

EC Certificate
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-19-627

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

SPINEART SA

Chemin du Pré-Fleuri 3, 1228 Plan-les-Ouates, Switzerland

Product: BGel® Synthetic Osteoconductive Gel	Class: III
Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System	Class: IIb
Product: Tryptik Ti Anterior Cervical Arthrodesis System	Class: IIb
Product: Tektona-Single Use Vertebral Fragment Reduction Device	Class: IIa
Product: Perla TL-Posterior Thoraco-Lumbar Fixation System	Class: IIb
Product: Juliet Ti OL Insert/Rotate Posterior Lumbar Cage	Class: IIb
Product: Juliet Ti LL Lateral Lumbar Cage	Class: IIb
Product: Baguera L Lumbar Disc Prosthesis	Class: IIb
Product: SCARLET® AL-T Hyperlordotic Secured Anterior Lumbar Cage	Class: IIb

The products defined at the enclosure which is the part of this certificate and contains eighteen (18) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.5701.01
Date of first issue: 29 November 2019
Date of last issue: 22 April 2020
Revision Number: 02
Expiry Date: 27 May 2024



Muhtesem Gökhan Yücel
Head of Notified Body

22 April 2020, Istanbul, Turkey



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Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II.3

Certificate Number: 1984-MDD-19-627, Revision Number: 02

Concerned medical devices;

Product: BGel® Synthetic Osteoconductive Gel

Reference	Models
20.00.01	βGel® synthetic osteoconductive gel Pack Volume 1 cc
20.00.25	βGel® synthetic osteoconductive gel Pack Volume 2.5cc
20.00.05	βGel® synthetic osteoconductive gel Pack Volume 5cc
20.00.10	βGel® synthetic osteoconductive gel Pack Volume 10cc

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
Smooth shank screw	CPF-SS 35 18-S Smooth shank screw Ø3.5 L18 CPF-SS 35 20-S Smooth shank screw Ø3.5 L20 CPF-SS 35 22-S Smooth shank screw Ø3.5 L22 CPF-SS 35 24-S Smooth shank screw Ø3.5 L24 CPF-SS 35 26-S Smooth shank screw Ø3.5 L26 CPF-SS 35 28-S Smooth shank screw Ø3.5 L28 CPF-SS 35 30-S Smooth shank screw Ø3.5 L30 CPF-SS 35 32-S Smooth shank screw Ø3.5 L32 CPF-SS 35 34-S Smooth shank screw Ø3.5 L34 CPF-SS 35 36-S Smooth shank screw Ø3.5 L36 CPF-SS 04 18-S Smooth shank screw Ø4 L18 CPF-SS 04 20-S Smooth shank screw Ø4 L20 CPF-SS 04 22-S Smooth shank screw Ø4 L22 CPF-SS 04 24-S Smooth shank screw Ø4 L24 CPF-SS 04 26-S Smooth shank screw Ø4 L26 CPF-SS 04 28-S Smooth shank screw Ø4 L28 CPF-SS 04 30-S Smooth shank screw Ø4 L30 CPF-SS 04 32-S Smooth shank screw Ø4 L32 CPF-SS 04 34-S Smooth shank screw Ø4 L34 CPF-SS 04 36-S Smooth shank screw Ø4 L36

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Concerned medical devices;

