

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000322025-PA-NA-IND

Project No.:
PRJC-579152-2018-PRC-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Jayon Implants Pvt. Ltd.

**IV/1064, Industrial Development Area, Kanjikode,
Palakkad-678 623, Kerala, India**

For design, production and final product inspection/testing of:
NON-STERILE SPINAL IMPLANTS

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 01 February 2021

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Palani Damodharan

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	01 February 2021

Products covered by this Certificate:

Product Description	Product Name						Class
	SI.No	Components	Dia/Holes/thickness	Length/ Other spec	Material	Brand Name	
Cervical Plate System	1	Cervical Bone Screws	Dia2 mm- 7 mm	2 mm – 10 mm	Titanium Grade 5	ANCER locking screw small	II b
	2	Cervical Bone Screws	Dia 3.0mm - 4.5 mm	8mm To 24 mm long	Titanium Grade 5	Anterior cervical bone screw self-drilling	
	3	Cervical Bone Screws	Dia 3.0mm - 4.5 mm	8mm To 24 mm long	Titanium Grade 5	Anterior Cervical Bone Screw Rescue	
	4	Cervical plate	4 Hole - 10 Hole	23mm To 120 mm long	Titanium Grade 2	Ace lock plate	
	5.	Cervical plate	4 Hole - 10 Hole	23 mm To 120 mm long	Titanium Grade 2	ANCER Cervical Locking Plate	
	6.	Cervical plate	NA	8 LG to 14 LG	Titanium Grade 2	CELINO Laminoplasty T plate	
	7.	Cervical plate	NA	8 LG to 14 LG	Titanium Grade 2	CELINO Laminoplasty Mini Plate	
Occipital Cervical Plate System	1	Posterior screws	Dia 3.0 mm to 4.5 mm (Range: 0.5 mm difference In diameter)	8 mm To 40 mm long (Range: 2 mm difference In length)	Titanium Grade 5	POCER Poly Axial Screws	II b
	2	Posterior screws	Dia 3.0 mm to 4.5 mm (Range: 0.5 mm difference In diameter)	8 mm To 40 mm long (Range: 2 mm difference In length)	Titanium Grade 5	POCER Rescue Screw	
	3	Posterior screws	Dia 3.0 mm to 4.5 mm (Range: 0.5 mm difference In diameter)	8 mm To 40 mm long (Range: 2 mm difference In length)	Titanium Grade 5	POCER Shank Screw	

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Occipital Cervical Plate System	4.	Connecting rods	Dia 3.0mm to 4.0 mm (Range: 0.5 mm difference In diameter) & 3.7 mm dia	30 mm to 400mm long (Range: 10 mm difference In length)	Titanium Grade 5	POCER Connecting Rod	
	5.	Connecting rods	Dia 3.0mm to 4.0 mm (Range: 0.5 mm difference In diameter) & 3.7 mm dia	30 mm to 400mm long (Range: 10 mm difference In length)	Titanium Grade 5	POCER Connecting Rod (Pre Bend)	
	6.	Lateral iliac screw connector	Dia 3.0 mm to 4.0mm (Range: 0.5 mm difference In diameter) & 3.7 mm dia	15 mm to 40 mm long (Range: 5 mm difference In length)	Titanium Grade 5	POCER Lateral Iliac Connector	
	7.	Transverse connector	Dia 3.0 mm to 4.0mm (Range: 0.5 mm difference In diameter) & 3.7 mm dia	25 mm to 80 mm long	Titanium Grade 5	POCER Top Loading Cross Link Small	II b
	8.	Cranio vertebral junction plates	1 holes to 3 holes (Range: 1 hole difference)	20 mm to 70 mm long	Titanium Grade 2	Occipital Plate	
	9.	Craniovertebral junction plates	5 holes & 7 holes	28 mm to 50 mm long	Titanium Grade 2	POCER Occipital Plate With Head	
	10.	Craniovertebral junction plate rods	2 holes to 6 holes (Range: 1 hole difference)	100 mm to 250 mm long	Titanium Grade 2	Occipito Cervical Plate Rod	
	11.	Craniovertebral junction screws	Dia 3.0 mm to 4.5 mm (Range: 0.5 mm difference In diameter)	6mm to 20mm long (Range: 2 mm difference In length)	Titanium Grade 5	POCER Occipital Screws	
	12.	Hooks	Dia 10mm to 16mm (Range 1mm difference in head diameter)	10mm to 30mm Long	Titanium Grade 5	POCER Offset Hook	
	13.	Titanium Wire	0.3 mm to 2.0 mm	50 mm to 5 mtrs	Titanium Grade 2	Malleable Wire	

