter-Locking Nail For Hyper Tibia (9.0 mm)
Inter-Locking Nail For Hyper Tibia (10.0 mm)
Inter-Locking Nail For Hyper Tibia (11.0 mm)
Inter-Locking Nail For Hyper Femoral (09.0 mm)
Inter-Locking Nail For Hyper Femoral (10.0 mm)
Inter-Locking Nail For Hyper Femoral (11.0 mm)
Inter-Locking Nail For Cyrus Tibia (8.0 mm)
Inter-Locking Nail For Cyrus Tibia (9.0 mm)

Date: 2016-08-09




RNDr. Radomir Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:


Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Inter-Locking Nail For Cyrus Tibia (10.0 mm)
Inter-Locking Nail For Cyrus Tibia (11.0 mm)
Inter-Locking Nail For Cyrus Femoral (9.0 mm) Right
Inter-Locking Nail For Cyrus Femoral (10.0 mm) Right
Inter-Locking Nail For Cyrus Femoral (11.0 mm) Right
Inter-Locking Nail For Cyrus Femoral (12.0 mm) Right
Inter-Locking Nail For Cyrus Femoral (9.0 mm) Left
Inter-Locking Nail For Cyrus Femoral (10.0 mm) Left
Inter-Locking Nail For Cyrus Femoral (11.0 mm) Left
Inter-Locking Nail For Cyrus Femoral (12.0 mm) Left
Antegrade Femoral Nail (AFN) Right - 135° & 130° 9 mm
Antegrade Femoral Nail (AFN) Right - 135° & 130° 10 mm
Antegrade Femoral Nail (AFN) Right - 135° & 130° 11 mm
Antegrade Femoral Nail (AFN) Left - 135° & 130° 9 mm
Antegrade Femoral Nail (AFN) Left - 135° & 130° 10 mm
Antegrade Femoral Nail (AFN) Left - 135° & 130° 11 mm
Trochanteric Femoral Nail (T.F.N), (Shot) 130° 18cm
Trochanteric Femoral Nail (T.F.N), (Shot) 135° 18cm
Elastic Nail 40 cm
Elastic Nail 44 cm
K - Nail For Femur 8.0 mm
K - Nail For Femur 9.0 mm
K - Nail For Femur 10.0 mm
K - Nail For Femur 11.0 mm
K - Nail For Femur 12.0 mm

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K - Nail For Femur 13.0 mm
V - Nail For Tibia 7.0 mm
V - Nail For Tibia 8.0 mm
V - Nail For Tibia 9.0 mm
V - Nail For Tibia 10.0 mm
V - Nail For Tibia 11.0 mm
V - Nail For Tibia 12.0 mm
V - Nail For Tibia 13.0 mm
Enders Nail (3.0 mm)
Enders Nail (3.5 mm)
Enders Nail (4.0 mm)
Enders Nail (4.5 mm)
Square Nail for Radius (2.0 mm)
Square Nail for Radius (2.5 mm)
Square Nail for Radius (3.0 mm)
Square Nail for Radius (3.5 mm)
Square Nail for Radius (4.0 mm)
Square Nail for Ulna (2.0 mm)
Square Nail for Ulna (2.5 mm)
Square Nail for Ulna (3.0 mm)
Square Nail for Ulna (3.5 mm)
Square Nail for Ulna (4.0 mm)
Rush Nail (2.0 mm)
Rush Nail (2.5 mm)
Rush Nail (3.0 mm)

Date: 2016-08-09




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Rush Nail (3.5 mm)
Rush Nail (4.0 mm)
Cap For Humerus Nail
Cap For Tibia Nail
Cap For Femur Nail
Cap For Proximal Femoral Nail (P.F.N)
Cap For Recon Nail
Cap For Supra Nail
Cap For Hyper Tibia Nail
Cap For Hyper Femur Nail
Cap For Cyrus Tibia Nail
Cap For Cyrus Femur Nail
Cap For Antegrade Femoral Nail (A.F.N)
Cap For Trochanteric Femoral Nail (T.F.N)
2.9 mm Inter-Locking Screw
3.4 mm Inter-Locking Screw
3.9 mm Inter-Locking Screw
4.9 mm Inter-Locking Screw
6.4 mm Proximal Femoral Screw (P.F.N)
8.0 mm Proximal Femoral Screw (P.F.N)

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issued for manufacturer:

Samay Surgical
Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India

Name:	Wires & Pins
Trade name(s):	Samay
Model(s):	see table bellow
Class:	IIb
GMDN:	61691

Kirschner Wire (0.8 mm)
Kirschner Wire (1.0 mm)
Kirschner Wire (1.2 mm)
Kirschner Wire (1.5 mm)
Kirschner Wire (1.8 mm)
Kirschner Wire (2.0 mm)
Kirschner Wire (2.5 mm)
Kirschner Wire (3.0 mm)
Kirschner Wire Threaded (0.8 mm)
Kirschner Wire Threaded (1.0 mm)
Kirschner Wire Threaded (1.2 mm)
Kirschner Wire Threaded (1.5 mm)
Kirschner Wire Threaded (1.8 mm)
Kirschner Wire Threaded (2.0 mm)
Kirschner Wire Threaded (2.5 mm)
Kirschner Wire Threaded (3.0 mm)
Steinmann Pin (3.0 mm)
Steinmann Pin (3.5 mm)