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
Cannulated Smooth shank screw	CPF-KS 04 18-S Cannulated Smooth Shank Screw Ø4 L18 CPF-KS 04 20-S Cannulated Smooth Shank Screw Ø4 L20 CPF-KS 04 22-S Cannulated Smooth Shank Screw Ø4 L22 CPF-KS 04 24-S Cannulated Smooth Shank Screw Ø4 L24 CPF-KS 04 26-S Cannulated Smooth Shank Screw Ø4 L26 CPF-KS 04 28-S Cannulated Smooth Shank Screw Ø4 L28 CPF-KS 04 30-S Cannulated Smooth Shank Screw Ø4 L30 CPF-KS 04 32-S Cannulated Smooth Shank Screw Ø4 L32 CPF-KS 04 34-S Cannulated Smooth Shank Screw Ø4 L34 CPF-KS 04 36-S Cannulated Smooth Shank Screw Ø4 L36
CC preferred angle screw	CPF-CS 35 08-S CC preferred angle screw Ø3.5 L08 CPF-CS 35 10-S CC preferred angle screw Ø3.5 L10 CPF-CS 35 12-S CC preferred angle screw Ø3.5 L12 CPF-CS 35 14-S CC preferred angle screw Ø3.5 L14 CPF-CS 35 16-S CC preferred angle screw Ø3.5 L16 CPF-CS 35 18-S CC preferred angle screw Ø3.5 L18 CPF-CS 35 20-S CC preferred angle screw Ø3.5 L20 CPF-CS 35 24-S CC preferred angle screw Ø3.5 L24 CPF-CS 35 28-S CC preferred angle screw Ø3.5 L28 CPF-CS 35 32-S CC preferred angle screw Ø3.5 L32 CPF-CS 35 36-S CC preferred angle screw Ø3.5 L36 CPF-CS 35 40-S CC preferred angle screw Ø3.5 L40 CPF-CS 35 44-S CC preferred angle screw Ø3.5 L44 CPF-CS 35 48-S CC preferred angle screw Ø3.5 L48 CPF-CS 35 52-S CC preferred angle screw Ø3.5 L52 CPF-CS 04 08-S CC preferred angle screw Ø4 L08 CPF-CS 04 10-S CC preferred angle screw Ø4 L10 CPF-CS 04 12-S CC preferred angle screw Ø4 L12 CPF-CS 04 14-S CC preferred angle screw Ø4 L14 CPF-CS 04 16-S CC preferred angle screw Ø4 L16 CPF-CS 04 18-S CC preferred angle screw Ø4 L18

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Concerned medical devices;

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
	CPF-CS 04 20-S CC preferred angle screw Ø4 L20 CPF-CS 04 24-S CC preferred angle screw Ø4 L24 CPF-CS 04 28-S CC preferred angle screw Ø4 L28 CPF-CS 04 32-S CC preferred angle screw Ø4 L32 CPF-CS 04 36-S CC preferred angle screw Ø4 L36 CPF-CS 04 40-S CC preferred angle screw Ø4 L40 CPF-CS 04 44-S CC preferred angle screw Ø4 L44 CPF-CS 04 48-S CC preferred angle screw Ø4 L48 CPF-CS 04 52-S CC preferred angle screw Ø4 L52
Cannulated CC preferred angle screw	CPF-KC 04 08-S Cannulated CC Preferred Angle Screw Ø4 L08 CPF-KC 04 10-S Cannulated CC Preferred Angle Screw Ø4 L10 CPF-KC 04 12-S Cannulated CC Preferred Angle Screw Ø4 L12 CPF-KC 04 14-S Cannulated CC Preferred Angle Screw Ø4 L14 CPF-KC 04 16-S Cannulated CC Preferred Angle Screw Ø4 L16 CPF-KC 04 18-S Cannulated CC Preferred Angle Screw Ø4 L18 CPF-KC 04 20-S Cannulated CC Preferred Angle Screw Ø4 L20 CPF-KC 04 24-S Cannulated CC Preferred Angle Screw Ø4 L24 CPF-KC 04 28-S Cannulated CC Preferred Angle Screw Ø4 L28 CPF-KC 04 32-S Cannulated CC Preferred Angle Screw Ø4 L32 CPF-KC 04 36-S Cannulated CC Preferred Angle Screw Ø4 L36 CPF-KC 04 40-S Cannulated CC Preferred Angle Screw Ø4 L40 CPF-KC 04 44-S Cannulated CC Preferred Angle Screw Ø4 L44 CPF-KC 04 48-S Cannulated CC Preferred Angle Screw Ø4 L48 CPF-KC 04 52-S Cannulated CC Preferred Angle Screw Ø4 L52
ML preferred angle screw	CPF-MS 35 08-S ML preferred angle screw Ø3.5 L08 CPF-MS 35 10-S ML preferred angle screw Ø3.5 L10 CPF-MS 35 12-S ML preferred angle screw Ø3.5 L12 CPF-MS 35 14-S ML preferred angle screw Ø3.5 L14 CPF-MS 35 16-S ML preferred angle screw Ø3.5 L16 CPF-MS 35 18-S ML preferred angle screw Ø3.5 L18