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Thoraco Lumbar Spinal Fixation System	1.	Monoaxial Screw	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference in length)	Titanium Grade 5	Monolock Monoaxial Screw	II b
	2	Monoaxial Screw	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Ultra Monolock Monoaxial Screw	
	3	Monoaxial Screw	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Deformity Monolock Monoaxial Screw	
	4.	Monoaxial Screw	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock PD Monoaxial Screw	
	5	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Poly Axial Screw	
	6	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Ultra Poly Axial Screw	
	7	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	DTAP Monolock Poly Axial Screw SQ	
	8.	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Deformity Poly Axial Screw	
	9	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock PD Poly Axial Screw	
	10	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	MIS Monolock Poly Axial Screw	

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Thoraco Lumbar Spinal Fixation System	11	Uniaxial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Deformity Uniaxial Screw	II b
	12	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Osteo Poly Axial Screw SQ	
	13	Poly axial screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Osteo Poly Axial Fenestrated Screw SQ	
	14	Polyaxial screw	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Polyaxial Reduction Screws	
	15	Polyaxial Screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Ultra Poly Axial Reduction Screws	
	16	Polyaxial Screws	Dia 3.5 mm to 8 mm (Range: 0.5 mm difference In diameter)	20 mm to 120 mm long (Range: 5 mm difference In length)	Titanium Grade 5	Monolock Deformity Polyaxial Reduction Screws	
	17	Connecting Rods Straight	Dia 3.0 mm To 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm To 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	Monolock Dual dia Connecting Rod	
	18	Connecting Rods Straight	Dia 3.0 mm To 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm To 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	Monolock Connecting Rod	
	19	Connecting Rods Straight	Dia 3.0 mm To 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm To 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	DTAP Connecting Rod	

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Thoraco Lumbar Spinal Fixation System	20	Connecting Rods Straight	Dia 3.0 mm - 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm To 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	MIS Monolock Straight Connecting Rod	II b
	21	Connecting Rods Straight	Dia 3.0 mm To 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm To 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	Clip Crosslink Connecting Bar	
	22	Connecting Rods Contoured	Dia 3.0 mm to 6.0 mm (Range: 0.5 mm difference In diameter)	30 mm to 500mm long (Range: 10 mm difference In length)	Titanium Grade 5	MIS Monolock Contoured Connecting Rod	
	23	Transverse Connector	Dia 3.5 mm to 6.0mm (Range: 0.5 mm difference In connecting rod diameter)	10 mm to 30 mm long	Titanium Grade 5	Clip Crosslink Connector 5.5 mm	
	24	Transverse Connector	Dia 3.5 mm to 6.0mm (Range: 0.5 mm difference In connecting rod diameter)	10 mm to 100 mm long (Range: 10 mm difference In length)	Titanium Grade 5	Monolock Transverse Connector	
	25	Transverse Connector	Dia 3.5 mm to 6.0mm (Range: 0.5 mm Difference In connecting rod diameter)	10 mm to 100 mm long (Range: 10 mm difference In length)	Titanium Grade 5	Monolock PD Transverse Connector	
	26	Rod connecting clamps	Dia 3.5 mm to 6.0 mm & dia 3.7 mm (Range: 0.5 mm difference In connecting rod diameter)	10 mm to 30 mm long	Titanium Grade 5	Parallel Connectors	
	27	Cross links	Dia 4.0 mm to 6.0 mm (Range: 0.5 mm difference In connecting rod diameter)	25 mm to 100 mm long	Titanium Grade 5	Monolock Top Loading Crosslink	

