

EC Certificate

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

Certificate Number: 1984-MDD-20-653

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:

NOVASPINE S.A.S.

Headquarters: 335 Rue Saint-Fuscien, 80090 Amiens, France

Operational Site: 10 rue Clément MAROT, 80480 Salouël, France

Product: Inter Somatic Cage (Diva-Sterile)

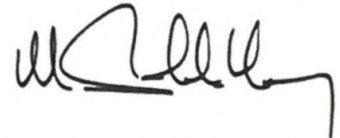
Product: Spinal Osteosynthesis System (Socore-Sterile)

Product: Inter Somatic Cage (Diva 3D)

The products defined at the enclosure which is the part of this certificate and contains sixteen (16) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5719.01

Expiry Date: 27 May 2024



Muhteşem Gökhan Yücel
Head of Notified Body

09 April 2020, Istanbul, Turkey

Enclosure of the EC Certificate:

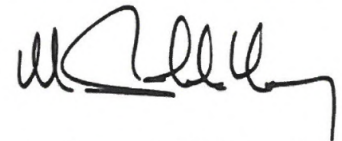
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

Product: Inter Somatic Cage (Diva-Sterile)

MODELS
Cervical Cage S.(4-5-6-7-8-9-10) PEEK - Sterile
Cervical Cage-Small S.(4-5-6-7-8-9) PEEK - Sterile
Plate for Cervical Cage S.(1-2-3) - Sterile
Assembling Screw - Sterile
Screw for Cervical Blocked Cage L.(10-12-14-16-18-20) - Sterile
Self-drilling Screw L.(10-12-14-16-18-20) - Sterile
Blocked Cervical Cage S.(4-5-6-7-8-9-10) PEEK - Sterile
Blocked Cervical Cage-Small S.(4-5-6-7-8-9) PEEK - Sterile
Revision Screw for Cervical Blocked Cage L.(10-12-14-16-18-20) - Sterile
Lumbar Cage S.(7-8-9-10-11-12-13-14)20-0° PEEK - Sterile
Lumbar Cage S.(7-8-9-10-11-12-13-14)20-4° PEEK - Sterile
Lumbar Cage S.(7-8-9-10-11-12-13-14)-20-8° PEEK - Sterile
Lumbar Cage S.(8-9-10-11-12-13-14)25-0° PEEK - Sterile
Lumbar Cage S.(8-9-10-11-12-13-14)25-4° PEEK - Sterile
Lumbar Cage S.(8-9-10-11-12-13-14)25-8° PEEK - Sterile
TLIF Curved Cage S.(7-8-9-10-11-12-13-14)-4° PEEK - Sterile
TLIF Curved Lumbar Cage Pivot S.(7-8-9-10-11-12-13-14)-4° PEEK - Sterile
Lumbar Cage S.(7-8-9-10-11-12-13-14)30-4° PEEK - Sterile
TLIF Rotating Cage S.(7-8-9-10-11-12-13-14)30-6° PEEK - Sterile
Anterior Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-18° PEEK - Sterile
Anterior Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Anterior Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Anterior Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-18° PEEK - Sterile
Anterior Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile



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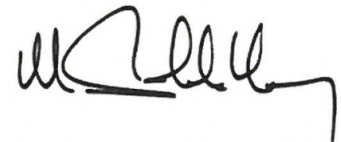
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Monoaxial Screw Ø4 L.(20-25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Monoaxial Screw Ø4.5 L.(20-25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Monoaxial Screw Ø5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70) + standard locking screw - Sterile
Monoaxial Screw Ø5.5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70) + standard locking screw - Sterile
Monoaxial Screw Ø6 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70-80) + standard locking screw - Sterile
Monoaxial Screw Ø6.5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70-80) + standard locking screw - Sterile
Monoaxial Screw Ø7 L.(20-30-32-35-37-40-42-45-47-50-52-55-57-60-65-70-80-90-100) + standard locking screw - Sterile
Monoaxial Screw Ø7.5 L.(20-30-32-35-37-40-42-45-47-50-52-55-57-60-65-70-80) + standard locking screw - Sterile
Monoaxial Screw Ø8 L.(30-35-40-45-50-55-60-70-80) + standard locking screw - Sterile
Monoaxial Screw Ø9 L.(30-35-40-45-50-55-60-70-80) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø4.5 L.(25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø5 L.(30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø5.5 L.(30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø6 L.(30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø7 L.(30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø8 L.(30-35-40-45-50-55-60-70-80) + standard locking screw - Sterile
Monoaxial Cannulated Screw Ø9 L.(30-35-40-45-50-55-60-70-80) + standard locking screw - Sterile



