



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
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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

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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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



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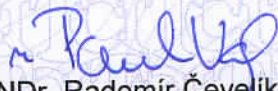
Samay Surgical

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

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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(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

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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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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

Date: 2016-08-09



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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

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(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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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 Radius Plate Extra Articular LCP Left
2.4 mm Distal Radius Plate Extra Articular LCP Right
2.4 mm Distal Radius Plate Extra Long LCP
Two-Column Distal Radius LCP Plate – Left
Two-Column 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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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)

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(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

Date: 2016-08-09




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



Notified Body 1023
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Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:

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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)

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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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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)

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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



Paul Vg
RNDr. Radomír Čevelík
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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

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Facility(ies):

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




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