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Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
	CPF-MS 35 20-S ML preferred angle screw Ø3.5 L20 CPF-MS 35 24-S ML preferred angle screw Ø3.5 L24 CPF-MS 35 28-S ML preferred angle screw Ø3.5 L28 CPF-MS 35 32-S ML preferred angle screw Ø3.5 L32 CPF-MS 35 36-S ML preferred angle screw Ø3.5 L36 CPF-MS 35 40-S ML preferred angle screw Ø3.5 L40 CPF-MS 35 44-S ML preferred angle screw Ø3.5 L44 CPF-MS 35 48-S ML preferred angle screw Ø3.5 L48 CPF-MS 35 52-S ML preferred angle screw Ø3.5 L52 CPF-MS 04 08-S ML preferred angle screw Ø4 L08 CPF-MS 04 10-S ML preferred angle screw Ø4 L10 CPF-MS 04 12-S ML preferred angle screw Ø4 L12 CPF-MS 04 14-S ML preferred angle screw Ø4 L14 CPF-MS 04 16-S ML preferred angle screw Ø4 L16 CPF-MS 04 18-S ML preferred angle screw Ø4 L18 CPF-MS 04 20-S ML preferred angle screw Ø4 L20 CPF-MS 04 24-S ML preferred angle screw Ø4 L24 CPF-MS 04 28-S ML preferred angle screw Ø4 L28 CPF-MS 04 32-S ML preferred angle screw Ø4 L32 CPF-MS 04 36-S ML preferred angle screw Ø4 L36 CPF-MS 04 40-S ML preferred angle screw Ø4 L40 CPF-MS 04 44-S ML preferred angle screw Ø4 L44 CPF-MS 04 48-S ML preferred angle screw Ø4 L48 CPF-MS 04 52-S ML preferred angle screw Ø4 L52



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Models	Types
Cannulated ML Preferred angle screw	CPF-KM 04 08-S Cannulated ML Preferred Angle Screw Ø4 L08 CPF-KM 04 10-S Cannulated ML Preferred Angle Screw Ø4 L10 CPF-KM 04 12-S Cannulated ML Preferred Angle Screw Ø4 L12 CPF-KM 04 14-S Cannulated ML Preferred Angle Screw Ø4 L14 CPF-KM 04 16-S Cannulated ML Preferred Angle Screw Ø4 L16 CPF-KM 04 18-S Cannulated ML Preferred Angle Screw Ø4 L18 CPF-KM 04 20-S Cannulated ML Preferred Angle Screw Ø4 L20 CPF-KM 04 24-S Cannulated ML Preferred Angle Screw Ø4 L24 CPF-KM 04 28-S Cannulated ML Preferred Angle Screw Ø4 L28 CPF-KM 04 32-S Cannulated ML Preferred Angle Screw Ø4 L32 CPF-KM 04 36-S Cannulated ML Preferred Angle Screw Ø4 L36 CPF-KM 04 40-S Cannulated ML Preferred Angle Screw Ø4 L40 CPF-KM 04 44-S Cannulated ML Preferred Angle Screw Ø4 L44 CPF-KM 04 48-S Cannulated ML Preferred Angle Screw Ø4 L48 CPF-KM 04 52-S Cannulated ML Preferred Angle Screw Ø4 L52
Polyaxial screw	CPF-PS 35 08-S Polyaxial screw Ø3.5 L08 CPF-PS 35 10-S Polyaxial screw Ø3.5 L10 CPF-PS 35 12-S Polyaxial screw Ø3.5 L12 CPF-PS 35 14-S Polyaxial screw Ø3.5 L14 CPF-PS 35 16-S Polyaxial screw Ø3.5 L16 CPF-PS 35 18-S Polyaxial screw Ø3.5 L18 CPF-PS 35 20-S Polyaxial screw Ø3.5 L20 CPF-PS 35 24-S Polyaxial screw Ø3.5 L24 CPF-PS 35 28-S Polyaxial screw Ø3.5 L28 CPF-PS 35 32-S Polyaxial screw Ø3.5 L32 CPF-PS 35 36-S Polyaxial screw Ø3.5 L36 CPF-PS 35 40-S Polyaxial screw Ø3.5 L40 CPF-PS 35 44-S Polyaxial screw Ø3.5 L44 CPF-PS 35 48-S Polyaxial screw Ø3.5 L48 CPF-PS 35 52-S Polyaxial screw Ø3.5 L52 CPF-PS 04 08-S Polyaxial screw Ø4 L08 CPF-PS 04 10-S Polyaxial screw Ø4 L10 CPF-PS 04 12-S Polyaxial screw Ø4 L12



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Models	Types
	CPF-PS 04 14-S Polyaxial screw Ø4 L14 CPF-PS 04 16-S Polyaxial screw Ø4 L16 CPF-PS 04 18-S Polyaxial screw Ø4 L18 CPF-PS 04 20-S Polyaxial screw Ø4 L20 CPF-PS 04 24-S Polyaxial screw Ø4 L24 CPF-PS 04 28-S Polyaxial screw Ø4 L28 CPF-PS 04 32-S Polyaxial screw Ø4 L32 CPF-PS 04 36-S Polyaxial screw Ø4 L36 CPF-PS 04 40-S Polyaxial screw Ø4 L40 CPF-PS 04 44-S Polyaxial screw Ø4 L44 CPF-PS 04 48-S Polyaxial screw Ø4 L48 CPF-PS 04 52-S Polyaxial screw Ø4 L52 CPF-PS 45 08-S Polyaxial screw Ø4.5 L08 CPF-PS 45 10-S Polyaxial screw Ø4.5 L10 CPF-PS 45 12-S Polyaxial screw Ø4.5 L12 CPF-PS 45 14-S Polyaxial screw Ø4.5 L14 CPF-PS 45 16-S Polyaxial screw Ø4.5 L16 CPF-PS 45 18-S Polyaxial screw Ø4.5 L18 CPF-PS 45 20-S Polyaxial screw Ø4.5 L20 CPF-PS 45 24-S Polyaxial screw Ø4.5 L24 CPF-PS 45 28-S Polyaxial screw Ø4.5 L28 CPF-PS 45 32-S Polyaxial screw Ø4.5 L32 CPF-PS 45 36-S Polyaxial screw Ø4.5 L36 CPF-PS 45 40-S Polyaxial screw Ø4.5 L40 CPF-PS 45 44-S Polyaxial screw Ø4.5 L44 CPF-PS 45 48-S Polyaxial screw Ø4.5 L48 CPF-PS 45 52-S Polyaxial screw Ø4.5 L52
Cannulated Polyaxial screws	CPF-KP 04 08-S Cannulated Polyaxial Screw Ø4 L08 CPF-KP 04 10-S Cannulated Polyaxial Screw Ø4 L10 CPF-KP 04 12-S Cannulated Polyaxial Screw Ø4 L12 CPF-KP 04 14-S Cannulated Polyaxial Screw Ø4 L14 CPF-KP 04 16-S Cannulated Polyaxial Screw Ø4 L16 CPF-KP 04 18-S Cannulated Polyaxial Screw Ø4 L18 CPF-KP 04 20-S Cannulated Polyaxial Screw Ø4 L20



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Models	Types
	CPF-KP 04 24-S Cannulated Polyaxial Screw Ø4 L24 CPF-KP 04 28-S Cannulated Polyaxial Screw Ø4 L28 CPF-KP 04 32-S Cannulated Polyaxial Screw Ø4 L32 CPF-KP 04 36-S Cannulated Polyaxial Screw Ø4 L36 CPF-KP 04 40-S Cannulated Polyaxial Screw Ø4 L40 CPF-KP 04 44-S Cannulated Polyaxial Screw Ø4 L44 CPF-KP 04 48-S Cannulated Polyaxial Screw Ø4 L48 CPF-KP 04 52-S Cannulated Polyaxial Screw Ø4 L52
Rod Titanium	CPF-SR T0 20-S Straight rod Titanium Ø3.5 CPF-SR T0 25-S Straight rod Titanium Ø3.5 CPF-SR T0 30-S Straight rod Titanium Ø3.5 CPF-SR T0 35-S Straight rod Titanium Ø3.5 CPF-SR T0 40-S Straight rod Titanium Ø3.5 CPF-SR T0 45-S Straight rod Titanium Ø3.5 CPF-SR T0 50-S Straight rod Titanium Ø3.5 CPF-SR T0 55-S Straight rod Titanium Ø3.5 CPF-SR T0 60-S Straight rod Titanium Ø3.5 CPF-SR T0 65-S Straight rod Titanium Ø3.5 CPF-SR T0 70-S Straight rod Titanium Ø3.5 CPF-SR T0 75-S Straight rod Titanium Ø3.5 CPF-SR T0 80-S Straight rod Titanium Ø3.5 CPF-SR T0 85-S Straight rod Titanium Ø3.5 CPF-SR T0 90-S Straight rod Titanium Ø3.5 CPF-SR T1 00-S Straight rod Titanium Ø3.5 CPF-SR T1 10-S Straight rod Titanium Ø3.5 CPF-SR T1 20-S Straight rod Titanium Ø3.5 CPF-SR T2 40-S Straight rod Titanium Ø3.5 CPF-SR T3 50-S Straight rod Titanium Ø3.5 CPF-PR T0 40-S Prebent rod Titanium Ø3.5 CPF-PR T0 45-S Prebent rod Titanium Ø3.5



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Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
	CPF-PR T0 50-S Prebent rod Titanium Ø3.5 CPF-PR T0 55-S Prebent rod Titanium Ø3.5 CPF-PR T0 60-S Prebent rod Titanium Ø3.5 CPF-PR T0 65-S Prebent rod Titanium Ø3.5 CPF-PR T0 70-S Prebent rod Titanium Ø3.5 CPF-PR T0 75-S Prebent rod Titanium Ø3.5 CPF-PR T0 80-S Prebent rod Titanium Ø3.5 CPF-PR T0 85-S Prebent rod Titanium Ø3.5 CPF-PR T0 90-S Prebent rod Titanium Ø3.5 CPF-OR TS 90-S Occipital Rod Titanium size S 90° CPF-OR TS 11-S Occipital Rod Titanium size S 110° CPF-OR TS 13-S Occipital Rod Titanium size S 130° CPF-OR TM 90-S Occipital Rod Titanium size M 90° CPF-OR TM 11-S Occipital Rod Titanium size M 110° CPF-OR TM 13-S Occipital Rod Titanium size M 130°
Setscrew	CPF-SC 00 00-S Setscrew CPF-SC 01 00-S Extended Setscrew CPF-SC 02 00-S Hexagonal Setscrew CPF-SC 00 02-S Setscrews packed by 2
Rod Cobalt Chromium	CPF-SR C0 20-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 25-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 30-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 35-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 40-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 45-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 50-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 55-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 60-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 65-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 70-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 75-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 80-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C0 85-S Straight rod Cobalt Chromium Ø3.5



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Concerned medical devices;

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
	CPF-SR C0 90-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C1 00-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C1 10-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C1 20-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C2 40-S Straight rod Cobalt Chromium Ø3.5 CPF-SR C3 50-S Straight rod Cobalt Chromium Ø3.5 CPF-PR C0 40-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 45-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 50-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 55-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 60-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 65-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 70-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 75-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 80-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 85-S Prebent rod Cobalt Chromium Ø3.5 CPF-PR C0 90-S Prebent rod Cobalt Chromium Ø3.5 CPF-OR CS 90-S Occipital Rod Cobalt Chromium size S 90° CPF-OR CS 11-S Occipital Rod Cobalt Chromium size S 110° CPF-OR CS 13-S Occipital Rod Cobalt Chromium size S 130° CPF-OR CM 90-S Occipital Rod Cobalt Chromium size M 90° CPF-OR CM 11-S Occipital Rod Cobalt Chromium size M 110° CPF-OR CM 13-S Occipital Rod Cobalt Chromium size M 130°
Transition Rod	CPF-TR T3 00-S Transition rod Titanium CPF-TR T6 00-S Transition rod Titanium CPF-TR C3 00-S Transition rod Cobalt Chromium CPF-TR C6 00-S Transition rod Cobalt Chromium CPF-T5 T3 00-S Transition Rod Ø5.5 Titanium L300 CPF-T5 T6 00-S Transition Rod Ø5.5 Titanium L600 CPF-T5 C3 00-S Transition Rod Ø5.5 Cobalt Chromium L300 CPF-T5 C6 00-S Transition Rod Ø5.5 Cobalt Chromium L600 CPF-T6 T3 00-S Transition Rod Ø6 Titanium L300 CPF-T6 T6 00-S Transition Rod Ø6 Titanium L600 CPF-T6 C3 00-S Transition Rod Ø6 Cobalt Chromium L300 CPF-T6 C6 00-S Transition Rod Ø6 Cobalt Chromium L600



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Concerned medical devices;

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
Occipital Rod Titanium Adjustable	CPF-OR TS AL-S Adjustable Occipital Rod Titanium size S – Right CPF-OR TS AR-S Adjustable Occipital Rod Titanium size S – Left CPF-OR TM AL-S Adjustable Occipital Rod Titanium size M – Right CPF-OR TM AR-S Adjustable Occipital Rod Titanium size M - Left
Hook	CPF-HO OF SR-S Hook offset right / S CPF-HO OF SL-S Hook offset left / S CPF-HO OF LR-S Hook offset right / L CPF-HO OF LL-S Hook offset left / L CPF-HO ST OS-S Hook straight / S CPF-HO ST OL-S Hook straight / L
Connector	CPF-AC 3O 5C-S Axial connector 3O-5C CPF-AC 3C 5O -S Axial connector 3C-5O CPF-PC 3O 3C-S Parallel connector 3O 3C CPF-PC 3C 3C-S Parallel connector 3C 3C CPF-PC 3C 5O-S Parallel connector 3C 5O CPF-PC 3O 5C-S Parallel connector 3O 5C CPF-PC 3C 6O-S Parallel Connector 3C-6O CPF-PC 3O 6C-S Parallel Connector 3O-6C CPF-PC CC TO-S Parallel Connector CC-TO CPF-PC CO TC-S Parallel Connector CO-TC CPF-LC 0O OS-S Lateral connector / S CPF-LC 0O OL-S Lateral connector / L
Cross Connector	CPF-CH 2O 25-S HTH Cross connector Size A CPF-CH 25 3O-S HTH Cross connector Size B CPF-CH 3O 35-S HTH Cross connector Size C CPF-CH 35 4O-S HTH Cross connector Size D CPF-CH 4O 45-S HTH Cross connector Size E CPF-CH 45 5O-S HTH Cross connector Size F CPF-CR 21 23-S RTR Cross connector Size 1 CPF-CR 23 26-S RTR Cross connector Size 2 CPF-CR 26 32-S RTR Cross connector Size 3 CPF-CR 32 44-S RTR Cross connector Size 4 CPF-CR 44 56-S RTR Cross connector Size 5



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Concerned medical devices;

Product: PERLA® Posterior Occipito-Cervico-Thoracic Fixation System

Models	Types
Occipital plates	CPF-OP 00 0S-S Occipital plate size S CPF-OP 00 0M-S Occipital plate size M CPF-OP 00 0L-S Occipital plate size L
Occipital screws	CPF-OS 45 06-S Occipital screw Ø4.5 L06 CPF-OS 45 08-S Occipital screw Ø4.5 L08 CPF-OS 45 10-S Occipital screw Ø4.5 L10 CPF-OS 45 12-S Occipital screw Ø4.5 L12 CPF-OS 45 14-S Occipital screw Ø4.5 L14 CPF-OS 45 16-S Occipital screw Ø4.5 L16 CPF-OS 05 06-S Occipital screw Ø5 L06 CPF-OS 05 08-S Occipital screw Ø5 L08 CPF-OS 05 10-S Occipital screw Ø5 L10 CPF-OS 05 12-S Occipital screw Ø5 L12 CPF-OS 05 14-S Occipital screw Ø5 L14 CPF-OS 05 16-S Occipital screw Ø5 L16

Product: Tryptik Ti Anterior Cervical Arthrodesis System

Reference	Models
TRY-TC SM 45-S	Ti-Life anterior convex cervical cage – Small D12 W15 H4.5
TRY-TC SM 50-S	Ti-Life anterior convex cervical cage – Small D12 W15 H05
TRY-TC SM 60-S	Ti-Life anterior convex cervical cage – Small D12 W15 H06
TRY-TC SM 70-S	Ti-Life anterior convex cervical cage – Small D12 W15 H07
TRY-TC SM 80-S	Ti-Life anterior convex cervical cage – Small D12 W15 H08
TRY-TC SM 90-S	Ti-Life anterior convex cervical cage – Small D12 W15 H09
TRY-TC SM 10-S	Ti-Life anterior convex cervical cage – Small D12 W15 H10
TRY-TC LA 45-S	Ti-Life anterior convex cervical cage – Large D14 W17 H4.5
TRY-TC LA 50-S	Ti-Life anterior convex cervical cage – Large D14 W17 H05
TRY-TC LA 60-S	Ti-Life anterior convex cervical cage – Large D14 W17 H06
TRY-TC LA 70-S	Ti-Life anterior convex cervical cage – Large D14 W17 H07
TRY-TC LA 80-S	Ti-Life anterior convex cervical cage – Large D14 W17 H08
TRY-TC LA 90-S	Ti-Life anterior convex cervical cage – Large D14 W17 H09
TRY-TC LA 10-S	Ti-Life anterior convex cervical cage – Large D14 W17 H10
TRY-TL SM 45-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H4.5
TRY-TL SM 50-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H05



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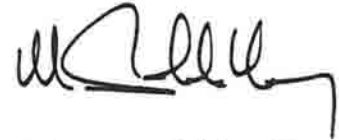
Concerned medical devices;

Product: Tryptik Ti Anterior Cervical Arthrodesis System

Reference	Models
TRY-TL SM 60-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H06
TRY-TL SM 70-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H07
TRY-TL SM 80-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H08
TRY-TL SM 90-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H09
TRY-TL SM 10-S	Ti-Life anterior lordotic cervical cage – Small D12 W15 H10
TRY-TL LA 45-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H4.5
TRY-TL LA 50-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H05
TRY-TL LA 60-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H06
TRY-TL LA 70-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H07
TRY-TL LA 80-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H08
TRY-TL LA 90-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H09
TRY-TL LA 10-S	Ti-Life anterior lordotic cervical cage – Large D14 W17 H10