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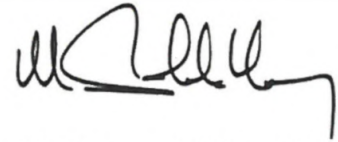
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

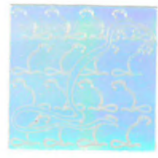
Product: Inter Somatic Cage (Diva-Sterile)

MODELS
Anterior Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Anterior Lumbar Blocked Cage S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Anterior Lumbar Blocked Cage S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Anterior Lumbar Blocked Cage S.(8-9-10-11-12-13-14-15-16-18)-18° PEEK - Sterile
Anterior Lumbar Blocked Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Anterior Lumbar Blocked Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Anterior Lumbar Blocked Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-18° PEEK - Sterile
Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-4° PEEK - Sterile
Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-4° PEEK - Sterile
Blocked Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Blocked Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Blocked Lateral Lumbar Cage S.(8-9-10-11-12-13-14-15-16-18)-4° PEEK - Sterile
Blocked Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-8° PEEK - Sterile
Blocked Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-12° PEEK - Sterile
Blocked Lateral Lumbar Cage-Small S.(8-9-10-11-12-13-14-15-16-18)-4° PEEK - Sterile
Screw for Anterior Lumbar Cage L.(20-25-30-35-40-45-50)- Sterile
Screw for Lateral Lumbar Cage L.(25-30-35-40-45-50-55-60)- Sterile



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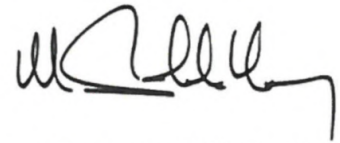
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

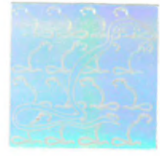
Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Monoaxial Reduction Screw Ø4 L.(25-30-35-40-45-50) + standard locking screw - Sterile
Monoaxial Reduction Screw Ø5 L.(30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoaxial Reduction Screw Ø6 L.(30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoaxial Reduction Screw Ø7 L.(30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Screw Ø4 L.(20-25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Screw Ø4.5 L.(20-25-30-35-40-45-50-55-60-65-70)+ standard locking screw - Sterile
Polyaxial Screw Ø5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70)+ standard locking screw - Sterile
Polyaxial Screw Ø5.5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70)+ standard locking screw - Sterile
Polyaxial Screw Ø6 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70-75-80-90-100)+ standard locking screw - Sterile
Polyaxial Screw Ø6.5 L.(20-30-35-37-40-42-45-47-50-52-55-57-60-65-70-75-80)+ standard locking screw - Sterile
Polyaxial Screw Ø7 L.(20-30-32-35-37-40-42-45-47-50-52-55-57-60-65-70-75-80-90-100-110)+ standard locking screw - Sterile
Polyaxial Screw Ø7.5 L.(20-30-32-35-37-40-42-45-47-50-52-55-57-60-65-70-75-80)+ standard locking screw - Sterile
Polyaxial Screw Ø8 L.(30-35-40-45-50-60-70-80-90-100) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø4 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø4.5 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø5 L.(25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø5.5 L.(30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø6 L.(30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø6.5 L.(30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Reduction Screw Ø7 L.(30-35-40-45-50-55-60-65-70-80-90-100) + standard locking screw - Sterile



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

Certificate Number: 1984-MDD-20-653

Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Polyaxial Pediatric Screw Ø4 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø4.5 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø5 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø5.5 L.(20-25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø6 L.(20-25-30-35-40-45-50-55-60-65-70-80) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø6.5 L.(20-25-30-35-40-45-50-55-60-65-70-80) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø7 L.(20-25-30-35-40-45-50-55-60-65-70-80-90-100) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø7.5 L.(20-25-30-35-40-45-50-55-60-65-70-80-90-100) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø8 L.(30-35-40-45-50-55-60-65-70-80-90-100) + standard locking screw - Sterile
Polyaxial Pediatric Screw Ø9 L.(30-35-40-45-50-55-60-65-70-80-90-100) + standard locking screw - Sterile
Standard Locking Screw - Sterile
Metric Locking Screw - Sterile
Pediatric Locking Screw - Sterile
Standard Locking Screw Torx - Sterile
Double Locking Screw - Sterile
Self-Breaking Locking Nut - Sterile
Long Locking Screw - Sterile
Rod Ø5.5 L.(30-35-40-45-50-55-60-64-70-75-78-80-85-90-92-95-100-106-110-120-132-140-144-150-158-185-250)- Sterile
Prebent Rod Ø5.5 L.(30-35-40-45-50-55-60-64-70-75-78-80-85-90-92-95-100-106-110-115-120-132-140-144-150-158-200) - Sterile
Rod Ø5.5 L.(30-35-40-45-50-55-60-65-70-75-80-85-90-95-100-105-110-115-120-125-130-135-140-145-150-160-170-180-190-200-220-240-260)Mini invasive - Sterile

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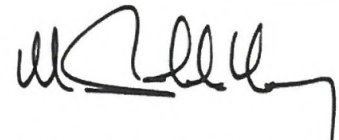
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Cervical Rod Ø4 L.(30-40-50-60-70-80-90-100-110-250) - Sterile
Rod Ø5.5 T.40 L.(30-35-40-45-50-55-60-64-70-75-78-80-85-90-92-95-100-106-110-120-132-140-144-150-158-185-250-500) - Sterile
Rod Ø5.5 T.40 L.(30-35-40-45-50-55-60-64-70-75-78-80-85-90-92-95-100-106-110-115-120-132-140-144-150-158-200) Prebent - Sterile
Rod Ø5.5 T.40 L.(30-35-40-45-50-55-60-65-70-75-80-85-90-95-100-105-110-115-120-130-135-140-150-160-170-180-190-200-220-240-260) Mini invasive - Sterile
Standard Pedicle Hook + standard locking screw - Sterile
Medium Pedicle Hook + standard locking screw - Sterile
Lumbar Hook + standard locking screw - Sterile
Lumbar Medium Hook + standard locking screw - Sterile
Lumbar Thoracic Hook + standard locking screw - Sterile
Sub Laminar Hook + standard locking screw - Sterile
Lengthened Body Hook + standard locking screw - Sterile
Transverse Hook + standard locking screw - Sterile
Right Offset Body Hook + standard locking screw - Sterile
Left Offset Body Hook + standard locking screw - Sterile
Right Offset Body Thoracic Hook + std locking screw - Sterile
Left Offset Body Thoracic Hook + std locking screw - Sterile
Right Offset Blade Hook + standard locking screw - Sterile
Left Offset Blade Hook + standard locking screw - Sterile
Crosslink Hook + locking screw - Sterile
Crosslink Hook-Long + locking screw - Sterile
Crosslink Bar L.(30-35-40-45-50-55-60-65-70-75-80-85-90-95-100) - Sterile
Flat Crosslink Bar L.(35-45-55-65-75-85-95-100) - Sterile



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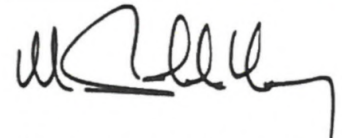
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Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653

Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Monoblock Crosslink L.(35-45-55-65-75-85-95-100) + locking screw - Sterile
Polyaxial Crosslink L.(35-45-55-65-75-85-95-100) + locking screws - Sterile
Locking screw-Short - Sterile
Medium Locking screw-Medium - Sterile
Locking screw-Long - Sterile
Square Domino + locking screw - Sterile
Straight Domino + locking screw - Sterile
Opened Square Domino + locking screw - Sterile
Pediatric Domino + locking screw - Sterile
Pediatric Domino-Short + locking screw - Sterile
Pediatric Domino Fenestrated L.(40-45-50-55-60-65-70-75-80-85-90-100) + 2 locking screws - Sterile
Domino Double Diameter + locking screw - Sterile
Opened Connector + locking screw - Sterile
Ilio-Sacral Plate + locking screw - Sterile
Ilio-Sacral Plate Screw L.(50-55-60-70-80) - Sterile
Sacral Plate + locking screw - Sterile
Screw for Sacral Plate L.(50-55-60-70) - Sterile
Pediatric Pedicle Hook + standard locking screw - Sterile
Pediatric Lumbar Hook + standard locking screw - Sterile
Pediatric Medium Lumbar Hook + standard locking screw - Sterile
Cervical Polyaxiale Screw Ø4 L.(10-12-14-16-18-20-22-25-30-35-40) + cervical locking screw - Sterile
Cervical Rod L.(80-120-225) - Sterile
Cervical Square Connector + locking screw - Sterile
Cervical Small Connector + locking screw - Sterile



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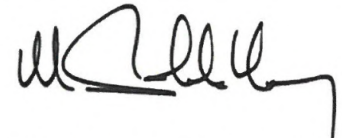
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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

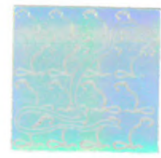
Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Cervical Straight Connector + locking screw - Sterile
Cervical Connector-Short + locking screw - Sterile
Cervical Connector + locking screw - Sterile
Cervical Opened Connector + locking screw - Sterile
Cervical Hook + cervical locking screw - Sterile
Cervical Hook-Small + cervical locking screw - Sterile
Cervical Right Offset Body Hook + cervical locking screw - Sterile
Cervical Left Offset Body Hook + cervical locking screw - Sterile
Cervical Crosslink Hook + locking screw - Sterile
Cervical Crosslink Bar L.(40-50-60-70) - Sterile
Cervical Right Offset Blade Hook + cervical locking screw - Sterile
Cervical Left Offset Blade Hook + cervical locking screw - Sterile
Cervical Polyaxial Crosslink-Short + locking screw - Sterile
Cervical Polyaxial Crosslink-Medium + locking screw - Sterile
Cervical Polyaxial Crosslink-Long + locking screw - Sterile
Cervical Polyaxial Crosslink-X-Long + locking screw - Sterile
Cervical Monoblock Crosslink-Short + locking screw - Sterile
Cervical Monoblock Crosslink-Medium + locking screw - Sterile
Cervical Monoblock Crosslink-Long + locking screw - Sterile
Cervical Monoblock Crosslink-X-Long + locking screw - Sterile
Cervical Locking Screw - Sterile
Monoplanar Screw Ø4 L.(25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoplanar Screw Ø5 L.(25-30-35-40-45-50-55-60) + standard locking screw - Sterile
Monoplanar Screw Ø6 L.(25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Monoplanar Screw Ø7 L.(25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile



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CERTIFICATE



Enclosure of the EC Certificate:

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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653**

Concerned medical devices;

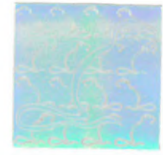
Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Monoplanar Screw Ø8 L.(25-30-35-40-45-50-55-60-65-70) + standard locking screw - Sterile
Polyaxial Multiplanar Screw Ø4 L.(25-30-35-40-45-50-55-60) + double locking screw - Sterile
Polyaxial Multiplanar Screw Ø5 L.(25-30-35-40-45-50-55-60) + double locking screw - Sterile
Polyaxial Multiplanar Screw Ø6 L.(25-30-35-40-45-50-55-60-65-70) + double locking screw - Sterile
Polyaxial Multiplanar Screw Ø7 L.(25-30-35-40-45-50-55-60-65-70) + double locking screw - Sterile
Polyaxial Multiplanar Cannulated Screw Ø5 L.(25-30-35-40-45-50-55-60) + double locking screw - Sterile
Polyaxial Multiplanar Cannulated Screw Ø6 L.(25-30-35-40-45-50-55-60-65-70) + double locking screw - Sterile
Polyaxial Multiplanar Cannulated Screw Ø7 L.(25-30-35-40-45-50-55-60-65-70) + double locking screw - Sterile
Polyaxial Cannulated Screw Ø4.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø5.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø6 L.(25-30-35-40-45-50-55-60-65-70-80) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø6.5 L.(25-30-35-40-45-50-55-60-65-70-80) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø7 L.(25-30-35-40-45-50-55-60-65-70-80-90-100) + std locking screw - Sterile
Polyaxial Cannulated Screw Ø8 L.(25-30-35-40-45-50-55-60-65-70-80-90-100) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw Ø4.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw Ø5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw Ø5.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw Ø6 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile

Muhtesem Gökhan Yücel
Head of Notified Body

09 April 2020, Istanbul, Turkey

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Enclosure of the EC Certificate:
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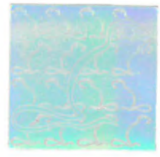
Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Polyaxial Cannulated Reduction Screw Ø6.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw Ø7 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø4.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø5.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø6 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø6.5 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø7 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Polyaxial Cannulated Reduction Screw-Long Ø8 L.(25-30-35-40-45-50-55-60-65-70) + std locking screw - Sterile
Flexible Rod L.(40-50-64-78-92-106-132-158-185-250) - Sterile
Occipito-Cervical Rod L.(185-230-270) - Sterile
Occipital Screw Ø4 L.(8-10-12-14-16) - Sterile
Occipital Plate-Short + locking screw - Sterile
Occipital Plate-Medium + locking screw - Sterile
Occipital Plate-Long + locking screw - Sterile
Occipital Plate-X-Long + locking screw - Sterile
Occipito-Cervical Screw Ø4.5 L.(8-10-12-14-16) - Sterile

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09 April 2020, Istanbul, Turkey



CERTIFICATE



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Concerned medical devices;

Product: Spinal Osteosynthesis System (Socore-Sterile)

MODELS
Right Polyaxial Sacro-Iliac Plate + standard locking screw - Sterile
Left Polyaxial Sacro-Iliac Plate + standard locking screw - Sterile
Sacral Screw for Sacro-Iliac Plate L.(35-40-45-50-55-60) - Sterile
Iliac Screw for Sacro-Iliac Plate L.(50-55-60-65-70-80-90-100-110-120) - Sterile
Iliac Connector Screw L.(60-70-80-90-100-110) - Sterile
Iliac Connector-Short + locking screw - Sterile
Iliac Connector + locking screw - Sterile
Iliac Connector-Long + locking screw - Sterile
Iliac Connector-Large Short + locking screw - Sterile
Iliac Connector-Large + locking screw - Sterile
Opened Connector-Short + locking screw - Sterile
Closed Connector + locking screw - Sterile
Closed Connector-Long + locking screw - Sterile
Screw for Iliac Connector L.(50-60-70-80-90-100-110-120) - Sterile
Cannulated Screw for Iliac Connector L.(50-60-70-80-90-100-110-120) - Sterile
Screw for Iliac Connector-Large L.(50-60-70-80-90-100-110-120) - Sterile

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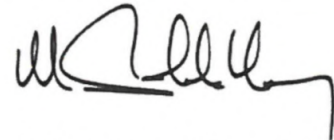
Medical Devices Directive 93/42/EEC Annex-II.3

Certificate Number: 1984-MDD-20-653

Concerned medical devices;

Product: Inter Somatic Cage (Diva 3D)

MODELS
Cervical Cage S(4-5-6-7-8-9-10)
Small Cervical Cage S(4-5-6-7-8-9-10)
Large Cervical Cage S(4-5-6-7-8-9-10)
Cervical Blocked Cage S(4-5-6-7-8-9-10)
Cervical Blocked Cage Small S(4-5-6-7-8-9-10)
Cervical Blocked Cage Large S(4-5-6-7-8-9-10)
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-18°
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-18°
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-18°
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-18°
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-12°



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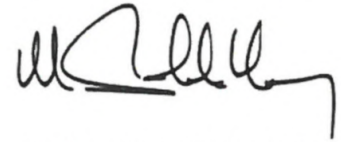
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Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-653

Concerned medical devices;

Product: Inter Somatic Cage (Diva 3D)

MODELS
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-8°



Muhteşem Gökhan Yücel
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09 April 2020, Istanbul, Turkey

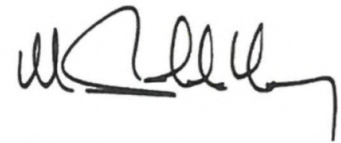
Enclosure of the EC Certificate:
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Concerned medical devices;

Product: Inter Somatic Cage (Diva 3D)

MODELS
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-12°
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-4°
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-8°
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-12°
Postero-Lateral Cage S(7-8-9-10-11-12-13-14)-4°
Lumbar Cage S(7-8-9-10-11-12-13-14)-L22-6°
Lumbar Cage S(7-8-9-10-11-12-13-14)-L26-6°
Lumbar Cage S(7-8-9-10-11-12-13-14)-L30-6°
TLIF Rotating Cage S.(10-11-12-13-14)-6°
Cervical Cage S(4-5-6-7-8-9-10) Sterile
Small Cervical Cage S(4-5-6-7-8-9-10) Sterile
Large Cervical Cage S(4-5-6-7-8-9-10) Sterile
Cervical Blocked Cage S(4-5-6-7-8-9-10) Sterile
Cervical Blocked Cage Small S(4-5-6-7-8-9-10) Sterile
Cervical Blocked Cage Large S(4-5-6-7-8-9-10) Sterile
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Anterior Cage S(8-9-10-11-12-13-14-15-16-18)-18° Sterile
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Anterior Cage Small S(8-9-10-11-12-13-14-15-16-18)-18° Sterile
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-8° Sterile



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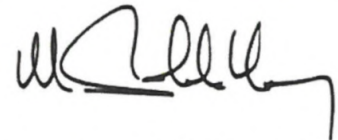
Medical Devices Directive 93/42/EEC Annex-II.3

Certificate Number: 1984-MDD-20-653

Concerned medical devices;

Product: Inter Somatic Cage (Diva 3D)

MODELS
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Anterior Blocked Cage S(8-9-10-11-12-13-14-15-16-18)-18° Sterile
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Anterior Blocked Cage Small S(8-9-10-11-12-13-14-15-16-18)-18° Sterile
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L35-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L40-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L45-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L50-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L55-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Cage L60-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L35-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile



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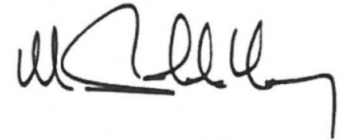
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Concerned medical devices;

Product: Inter Somatic Cage (Diva 3D)

MODELS
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L40-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L45-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L50-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L55-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-4° Sterile
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-8° Sterile
Lumbar Lateral Blocked Cage L60-S(8-9-10-11-12-13-14-15-16-18)-12° Sterile
Postero-Lateral Cage S(7-8-9-10-11-12-13-14)-4° Sterile
Lumbar Cage S(7-8-9-10-11-12-13-14)-L22-6° Sterile
Lumbar Cage S(7-8-9-10-11-12-13-14)-L26-6° Sterile
Lumbar Cage S(7-8-9-10-11-12-13-14)-L30-6° Sterile
TLIF Rotating Cage S.(10-11-12-13-14)-6° Sterile

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhtesem Gökhan Yücel
Head of Notified Body

09 April 2020, Istanbul, Turkey