Date: 2016-08-09



Paul Voj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:


Samay Surgical

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(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Steinmann Pin (4.0 mm)
Steinmann Pin (4.5 mm)
Steinmann Pin (5.0 mm)
S.S. Wire Reel
Guide wire (simple)
Guide wire (Threaded)
Guide wire Long simple
Guide wire Long Bided
Cerclage wire
Dromond Wire
DENHAM PIN 9"
Schanz Screw (2.0 mm)
Schanz Screw (2.5 mm)
Schanz Screw (3.0 mm)
Schanz Screw (3.5 mm) 16 Threaded & 32 Threaded
Schanz Screw (4.5 mm) 16 Threaded & 32 Threaded
Schanz Screw (5.0 mm) 16 Threaded & 32 Threaded
Schanz Screw (Cancellous Thread) Shaft Dia. 4.5mm &
Thread Dia. 6.5mm X Length 9"
Schanz Screw (Drill Tapping) 4.5 mm
Schanz Screw (Drill Tapping) 5.0 mm
U - Staples 1.5 mm
U - Staples 2.0 mm
U - Staples 2.5 mm
U - Staples 3.0 mm
Coventary Staples

Date: 2016-08-09




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Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:

Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

Name:	Spinal Implants
Trade name(s):	Samay
Model(s):	see bellow
Class:	IIb
GMDN:	61325

Mono Axial Screw - Single lock
Mono Axial Reduction Screw - Single Lock
Poly Axial Screw - Single Lock\
Poly Axial Reduction Screw - Single Lock
Connectiong Rod 3.0mm
Connecting Rod 5.0mm
Cross lomk With 3.0 mm Rod
Transverse Connector
Staple Washer
Hook
4.0mm Screw For Cervical Plate
Cervicle Cage
Eco Cage
Expandable Cage
Plif Cage
Tlif Cage (Banana Type)
Plif Cage (Bullet Type)
IMF Screw Groove & Hole 2.0 mm
IMF Screw Groove & Hole 2.5mm

Date: 2016-08-09



m. Paulík
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0673 QS/NB
issued for manufacturer:


Samay Surgical
Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India

Facility(ies):

Samay Surgical
Survey No.212, Plot No.6, Nr. Patidar Plastic, NH-8B, Veraval (Shapar) – 360 024,
Dist. Rajkot, Gujarat, India

Date: 2016-08-09




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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

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Samay Surgical
Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India

Certificate History:

Revision	Date	Reference Number	Action
	2011-08-09	803601260	Certification
a	2012-10-19	803601721	Addition of new models
b	2016-08-09	803602520	Re-certification process

Date: 2016-08-09




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60124981 0001

Report No.: 15096167 001

Manufacturer: Jiangsu Jinlu Group Medical Device
Co., Ltd.
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

Products:

- Metal Bone Plates & Screw Systems
- Metallic Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Spinal Fixation Devices
- External Fixation Devices with Needles
- Suture Wires

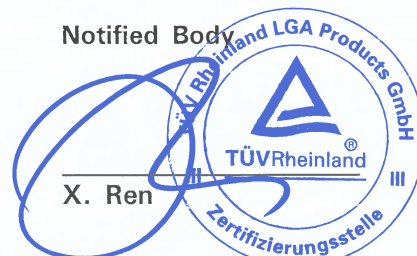
Expiry Date: 2022-06-30

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-12-11

Date: 2017-12-11

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Management System Certificate

Certificate No. **MD-QMS/91/R/1933**

This is to certify that

Samay Surgicals

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, Nh-8b,
Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard :

ISO 13485:2016

This certificate is valid for the following scope :

**Design, Manufacture & Supply of Orthopedic Implants,
Spinal Implant & related Instruments.**

Initial Certification : 20th August, 2011
Re-certification : 20th August, 2017
Valid until : 19th August, 2020



UK

Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>. Further clarification regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the certified organization. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid.

Zenith Quality Assessors Pvt. Ltd.

(Management System Certification Division, MSCD002)

306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar, Pune - 411 014, Maharashtra, India.
www.zenith-worldwide.com

Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.

6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.

www.ascb.co.uk

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Jiangsu Jinlu Group Medical Device
Co., Ltd.**
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Medical Devices**
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

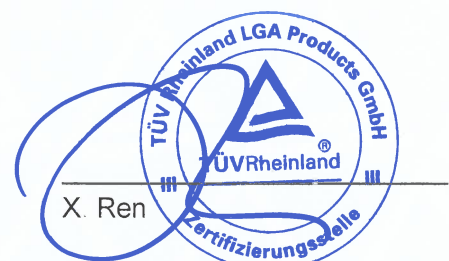
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-12-11
Certificate Registration No.: SX 60124982 0001
An audit was performed. Report No.: 15096167 001
This Certificate is valid until: 2020-06-30

Certification Body



Date 2017-12-11



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60124982 0001
Report No.: 15096167 001

Organization: Jiangsu Jinlu Group Medical Device
Co., Ltd.
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

Scope:

Products:

- Metal Bone Plates & Screw Systems
- Metallic Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Spinal Fixation Devices
- External Fixation Devices with Needles
- Suture Wires

Certification Body



Date: 2017-12-11