Product: Tektona-Single Use Vertebral Fragment Reduction Device

Reference	Models
TEK-IN 02 02-S	Vertebral fragment reduction instrument - LARGE
TEK-IN 02 03-S	Vertebral fragment reduction instrument - SMALL
TEK-IN 03 02-S	Working cannula - SMALL
TEK-IN 03 03-S	Working cannula - LARGE
TEK-IN 07 03-S	Cement filler - SMALL
TEK-IN 07 04-S	Cement filler - LARGE
TEK-IN 30 01-S	Preparation kit – SMALL
TEK-IN 30 02-S	Preparation kit – LARGE



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Concerned medical devices;

Product: Perla TL-Posterior Thoraco-Lumbar Fixation System

Models	Types
Sterile and Nonsterile Cortical bone screws	Cortical Bone Screw (Ø4.5- Ø7.5, L25-L50)
Sterile and Nonsterile Modular Heads	Modular Polyaxial Head Modular Reduction Head Modular XTAB Cannulated Polyaxial Screw Head
Sterile and Nonsterile Degenerative Bone Screws	Degenerative Bone Screw (Ø4.5- Ø9.5, L25-L120)
Sterile and Nonsterile Modular Cannulated Bone Screws	Modular Cannulated Polyaxial Bone Screw (Ø4.5 – Ø8.5, L25-L30) Modular Cannulated Fenestrated Polyaxial Bone Screw (Ø4.5 – Ø8.5, L35-L60)
Sterile and Nonsterile Monoaxial screws	Monoaxial Screw (Ø4.5- Ø9.5 ,L25-L120)
Sterile and Nonsterile Polyaxial screws	Polyaxial Screw (Ø4.5- Ø10.5, L25-L120)
Sterile and Nonsterile Cannulated PS screws	Cannulated Polyaxial Screw (Ø4.5 – Ø6.5, L25-L30) Cannulated Polyaxial Screw (Ø7.5 – Ø8.5, L30) Cannulated Polyaxial Screw (Ø7.5 – Ø10.5, L70-L120) Cannulated Fenestrated Polyaxial Screw (Ø4.5 – Ø8.5, L35-L60)
Sterile and Nonsterile XTAB Cannulated PS screws	XTAB Cannulated Polyaxial Screw (Ø4.5 – Ø6.5, L25-L30) XTAB Cannulated Polyaxial Screw (Ø7.5 – Ø8.5, L30) XTAB Cannulated Fenestrated Polyaxial Screw (Ø4.5 – Ø8.5, L35-L60)



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Concerned medical devices;

Product: Perla TL-Posterior Thoraco-Lumbar Fixation System

Models	Types
Sterile and Nonsterile Reduction screws	Reduction Screw (Ø4.5- Ø10.5, L25-120)
Sterile and Nonsterile Cannulated SS screws	Cannulated Sagittal Screw (Ø4.5 – Ø8.5, L25-L30) Cannulated Fenestrated Sagittal Screw (Ø4.5 – Ø8.5, L35-L60)
Sterile and Nonsterile XTAB Cannulated SS screws	XTAB Cannulated Sagittal Screw (Ø4.5 – Ø8.5, L25-L30) XTAB Cannulated Fenestrated Sagittal Screw (Ø4.5 – Ø8.5, L35-L60)
Sterile and Nonsterile 25D Screws	25D Screw (Ø4- Ø 6.5, L25-L90)
Sterile and Nonsterile Rods - Titanium	Straight rod Ø5.5 Titanium (L30-L90) Straight rod Hexa Ø5.5 Titanium (L100-L550) Prebent rod Ø5.5 Titanium (L30-L130) Straight rod Ø6 Titanium (L30-L90) Straight rod Hexa Ø6 Titanium (L100-L550) Prebent rod Ø6 Titanium (L30-L130) Percutaneous rod/Straight Ø5.5 (L30-L250) Percutaneous rod/Straight Ø6 (L30-L250) Percutaneous rod/Pre-bent Ø5.5 (L30-L130) Percutaneous rod/Pre-bent Ø6 (L30-L130)



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Concerned medical devices;

Product: Perla TL-Posterior Thoraco-Lumbar Fixation System

Models	Types
Sterile and Nonsterile Rods – Cobalt chromium	Straight rod Hexa Ø5.5 Cobalt Chromium L100-L550 Straight rod Hexa Ø6 Cobalt Chromium L100-L550 Prebent rod Ø5.5 Cobalt Chromium(40°- 60°-80°) L550 Prebent rod Ø6 Cobalt Chromium (40°- 60°-80°) L550
Sterile and Nonsterile Setscrews	Setscrew
Sterile Setscrews	Setscrews packed by (2,4,6)
Sterile and Nonsterile Cross-connectors	Multiaxial Cross connector prebent L31 to 33 Multiaxial Cross connector prebent L33 to 36 Multiaxial Cross connector prebent L36 to 43 Multiaxial Cross connector prebent L43 to 55 Multiaxial Cross connector prebent L55 to 80 Cross connector monobloc L18 Cross connector monobloc L21 Cross connector monobloc L24 Cross connector monobloc L27 Cross connector monobloc L30 Multiaxial Cross connector L30 to 31 Multiaxial Cross connector L31 to 33 Multiaxial Cross connector L33 to 36 Multiaxial Cross connector L36 to 43 Multiaxial Cross connector L43 to 55 Multiaxial Cross connector L55 to 80

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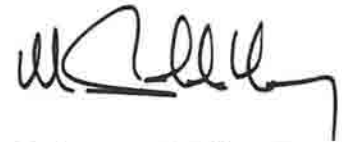
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Concerned medical devices;

Product: Perla TL-Posterior Thoraco-Lumbar Fixation System

Models	Types
Sterile and Nonsterile Lateral connectors	Lateral Connector Open L15 Lateral Connector Open L20 Lateral Connector Open L30 Lateral Connector Open L40 Lateral Connector Open L50 Lateral Connector Open L60 Lateral Connector closed L15 Lateral Connector closed L20 Lateral Connector closed L30 Lateral Connector closed L40 Lateral Connector closed L50 Lateral Connector closed L60
Sterile and Nonsterile Rod connectors	Rod Connector Parallel Open/Open Rod Connector Parallel Open/Close Rod Connector Axial Open/Close
Sterile and Nonsterile Hooks	Hook Laminar Lumbar Small Hook Laminar Lumbar Large Hook Laminar Lumbar Extended Hook Laminar Thoracic Supra Hook Laminar Thoracic Infra Hook Angled Left Hook Angled Right Hook Offset Left Hook Offset Right Hook Pedicular

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Concerned medical devices;

Product: Juliet Ti OL Insert/Rotate Posterior Lumbar Cage

Models	Types
Straight transforaminal lumbar Ti cage Insert/Rotate	L28-L36, W08-W10.5, H09-H16, 6° L28-L36, W08-W10.5, H09-H16, 12°

Product: Juliet Ti LL Lateral Lumbar Cage

Models	Types
Lateral lumbar cage - anatomic	Ti-LIFE Lateral Cage W17, 0°-8°, L40-L60, H06-H16 Ti-LIFE Lateral Cage W21, 0°-8°, L40-L60, H08-H16
Lateral lumbar cage - hyperlordotic	Ti-LIFE Lateral Cage W21, 15°-25°, L40-L60, H12-H20
Lateral lumbar plate	Ti-LIFE Lateral Plate Small H08-H20 Ti-LIFE Lateral Plate Large H08-H20
Bone screws	Bone screw Dia 5 (L45-L60) Bone screw Dia 5.5 (L45-L60)

Product: Baguera L Lumbar Disc Prosthesis

Models	Types
Lumbar Disc Prosthesis BAGUERA L	05°-10°, Small-Medium-Large, H08-H12 Mobile PE Inlay Fixed PE Inlay



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Concerned medical devices;

Product: SCARLET® AL-T Hyperlordotic Secured Anterior Lumbar Cage

Models	Types
Secured anterior lumbar cage - hyperlordotic	Secured lumbar anterior cage Small 20° H(13-15-17-19) - Hyperlordotic
	Secured lumbar anterior cage Small 25° H(15-17-19-21) - Hyperlordotic
	Secured lumbar anterior cage Small 30° H(17-19-21-23) - Hyperlordotic
	Secured lumbar anterior cage Medium 20° H(14-16-18-20) - Hyperlordotic
	Secured lumbar anterior cage Medium 25° H(18-20-22-24) - Hyperlordotic
	Secured lumbar anterior cage Medium 30° H(19-21-23-25) - Hyperlordotic
	Secured lumbar anterior cage Large 20° H(15-17-19-21) - Hyperlordotic
	Secured lumbar anterior cage Large 25° H(19-21-23-25) - Hyperlordotic
	Secured lumbar anterior cage Large 30° H(20-22-24-26) - Hyperlordotic



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