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Thoraco Lumbar Spinal Fixation System	28	Cross links	Dia 4.0 mm to 6.0 mm (Range: 0.5 mm difference In connecting rod diameter)	25 mm to 100 mm long	Titanium Grade 5	DTAP Top Loading Cross Link	II b
	29	Cross links	Dia 4.0 mm to 6.0 mm (Range: 0.5 mm difference In connecting rod diameter)	25 mm to 100 mm long	Titanium Grade 5	Monolock PD Top Loading Cross Link	
	30	Illiatic connectors	Dia 4.0 mm to 6.0 mm (Range: 0.5 mm difference In connecting rod diameter)	15mm to 50mm long (Range: 5 mm difference In length)	Titanium Grade 5	Lateral Illiatic Connector	
	31	Illiatic connectors	Dia 4.0 mm to 6.0 mm (Range: 0.5 mm difference In connecting rod diameter)	15mm to 50mm long (Range: 5 mm difference In length)	Titanium Grade 5	DTAP Monolock Lateral Illiatic Connector	
	32	Locking Screws	Dia 5 mm to 10 mm (Range: 0.5 mm difference In outer diameter)	3.0mm to 10 mm long	Titanium Grade 5	Set Screw Star Socket	
	33	Locking Screws	Dia 5 mm to 10 mm (Range: 0.5 mm difference In outer diameter)	3.0mm to 10 mm long	Titanium Grade 5	Set Screw Square Thread	
	34	Locking Screws	Dia 5 mm to 10 mm (Range: 0.5 mm difference In outer diameter)	3.0mm to 10 mm long	Titanium Grade 5	Set Screw Break Off	

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Thoraco Lumbar Spinal Fixation System	35	Locking Screws	Dia 5 mm to 10 mm (Range: 0.5 mm difference In outer diameter)	3.0mm to 10 mm long	Titanium Grade 5	Set Screw Buttress Thread	II b
	36	Spinal Staples	Dia 10mm to 16mm (Range 1mm Difference in head diameter)	10mm to 20mm Long	Titanium Grade 5	Monolock Vertebra; body staples	
	37	Spinal Hooks	Dia 10mm to 16mm (Range 1mm Difference in head diameter)	10mm to 30mm Long	Titanium Grade 5	Monolock Hooks	
	38	Spinal Hooks	Dia 10mm to 16mm (Range 1mm Difference in head diameter)	10mm to 30mm Long	Titanium Grade 5	Monolock PD Hooks	
Cervical Interbody Fusion Devices	1	Spacers	5 mm to 12 mm thickness (Range: 1 mm difference In Thickness)	10 mm to 25 mm long	Titanium Grade 2	CEDIX Spacer	II b
	2	Spacers	5 mm to 12 mm thickness (Range: 1 mm difference In Thickness)	10 mm to 25 mm long	Titanium Grade 2	CEDIX P Spacer	
	3	Spacers	5 mm to 12 mm thickness(Range: 1 mm difference In Thickness)	10 mm to 25 mm long	Titanium Grade 2	PROLESS Cage	
	4	Locking bone screws	Dia 3.0 mm to 5.0 mm (Range: 0.5 mm difference In outer diameter)	10 mm to 70 mm long (Range: 2 mm difference In length)	Titanium Grade 5	Disc Spacer Locking Bone Screw	
	5	Locking bone screws	Dia 3.0 mm to 5.0 mm (Range: 0.5 mm difference In outer diameter)	10 mm to 70 mm long (Range: 2 mm difference In length)	Titanium Grade 5	PROLESS Bone Screw	
	2	Expandable cages	Dia 12 mm to 20 mm (Range: 2 mm difference In outer diameter)	20 mm to 80 mm long	Titanium Grade 5	CORPEX cage P	

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Vertebral body Corpectomy Cage System	1	Expandable cages	Dia 12 mm to 20 mm (Range: 2 mm difference In outer diameter)	20 mm to 80 mm long	Titanium Grade 5	CORPEX Cage	II b
	2	Expandable cages	Dia 12 mm to 20 mm (Range: 2 mm difference In outer diameter)	20 mm to 80 mm long	Titanium Grade 5	CORPEX cage P	
	3	Spinal cages	Dia 12 mm to 26 mm (Range: 2 mm difference In outer diameter)	10 mm to 100 mm long (Range: 2.5 mm difference In length)	Titanium Grade 5	CORCAGES	
Thoracolumbar Interbody Fusion Devices	1.	Spinal cages	7 mm to 15 mm thickness (Range: 1 mm difference In Thickness)	10 mm to 35 mm long	Titanium Grade 2	POSFUSE PLIF Cage	II b
	2	Spinal cages	7 mm to 15 mm thickness (Range: 1 mm difference In Thickness)	10 mm to 35 mm long	Titanium Grade 2	POSFUSE TLIF Cage	
	3	Spinal cages	7 mm to 15 mm thickness (Range: 1 mm difference In Thickness)	10 mm to 35 mm long	Titanium Grade 2	POSFUSE OBLIQUE Cages	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Jayon Implants Pvt.Ltd.	IV/1064, Industrial Development Area, Kanjikode, Palakkad 678 623, Kerala, India

EU Representative

EUROPECERT, Alstr. 97, 41063 Mönchengladbach, Germany

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate